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Felix Beck

Self-Spreading Biotechnology and International Law

Prevention, Responsibility, and Liability in a Transboundary Context

Nomos

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Volume 316

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Berlin, June 2022 *Felix Beck*

Overview of Chapters

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Table of Abbreviations

ACHR	American Convention on Human Rights
AHTEG	Ad Hoc Technical Group of Experts
AIA	Advance Informed Agreement
AJIL	American Journal of International Law
Am. J. Trop. Med. Hyg.	The American Journal of Tropical Medicine and Hygiene
Appl. Biosaf.	Applied Biosafety
ARSIWA	Articles on the Responsibility of States for Internationally Wrongful Acts
Asia Pac. JEL	Asia Pacific Journal of Environmental Law
ASIL Proceedings	Proceedings of the American Society of International Law at its Annual Meeting
BCH	Biosafety Clearing-House
BSL	Biosafety Level
BSWG	Open-Ended Ad Hoc Working Group on Biosafety
BWC	Biological Weapons Convention (Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction)
BYIL	British Yearbook of International Law
Canadian YBIL	Canadian Yearbook of International Law
Cas	CRISPR-associated proteins
CBD	Convention on Biological Diversity
CESCR	Committee on Economic, Social and Cultural Rights
CJEU	Court of Justice of the European Union
CMEA	Council for Mutual Economic Assistance
Colum. J. Envt'l L.	Columbia Journal of Environmental Law

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COP	Conference of the Parties
COP-MOP	Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety
CP	Cartagena Protocol
CRAMRA	Convention on the Regulation of Antarctic Mineral Resource Activities
CRISPR	Clustered regularly interspaced short palindromic repeats
crRNA	CRISPR RNAs
DARPA	Defense Advanced Research Projects Agency
Denver J. Int'l. L. & Pol'y	Denver Journal of International Law and Policy
DNA	Deoxyribonucleic acid
DSB	Dispute Settlement Body of the World Trade Organization
ECHR	European Convention on Human Rights (Convention for the Protection of Human Rights and Fundamental Freedoms)
ECOSOC	Economic and Social Council of the United Nations
ECtHR	European Court of Human Rights
EEZ	Exclusive Economic Zone
EIA	Environmental Impact Assessment
EJIL	European Journal of International Law
ELQ	Ecology Law Quarterly
ENB	Earth Negotiations Bulletin
ENMOD Convention	Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques
EU	European Union

EurUP	Zeitschrift für Europäisches Umwelt- und Planungsrecht
FAO	Food and Agriculture Organization of the United Nations
FPIC	Free, Prior and Informed Consent
Front. Bioeng. & Biotechnol.	Frontiers in Bioengineering and Biotechnology
Front. Plant Sci.	Frontiers in Plant Science
Geo. Int'l Envtl. L. Rev.	Georgetown International Environmental Law Review
Geo. Wash. Int'l L. Rev.	George Washington International Law Review
German YBIL	German Yearbook of International Law
GATT	General Agreement on Tariffs and Trade
GM	Genetically modified
GMM	Genetically modified microorganism
GMO	Genetically modified organism
Group of Friends on L&R	Group of the Friends of the Co-Chairs on Liability and Redress in the Context of the Cartagena Protocol on Biosafety
Harv. Int'l L. J.	Harvard International Law Journal
HEA	Habitat equivalency analysis
HDR	Homology-directed repair
HEG	Homing Endonuclease Genes
IACtHR	Inter-American Court of Human Rights
ICAO	International Civil Aviation Organization
ICJ	International Court of Justice
ICLQ	International & Comparative Law Quarterly
ICSID	International Centre for Settlement of Investment Disputes
ICTY	International Criminal Tribunal for Former Yugoslavia
IHR	International Health Regulations
IISD	International Institute for Sustainable Development

ILA	International Law Association
ILC	International Law Commission
ILM	International Legal Materials
Int. Environ. Agreements	International Environmental Agreements
IOPC Funds	International Oil Pollution Compensation Funds
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
Italian YBIL	Italian Yearbook of International Law
ITLOS	International Tribunal for the Law of the Sea
J. Envt'l L.	Journal of Environmental Law
J. Int. Econ. L.	Journal of International Economic Law
JEEPL	Journal for European Environmental & Planning Law
Leiden J. Int'l L.	Leiden Journal of International Law
LMO	Living modified organism
LNTS	League of Nations Treaty Series
LRTAP	Convention on Long-range Transboundary Air Pollution
MEA	Multilateral Environmental Agreement
Medea	Maternal-Effect Dominant Embryonic Arrest
Melb. J. Int'l L.	Melbourne Journal of International Law
Mich. J. Int'l L.	Michigan Journal of International Law
MOP	Meeting of the Parties, see COP-MOP
MPEPIL	Max Planck Encyclopedia of Public International Law
NASEM	National Academies of Sciences, Engineering, and Medicine
Nature Biotech.	Nature Biotechnology
Nature Comms.	Nature Communications
Nature Rev. Genet.	Nature Reviews Genetics
N. Engl. J. Med.	The New England Journal of Medicine

NGO	Non-Governmental Organization
NHEJ	Non-homologous end joining
NLR	Netherlands International Law Review
Nucleic Acids Res.	Nucleic Acids Research
NYL	Netherlands Yearbook of International Law
OIE	World Organisation for Animal Health
OTIF	Intergovernmental Organisation for International Carriage by Rail
Pace Envtl. L. Rev.	Pace Environmental Law Review
PCA	Permanent Court of Arbitration
PCIJ	Permanent Court of International Justice
Philos. Trans. R. Soc. A	Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences
Philos. Trans. R. Soc. B	Philosophical Transactions of the Royal Society B: Biological Sciences
PIC	Prior Informed Consent
PNAS	Proceedings of the National Academy of Sciences of the United States of America
Proc. R. Soc. B	Proceedings of the Royal Society B: Biological Sciences
QIL	Questions of International Law
REA	Resource equivalency analysis
RdC	Recueil des Cours
RECIEL	Review of European Community & International Environmental Law
Rep.	Reports
RIAA	Reports of International Arbitral Awards
RNA	Ribonucleic acid
SAYIL	South African Yearbook of International Law
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
Sci. Rep.	Scientific Reports
SDN	Site-directed nuclease

SDR	Special Drawing Rights
Ser.	Series
sgRNA	Single guide RNA
SP	Nagoya – Kuala Lumpur Supplementary Protocol on Redress and Liability
SPS	Sanitary and Phytosanitary Measures
Stan. J. Int'l L.	Stanford Journal of International Law
TALENs	Transcription activator-like effector nucleases
TEV	Total Economic Value
tracRNA	Trans-activating crRNA
UN OLA	United Nations Office of Legal Affairs
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNCC	United Nations Compensation Commission
UNCLOS	United Nations Convention on the Law of the Sea
UNCITRAL	United Nations Commission On International Trade Law
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention on Climate Change
UNGA	United Nations General Assembly
UNTS	United Nations Treaty Series
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WTO	World Trade Organization
Yale L.J.	Yale Law Journal
YB Int'l Env. L.	Yearbook of International Environmental Law
YBIL	Yearbook of International Law
YBILC	Yearbook of the International Law Commission

ZaöRV	Zeitschrift für ausländisches öffentliches Recht und Völkerrecht
ZFN	Zinc-finger nuclease

Introduction

> *'We have thus far been concerned with ultra-hazardous activities arising from the skills and achievements of the physicists, chemists and engineers. The biologists are now entering the picture with experiments which, we are responsibly told, can fundamentally reshape the constituent elements of life, memory and learning. […] There may well be cases in which the current experiments of molecular biologists involve dangers which pose acutely the problem of liability for the objective risks involved in ultra-hazardous activities.'*
> *– C. Wilfried Jenks*[1]

It appears that *Jenks* was far ahead of this time when, in his 1966 lecture at the *Hague Academy of International Law*, he mentioned molecular biology as a potential field of application for international law on liability for ultra-hazardous activities. That same year, the genetic code had been 'cracked' when *Marshall Nirenberg* and others had fully elucidated the chemical structure of *deoxyribonucleic acid* or DNA. It took seven more years for the first transgenic organism to be created, and until 1983 for the first genetically engineered crop to be developed.

Nevertheless, legal scholars had long taken up Jenks' initiative and begun contemplating the role of international law in regulating the potential transboundary effects of molecular biotechnology. Already in 1980, *Cripps* assumed that the problem identified by Jenks was now 'far more acute'.[2] At the same time, she observed that 'there is room for doubt regarding the application of recognised general principles of State responsibility to the release of genetically engineered viruses and organisms which traverse national boundaries'.[3]

The global COVID-19 pandemic has made the need to address potential transboundary effects of biotechnology self-evident.[4] Nevertheless, al-

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1 Liability for Ultra-Hazardous Activities in International Law, 117 (1966) RdC 99, 169.
2 *Yvonne Cripps*, A New Frontier for International Law, 29 (1980) ICLQ 1, 6.
3 *Ibid.*
4 *Jing-Bao Nie*, In the Shadow of Biological Warfare: Conspiracy Theories on the Origins of COVID-19 and Enhancing Global Governance of Biosafety as a Matter of Urgency, 17 (2020) Bioethical Inquiry 567.

though a laboratory escape has been discussed as a potential origin of the SARS-CoV-2 coronavirus,[5] there is currently no evidence that the virus emerged from a deliberate genetic manipulation.[6] Hence, despite the persistent controversy over the risks of genetic engineering, there appears to be no case in which a *genetically modified organism* (GMO) has ever caused significant transboundary harm; there has never been a GMO 'equivalent of the Torrey Canyon disaster or Chernobyl'.[7] Genetically modified crops, which are the most widespread instance of biotechnology released into the environment, are not known to have a direct cause-and-effect relationship with present environmental problems; common issues are rather caused by the agricultural practices associated with – but not exclusive to – the use of such crops, such as monoculture farming and intensive herbicide spraying.[8]

However, recent advances in molecular biology will likely produce entirely new classes of GMOs that may well have transboundary effects in the foreseeable future. These advances are led by the development of *genome editing* techniques, which can modify genetic information on the level of individual *base pairs* (or 'letters') in the DNA of virtually any organism. Compared to conventional genetic engineering techniques applied since the 1970s, genome editing is much more precise, versatile, and cheaper to apply. Moreover, it potentially allows the introduction of genetic modifications without inserting DNA derived from other species (so-called *transgenes*). This challenges existing regulatory frameworks that mostly attach to the presence of transgenic DNA in the resulting organism.

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5 *Filippa Lentzos*, WHO: COVID-19 Didn't Leak from a Lab. Also WHO: Maybe It Did, Bulletin of the Atomic Scientists, 11 November 2021, available at: https://thebulletin.org/2021/02/who-covid-19-didnt-leak-from-a-lab-also-who-maybe-it-did/ (last accessed 28 May 2022); but see WHO, WHO-Convened Global Study of Origins of SARS-CoV-2: China Part (2021), 118–120, concluding that 'a laboratory origin of the pandemic was considered to be extremely unlikely'; *Thomas Gaulkin/Matt Field*, WHO's "Exciting Adventure" to Find the Origins of COVID-19 Runs into Trouble, Bulletin of the Atomic Scientists, 30 March 2021, available at: https://thebulletin.org/2021/03/whos-exciting-adventure-to-find-the-origins-of-covid-19-runs-into-trouble/ (last accessed 28 May 2022).

6 *Kristian G. Andersen* et al., The Proximal Origin of SARS-CoV-2, 26 (2020) Nature Medicine 450; *Stephan Lewandowsky* et al., Conspiracy Theories Made It Harder for Scientists to Seek the Truth, 326 (2022) Scientific American 72.

7 *Kate Cook*, Liability: 'No Liability, No Protocol', in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 371, 373.

8 See NASEM, Genetically Engineered Crops (2016), 97–170; see chapter 1, section B.V.2.

The advent of genome editing also enables new approaches in the development of *self-spreading biotechnology*, by which I refer to genetically modified organisms and viruses specifically engineered to spread rapidly through natural populations. This includes *gene drives*, which are 'selfish' genetic elements that use various molecular mechanisms to bias inheritance in their favour, thus overriding the natural 50 % probability of inheritance commonly found in sexually reproducing organisms.[9] Engineered gene drives can be used to disseminate genetic modifications through natural populations of a particular species, either to change certain characteristics of that species or to reduce its abundance, potentially to the point of extinction. The currently most advanced research in the field of engineered gene drives aims to suppress populations of mosquito species that transmit malaria to humans.[10]

Since gene drives create a *vertical spread* by increasing the rate of their transmission to subsequent generations, it usually takes several generations for the drive construct to become prevalent in a population. In contrast, *horizontal* self-spreading techniques aim for a spread within the same generation of organisms. This can be achieved by genetically engineering pathogens or symbionts so that they perform certain tasks in the target organism once they have reached it. For instance, genetically modified viruses have been used to protect crops against infectious diseases.[11] Moreover, current research aims at developing viruses that perform genome editing directly in their target organism, which potentially allows to genetically modify entire populations or even species of organisms within a single generation.[12] These so-called *horizontal environmental genetic alteration agents* (HEGAAs) also raise concerns about their potential for misuse as biological weapons.[13]

Engineered gene drives and HEGAAs share a feature that distinguishes them fundamentally from conventional approaches to genetic engineering: genetic modification is no longer performed under controlled conditions in a laboratory but takes place directly in the environment. These approaches thus imply a 'shift from the release of a finished and tested

9 Cf. *Luke S. Alphey* et al., Opinion: Standardizing the Definition of Gene Drive, 117 (2020) PNAS 30864; see generally *Austin Burt/Robert Trivers*, Genes in Conflict (2006).
10 See chapter 1, section C.III.1.c).
11 See chapter 1, section E.I.
12 See chapter 1, section D.
13 Cf. *R. Guy Reeves* et al., Agricultural Research, or a New Bioweapon System?, 362 (2018) Science 35.

product to the release of an adjustable tool for genetic modification that is released into ecosystems'.[14] Most existing risk assessment and management frameworks are not yet equipped to address the particular risks that arise from such uncontrolled modification processes.

It appears to be undisputed that the emergence of self-spreading biotechnology presents significant challenges to international law. These challenges are aptly exemplified by the case of live viruses engineered into 'transmissible vaccines'. Around two decades ago, Spanish researchers developed such a transmissible vaccine to protect wild rabbits, which are an endangered species in their native habitat, the Iberian Peninsula.[15] This vaccine, however, protects rabbits against the very same natural viruses used for biological control in Australia, where the European rabbit is an invasive species that has caused devastating effects on local ecosystems.[16] Considering previous examples of unintentional or illegal transboundary movements of biocontrol agents,[17] it would seem just a matter of time until such a vaccine occurred in Australia and undermined biocontrol efforts there.

A similar example is the proposed use of an engineered gene drive to suppress *Palmer amaranth*, which has developed resistance to glyphosate and has become a major agricultural weed in the Southern United States.[18] However, Palmer amaranth can interbreed with related *Amaranthus* species cultivated as food crops in nearby Mexico and elsewhere.[19] An unintended spread of a suppression drive in Palmer amaranth could, therefore, severely impact the production of Amaranth crops.[20] There are numerous similar examples where the use of self-spreading biotechnology by one state may

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14 *Samson Simon* et al., Synthetic Gene Drive: Between Continuity and Novelty (2018) EMBO Reports e45760, 2.

15 *Juan M. Torres* et al., First Field Trial of a Transmissible Recombinant Vaccine Against Myxomatosis and Rabbit Hemorrhagic Disease, 19 (2001) Vaccine 4536; see chapter 1, section E.II.

16 *Elena Angulo/Ben Gilna*, When Biotech Crosses Borders, 26 (2008) Nature Biotech. 277, 278–279.

17 See, e.g., *Peter O'Hara*, The Illegal Introduction of Rabbit Haemorrhagic Disease Virus in New Zealand, 25 (2006) Revue scientifique et technique (International Office of Epizootics) 119.

18 Cf. NASEM, Gene Drives on the Horizon (2016), 57–58; *Jacob S. Montgomery* et al., Sex-Specific Markers for Waterhemp (Amaranthus Tuberculatus) and Palmer Amaranth (Amaranthus Palmeri), 67 (2019) Weed Science 412.

19 Cf. *D. M. Brenner* et al., Genetic Resources and Breeding of Amaranthus, in: Jules Janick (ed.), Plant Breeding Reviews, Volume 19 (2000) 227, 239–240.

20 NASEM, Gene Drives on the Horizon (n. 18), 168.

be incompatible with the priorities and interests of other states.[21] Genetic techniques aimed at suppressing or eradicating entire species may even be incompatible with international law altogether.[22]

While it is commonplace that uncontrolled transboundary dispersals and adverse side-effects of self-spreading biotechnology shall be prevented, it is yet uncertain under which conditions accountability can be established when such effects occur nevertheless. Only recently, a paper in the journal *Science* asked: 'Who is responsible, or liable, if self-spreading viruses don't behave as expected or cross national borders?'[23] For this reason, the present study addresses the challenges to international law posed by self-spreading biotechnology not only from the perspective of *prevention* but also gives prominence to the issues of *responsibility* and *liability*.

In the context of hazardous activities such as those at stake, the concept of liability serves two purposes. The most natural and important function of liability is *reparation*, which means that the injury suffered by the victim of a harmful event shall be remedied.[24] The reparative dimension of liability gives effect to the 'polluter-pays principle', seeking to ensure that the injurious consequences of harm should not 'lie where they fall' but be repaired by the party which has caused the damage.[25] In other words, the purpose of reparation is 'to shift the loss unreasonably suffered by the victim to the tortfeasor'.[26] Moreover, reparation also may have a *corrective* function in that it provides a method of enforcing the law *ex post facto*.[27] This is particularly relevant in the context of international law, which provides only limited means to 'punish' states for serious breaches of their obligations.[28]

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21 See *Wendy R. Henderson/Elaine C. Murphy*, Pest or Prized Possession? Genetically Modified Biocontrol from an International Perspective, 34 (2007) Wildlife Research 578; *Angulo/Gilna* (n. 16).

22 *Axel Hochkirch* et al., License to Kill?, 11 (2018) Conservation Letters e12370; see chapter 3, section B.VIII.

23 *Filippa Lentzos* et al., Eroding Norms over Release of Self-Spreading Viruses, 375 (2022) Science 31, 31.

24 *Johan G. Lammers*, International Responsibility and Liability for Damage Caused by Environmental Interferences, 31 (2001) Environmental Policy and Law 42–50 and 94–105, 43.

25 *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 1–3.

26 *Hanqin Xue*, Transboundary Damage in International Law (2003), 277.

27 *Lefeber* (n. 25), 1.

28 See *James Crawford*, International Crimes of States, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 405.

Besides its *reparative* function, liability also has a *preventive* effect. It is assumed that the risk of being exposed to liability deters noxious behaviour and provides an incentive to act diligently and prevent damage.[29] In other words, it may be more economical for a party to prevent damage from the outset rather than having to compensate for it later.[30] In the context of molecular biotechnology, it has even been assumed that the prevention of damage was the 'primary goal of liability'.[31]

The prevention of, and responsibility and liability for, transboundary harm under international law is already a thoroughly studied field. The United Nations' *International Law Commission* has spent decades of work on this issue,[32] and the body of scholarly literature in the field is overwhelming.[33] However, the specific problems evoked by self-spreading biotechnology demand a fresh look at the topic. Moreover, the *Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress*, which provides dedicated rules and procedures for transboundary damage caused by genetically engineered organisms, entered into force in 2018.[34] This is notable far beyond the present context, as the Supplementary Protocol is the first global treaty on liability for transboundary harm outside the areas

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29 *Lammers* (n. 24), 43.

30 *Michael G. Faure/Andri Wibisana*, Liability in Cases of Damage Resulting from GMOs: An Economic Perspective, in: Bernhard A. Koch/Bjarte Askeland (eds.), Economic Loss Caused by Genetically Modified Organisms (2008) 531, 536–537.

31 *Ibid.*, MN. 15. The preventive function of liability is also recognized in the *Nagoya – Kuala Lumpur Supplementary Protocol*, whose stated objective is to 'contribute to the conservation and sustainable use of biological diversity […] by providing international rules and procedures in the field of liability and redress', cf. Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64, Article 1.

32 For a detailed account of the ILC's work, see *Julio Barboza*, The Environment, Risk and Liability in International Law (2011).

33 Leading studies in the field are, to name but a few, *Jenks* (n. 1); *L.F.E. Goldie*, Concepts of Strict and Absolute Liability and the Ranking of Liability in Terms of Relative Exposure to Risk, 16 (1985) NYL 175; *Francesco Francioni/Tullio Scovazzi* (eds.), International Responsibility for Environmental Harm (1991); *Lefeber* (n. 25); *Phoebe N. Okowa*, State Responsibility for Transboundary Air Pollution in International Law (2000); *Edward H. P. Brans*, Liability for Damage to Public Natural Resources (2001); *Lucas Bergkamp*, Liability and Environment (2001); *Xue* (n. 26); *Rebecca M. Bratspies/Russell A. Miller* (eds.), Transboundary Harm in International Law (2006); *Barboza* (n. 32).

34 CBD Secretariat, Press Release: Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress Comes into Force (05 March 2018), available at: http://bch.cbd.int/protocol/e-doc/?news=116175 (last accessed 28 May 2022).

of oil pollution, nuclear damage, and space law that has ever attracted sufficient ratifications to enter into force.[35] The Supplementary Protocol also signifies the result of a 'paradigm evolution' by providing for an 'administrative approach' to liability instead of pursuing the conventional civil liability approach.[36] Nevertheless, it has only received comparatively little scholarly attention since it was adopted in 2010.[37]

While the Supplementary Protocol provides for the liability of 'operators', it leaves the role of states largely unaddressed. In fact, the responsibility and liability of states in the context of transboundary harm caused by biotechnology are still unsettled. The ongoing negotiations about the international regulation of engineered gene drives aptly demonstrate the dire need for conceptual clarity on the obligations, responsibilities, and – ultimately – the liability of states for transboundary harm caused by such techniques.[38] In 2020, two leading Australian and German regulators noted that whether the international law of state responsibility for wrongful acts 'may apply for negative effects caused by [Gene Drive] releases is […] not completely solved yet'.[39] The present study seeks to capture the current state of development of international law by taking stock of the existing rules pertaining to transboundary effects of biotechnology and by carving out the remaining gaps and grey areas.

Part One sets the scene by reviewing the recent developments in biotechnology and the resulting challenges to international law. *Chapter 1* reviews the aforementioned advances in molecular biology, particularly the emergence of self-spreading biotechnology. It also identifies the limitations and risks of these techniques which may potentially give rise to transboundary harm. Subsequently, *chapter 2* briefly introduces key terms and concepts relevant to responsibility and liability for transboundary harm under international law.

Part Two analyses the rules of international law relating to the prevention of harm from conventional and self-spreading biotechnology. The principal instrument in this field is the *Cartagena Protocol on Biosafety*,

35 On this problem generally, see *Anne Daniel*, Civil Liability Regimes as a Complement to Multilateral Environmental Agreements, 12 (2003) RECIEL 225.

36 *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73; see chapter 2, section G.

37 See the references in chapter 6, n. 6.

38 See chapter 5.

39 *Heidi J. Mitchell/Detlef Bartsch*, Regulation of GM Organisms for Invasive Species Control, 7 (2020) Front. Bioeng. & Biotechnol. 927, 4.

which applies to 'living modified organisms' (LMOs).[40] However, it is currently controversial whether the Protocol's scope extends to genome-edited organisms that do not contain transgenic DNA. Moreover, some authors have contended that the Protocol may not apply to organisms containing engineered gene drives. Therefore, *chapter 3* clarifies the Protocol's scope before assessing its substantive provisions, which focus on the *transboundary movement* of LMOs. The chapter also addresses a range of other relevant instruments, including the *Convention on Biological Diversity* and the *Biological Weapons Convention*.

In addition to international treaties, the general rules of customary international law on the prevention of transboundary harm are highly relevant. On the one hand, this is because several states that are key actors in the field have not ratified the Cartagena Protocol. On the other hand, the general obligation of prevention is only insufficiently incorporated in the aforementioned treaties, thus giving even higher relevance to the general rules of customary international law. *Chapter 4* assesses the pertinent rules of custom relating to the prevention of transboundary harm, including the precautionary principle. The chapter also explores how breaches of these rules can be established.

As previously mentioned, there is currently a vivid debate among states on the general lawfulness of, but also the conditions for, environmental releases of organisms containing engineered gene drives. *Chapter 5* captures the current state of this debate and analyses the consequences of the first set of conditions agreed upon by states in 2018. It also identifies issues that have not yet been adequately addressed, such as the lack of binding standards on laboratory biosafety – an issue that may have become literally virulent as coronaviruses were routinely studied in medium-safety BSL-2 laboratories around the world before the outbreak of COVID-19.[41]

Part Three focuses on the liability of *operators*, which means those state and non-state actors involved in developing, producing and releasing biotechnological products. *Chapter 6* undertakes a thorough analysis of the aforementioned *Nagoya – Kuala Lumpur Supplementary Protocol*. The Supplementary Protocol addresses damage to biological diversity resulting

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40 The Cartagena Protocol as well as the Supplementary Protocol refer to 'living modified organisms' (LMOs) instead of the more common term 'genetically modified organisms' (GMOs). The present study refers to LMOs unless where addressing other national or international instruments that apply to GMOs. See chapter 3, section A.I.1.

41 *Andersen* et al. (n. 6).

from transboundary movements of LMOs and provides for the imposition of operator liability under the domestic legal systems of its state parties. However, it only insufficiently regulates several issues that are crucial in those transboundary situations to which the Protocol applies. In any event, the largest weakness of the Supplementary Protocol lies in its limited membership – as of May 2022, it has only 49 parties, missing many states that are key players in the field of biotechnology.

An alternative approach to operator liability is offered by the *Biodiversity Compact*, a private scheme by which a group of major biotechnology corporations have voluntarily assumed liability for biodiversity damage caused by any of their LMOs. *Chapter 7* examines this instrument and discusses whether it can fill the gaps left by the Supplementary Protocol. Furthermore, it has been suggested that there is an emerging rule of international law that states must ensure 'prompt and adequate compensation' of foreign victims in the event of significant transboundary harm. *Chapter 8* assesses whether this obligation, which aims at the provision of transnational operator liability, is already part of current international customary law.

Part Four addresses the responsibility and liability of states. *Chapter 9* analyses the law of state responsibility for breaches of international law. It thus builds upon the preceding chapters, which have focused on 'primary' obligations of states to prevent transboundary harm and to provide for operator liability when such harm occurs. The chapter analyses the conditions under which states are internationally responsible as well as the consequences and implementation of such responsibility.

Due to the legal nature of the obligation to prevent transboundary harm, the mere occurrence of such harm does not always indicate a breach of international law. Thus, there may well be cases in which transboundary harm occurs but neither the operator nor the state is required to compensate under the aforementioned regimes. Against this background, there are convincing policy arguments in favour of strict state liability, which refers to an obligation of states to compensate for transboundary damage regardless of whether they have breached international law. *Chapter 10* undertakes an analysis of international practice to determine whether strict state liability can be established as a rule of contemporary customary international law.

Finally, a controversial topic cutting across all of the aforementioned instruments and regimes is to which extent international law provides for compensation for environmental damage. The underlying question is whether the intrinsic value of the environment *per se* can be quantified in monetary terms, which is widely seen as a precondition for compensability. But determining the 'nature and quantum' of compensation for environmental damage raises complex problems, as shown by the first-ever judgment on this issue by the *International Court of Justice* in 2018.[42] *Chapter 11* analyses this judgment as well as other international practice and carves out generally accepted principles.

In sum, the present study seeks to provide conceptual clarity on the complex interaction between prevention, responsibility, and liability for transboundary harm under international law. It demonstrates how states are required to prevent transboundary harm from being caused by applications of biotechnology. It establishes that states must ensure that operators who have caused such harm can be held liable under their domestic legal system. States themselves are only responsible for transboundary harm if they have failed to take diligent action towards preventing such harm or if they fail to ensure that foreign victims can obtain prompt and adequate compensation from the responsible operators under their domestic legal system. Thus, although states will rarely be liable themselves, they must still ensure that such harm does not remain unredressed. Clarifying the interplay between primary and secondary obligations in international law as it stands today will help to gradually improve these obligations and to fill the remaining gaps.

42 ICJ, Certain Activities Carried out by Nicaragua in the Border Area (Costa Rica v. Nicaragua), Compensation Owed by Nicaragua to Costa Rica, Judgment of 02 February 2018, ICJ Rep. 15.

Part One:
Self-Spreading Biotechnology Challenges International Law

Chapter 1:
The Emergence of Self-Spreading Biotechnology

Legal practitioners and scholars alike often tend to break down the facts of a case to only those aspects they deem essential for appreciating that case from the legal perspective. At the interface of science and law, however, this habit runs the risk of oversimplifying the facts, which can result in the legal analysis being incomplete or even incorrect. Therefore, to provide a solid factual basis for the ensuing legal discussion, this first chapter undertakes a concise review of the recent advances in molecular biology in general and the emergence of self-spreading biotechnology in particular.

Since apprehending these developments requires a general understanding of the underlying biological principles, the first section will provide a brief introduction to genetics and molecular biology (A.). For a more detailed account, extensive monographs and treatises are available.[1] Subsequently, techniques for *genome editing* will be discussed, which are methods for precisely modifying the genetic information of any organism (B.). These techniques also enable the development of *engineered gene drives*, which are methods to increase the inheritance of a genetic modification in wild populations (C.). Besides gene drives, *horizontal environmental genetic alteration techniques* are developed to modify large numbers of individual organisms of the same generation simultaneously (D.). The last section will address approaches that also involve self-spreading techniques but are not aimed at genetically modifying their target organisms (E.).

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1 For a compelling and non-technical introduction, see *Siddhartha Mukherjee*, The Gene (2016). On plant breeding, see *Noël Kingsbury*, Hybrid: The History and Science of Plant Breeding (2009). For an introduction to genetics, see *Benjamin A. Pierce*, Genetics (7th ed. 2020). For a detailed account of molecular biology, see *Bruce Albers* et al., Molecular Biology of the Cell (6th ed. 2015). For a treatise on modern biotechnology, see *David P. Clark* et al., Molecular Biology (3rd ed. 2019).

A. Principles of Genetics and Molecular Biology

When *Gregor Mendel* described his observations on the heredity of traits in pea breeding in 1866,[2] he was not aware of the underlying biological principles. However, the discovery of these principles later validated Mendel's assumptions. In the last few decades, large progress has been made in the study of the molecular biology of the cell. Today, we have discovered not only how genetic information is stored, but also how this information is processed, passed on to subsequent generations and how genetic variations contribute to evolution. The present section will briefly recall the most important aspects of molecular biology (I.), natural genetic change and inheritance (II.), and human-made or *anthropogenic* genetic change (III.).

I. Basics of Molecular Biology

Genetic information is encoded in sequences of *nucleic acid*. Nucleic acids are made up of chains of *nucleotides*. Nucleotides are molecules comprised of sugar, phosphate, and a *nitrogenous base*. There are four different types of nitrogenous bases in nucleic acid: *adenine* (A), *cytosine* (C), *guanine* (G), and *thymine* (T). Because only the base differs in each of the four types of nucleotides, a polynucleotide chain resembles a necklace made from sugar and phosphate, from which hang the four types of beads (the bases A, C, G, and T).[3] The sequence in which these bases occur in a polynucleotide chain encodes genetic information, similar to a human message written in an alphabetic script.[4] The term *gene* often refers to pieces of nucleic acid encoding a certain genetic characteristic.[5] In contrast, the term *genome* denotes the entirety of an organism's genetic (or heritable) material.[6]

Most organisms carry their genome in *deoxyribonucleic acid* (DNA). DNA consists of two strands of nucleotides that usually take the form of a *double helix*.[7] These strands are complementary to each other, which

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2 *Gregor Mendel*, Versuche über Pflanzen-Hybriden (Experiments on Plant Hybrids), 4 (1866) Verhandlungen des Naturforschenden Vereins zu Brünn 3.
3 *Albers* et al. (n. 1), 175.
4 *Ibid.*, 5.
5 *Pierce* (n. 1), 12; cf. 'gene', in: *Eleanor Lawrence* (ed.), Henderson's Dictionary of Biology (16th ed. 2016), 224.
6 *Albers* et al. (n. 1), 7; cf. 'genome', in: Henderson's Dictionary of Biology (n. 5), 228.
7 *Albers* et al. (n. 1), 176.

means that any A base on the first strand always pairs with T on the second strand, and G always pairs with C.[8] This principle is important for how DNA is replicated during cell division (*mitosis* and *meiosis*): in these processes, the two strands of the DNA double helix are pulled apart, and each serves as a template for synthesis of a new complementary strand. These newly formed complementary strands then pair with the original strands forming an additional DNA double helix.[9]

In *eukaryotes* (i.e. organisms whose cells possess a complex structure including a membrane-enclosed nucleus[10]), DNA is organized in sets of *chromosomes*, which are compact packages of long, thread-like DNA strands and associated proteins.[11] Most eukaryotes possess two copies of each chromosome, one of which is inherited from each parent. These pairs of *homologous chromosomes* (or *homologs*) are usually alike in structure and size and carry the genetic information for the same set of hereditary characteristics.[12] Of any given gene, the corresponding variants situated on the maternal and paternal chromosomes are called *alleles*.[13] When both alleles of a certain gene are identical, the organism is called *homozygous* with respect to that gene.[14] On the other hand, when the alleles encode different information, the organism is referred to as *heterozygous*.[15] The only *non-homologous* chromosome pair are the sex chromosomes in males of many species, where a Y chromosome is inherited from the father and an X chromosome from the mother.[16]

Eukaryotic *gametes* (i.e. eggs and sperm[17]) are *haploid*, which means that they only possess one copy of each gene. The formation of gametes, which is called *meiosis*, follows a different procedure than regular (*mitotic*) cell division and is discussed below.[18] When the egg becomes fertilized

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8 *Ibid.*
9 *Ibid.*, 4.
10 Cf. 'Eukarya', in: Henderson's Dictionary of Biology (n. 5), 192.
11 *Albers* et al. (n. 1), 180–181.
12 *Pierce* (n. 1), 21.
13 Cf. 'allele', in: Henderson's Dictionary of Biology (n. 5), 20.
14 Cf. 'homozygous', in: *ibid.*, 267.
15 Cf. 'heterozygous', in: *ibid.*, 260.
16 *Albers* et al. (n. 1), 180. Note that some species have different sex determination systems, including such that rely fully or in part on environmental factors. See generally *Pierce* (n. 1), 83–89; on environmental sex determination, see *F. J. Janzen/P. C. Phillips*, Exploring the Evolution of Environmental Sex Determination, Especially in Reptiles, 19 (2006) Journal of Evolutionary Biology 1775.
17 Cf. 'gamete', in: Henderson's Dictionary of Biology (n. 5), 220.
18 See *infra* section A.II.2.

by the sperm in sexual reproduction, the egg and sperm each contribute one set of chromosomes, which are subsequently merged into the new homologous chromosome set of the offspring.[19] This process constitutes the molecular background behind *Mendel's laws* on the inheritance of traits, which will be discussed below.[20]

The cells of each species have a characteristic number of chromosomes.[21] For example, the cells of most mosquito species possess 2n=6 chromosomes (i.e. 3 pairs);[22] human cells possess 2n=46 (i.e. 23 pairs) and pigeon cells possess 2n=80 chromosomes (i.e. 40 pairs).[23] Some eukaryotic organisms, in particular many plants that are bred as crops, are *polyploid* which means that they possess more than two chromosomal copies. For example, ancestral wheat has seven pairs of chromosomes (i.e. 2n=14), whereas contemporary bread wheat is *hexaploid*, meaning that it possesses six sets of seven chromosomes each (i.e. 6n=42).[24]

The process of implementing the information stored in the genome is called *gene expression*. Gene expression commonly appears as a two-step process. First, in *transcription*, segments of the DNA sequence are guiding the synthesis of snippets of *ribonucleic acid* (RNA).[25] RNA is closely related to DNA but appears as a single-stranded chain of nucleotides (as opposed to DNA, which consists of two complementary nucleotide strands).[26]

In the second step, called *translation*, the RNA molecules created in the first step direct the synthesis of *proteins*.[27] Proteins, which are polypeptide chains composed of amino acids,[28] are then responsible for actually implementing the genetic information by performing various functions within the cell. Many proteins are enzymes that catalyse chemical reactions. Other

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19 *Pierce* (n. 1), 21.
20 See *infra* section A.II.3.
21 *Clark* et al. (n. 1), 13–15.
22 *Karamjit S. Rai/William C. Black*, Mosquito Genomes, 41 (1999) Advances in Genetics 1, 5–6.
23 *Pierce* (n. 1), 13.
24 *Clark* et al. (n. 1), 45.
25 *Albers* et al. (n. 1), 4.
26 RNA also has a biochemical composition that slightly differs from that of DNA: it uses a different sugar as its backbone (ribose instead of deoxyribose) and the base *thymine* (T) is replaced by *uracil* (U), which however are compatible with each other. See *ibid.*
27 *Ibid.*
28 Cf. 'protein', in: Henderson's Dictionary of Biology (n. 5), 475.

proteins form structural components, help transport substances or perform various regulatory, sensory, communication, or defence functions.[29]

Notably, not all information stored in the genome of an organism (*genotype*) is necessarily expressed in the physical, physiological, biochemical, or behavioural characteristics of that organism (*phenotype*). The genotype merely determines the *boundaries* for development, while the phenotype is determined by the interplay of various genes and by environmental factors.[30]

II. Natural Genetic Change and Inheritance

Evolution denotes the development of new types of living organisms by the accumulation of genetic variations over several generations.[31] The main triggers of genetic variation are *genetic mutation* (1.) and the *recombination and segregation of DNA* from two individuals during sexual reproduction (2.).[32] These mechanisms lead to genetic inheritance in line with the principles discovered by Mendel (3.). The frequency at which alleles occur in the gene pool is influenced by several factors.[33] One of these factors is *natural selection*, which results from the fact that different phenotypes resulting from genetic variation have different rates of physical and reproductive fitness in different environments.[34]

1. Genetic Mutation

The term *mutation* generally denotes a change in the amount of chemical structure of DNA.[35] Mutations can take the form of *point mutations*, which are local changes in the DNA sequence such as the substitution of one base pair with another, but may also appear as large-scale genome rearrangements, including deletions, duplications, insertions and even translo-

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29 *Pierce* (n. 1), 439; *Albers* et al. (n. 1), 6.
30 *William S. Klug* et al., Concepts of Genetics (2019), 82–85.
31 Cf. 'evolution', in: Henderson's Dictionary of Biology (n. 5), 195.
32 See 'genetic variation', in *ibid.*, 227.
33 The study of these factors is called *Population Genetics*, see *Pierce* (n. 1), 765–795.
34 *Richard C. Lewontin*, The Units of Selection, 1 (1970) Annual Review of Ecology and Systematics 1, 1.
35 Cf. 'mutation', in: Henderson's Dictionary of Biology (n. 5), 371–372.

cations of DNA from one chromosome to another.[36] Mutations that occur in the body cells are called *somatic mutations* and are only passed on to the immediate descendants of that cell. However, mutations occurring in germline cells can be inherited by the offspring organism.[37]

Mutations are caused by several factors. Most mutations arise from failures in the cell's own mechanisms by which DNA is replicated, recombined, or repaired.[38] However, damage to DNA can also be caused by external influences such as heat, metabolic accidents, radiation of various sorts, or exposure to chemical substances in the environment.[39]

Another source of genetic change is so-called *transposable DNA elements* or *transposons*, which are DNA elements that possess the property of changing their position within the genome.[40] Transposable elements are *selfish genetic elements* that can bias their transmission to subsequent generations in their favour. Transposable elements thus are naturally occurring *gene drive* mechanisms that can spread through populations at a higher rate than it would normally be expected under the laws of *Mendelian inheritance*.[41]

Cells contain multiple systems that can recognize and repair many types of damaged or altered DNA.[42] Since most spontaneous changes are remedied by these mechanisms, only very few of them cause a permanent alteration of the genome. The mutation rate across all living organisms is approximately one nucleotide change per 10^{10} (ten billion) nucleotides each time the DNA is replicated.[43] This rate appears to create an *equilibrium* between genetic stability and genetic variability, which are both required to maintain permanent life.[44]

Due to the double-helical structure of DNA, damage on one DNA strand can easily be repaired by taking the second, complementary strand as a template.[45] *Double-strand breaks*, i.e. complete cuts affecting both DNA

36 *Albers* et al. (n. 1), 217–218.
37 Cf. 'mutation', in: Henderson's Dictionary of Biology (n. 5), 372.
38 *Albers* et al. (n. 1), 217–218.
39 *Ibid.*, 266.
40 Cf. 'transposable genetic elements', in: Henderson's Dictionary of Biology (n. 5), 598; see *Thomas Wicker* et al., A Unified Classification System for Eukaryotic Transposable Elements, 8 (2007) Nature Rev. Genet. 973, 973.
41 See *infra* section A.II.3.
42 See *Albers* et al. (n. 1), 269–276.
43 *Ibid.*, 239.
44 Cf. *ibid.*, 238–239.
45 *Ibid.*, 268–271.

strands, are more dangerous to the cell. If such a cut remains unrepaired, it can cause the chromosome to break down into fragments and lead to the loss of genes when the cell divides.[46] Cells possess two different mechanisms to repair double-strand breaks. *Homology-directed repair* (HDR, also called *homologous recombination*) fully restores the damage by using the homologous chromosome as a template. Therefore, HDR can only be applied in those phases of the cell cycle in which a sister chromosome is present.[47] In other cases, the damage is repaired by *non-homologous end joining* (NHEJ), in which the broken ends are brought together and rejoined. This generally involves losing a number of nucleotides at the site of joining, which results in a point mutation. For this reason, some genome editing techniques make use of NHEJ by introducing double-strand breaks at specific locations in the DNA in order to induce mutations there.[48]

2. Sexual Reproduction

Sexual reproduction and the associated recombination of DNA is a second important source of genetic variation. Sexual reproduction consists of two processes. The first is *meiosis*, which denotes the formation of *haploid* gametes in which the number of chromosomes is reduced by half. The second process is *fertilization*, in which the egg cell and the sperm cell fuse to form a *zygote* in which the maternal and paternal chromosome sets are joined to form the new diploid genome of the offspring.[49]

The process of meiosis begins with a stem cell that is *diploid*, which means that the cell possesses two complete sets of chromosomes, of which one set is of maternal and one is of paternal origin. During meiosis, each set of chromosomes is first replicated, resulting in four complete sets. These are then distributed to a total of four *haploid* gametes in two successive cell divisions. During this process, genetic variation is generated by two different mechanisms. Firstly, *inter-chromosomal recombination* causes a ‘reshuffling' of genetic information between the corresponding maternal and paternal chromosomes after they have been replicated.[50] Secondly, during cell division, the resulting chromosomes are randomly distributed

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46 *Ibid.*, 274.
47 *Ibid.*, 278–279.
48 See *infra* section B.I.
49 *Pierce* (n. 1), 28.
50 *Albers* et al. (n. 1), 1004–1010.

onto the gametes, so that each gamete receives either the maternal or the paternal copy of each chromosome (*chromosomal segregation*).[51] Consequently, each of the four resulting gametes carries a different combination of alleles. Despite certain differences, these processes are essentially the same in plants and animals.[52]

3. Mendel's Laws of Inheritance

The molecular biology of sexual reproduction I described above forms the background for Mendel's observations on the principles (or 'laws', as they are often called) of inheritance.[53] The first, called *principle of segregation*, describes the observation that diploid organisms possess two *alleles* (i.e. variants of a given gene) for any particular trait and that these alleles segregate during meiosis. Consequently, for any given gene, half the gametes will carry one allele and half the other.[54] The second observation, termed *independent assortment*, is that alleles for separate traits are passed on independently from each other (which occurs as a result of the chromosomal segregation during meiosis).[55] Mendel's third rule, called the *principle of dominance*, describes the consequences of segregation and independent assortment: whenever an organism possesses two different genes for a particular trait, only one of them (the *dominant* allele) is expressed in the phenotype.[56] The other allele, which is called *recessive*, remains part of the genotype and will be passed on to half of the organism's gametes.

III. Anthropogenic Genetic Change

Humankind has been a source of genetic change for a long time. On the one hand, human activity such as land development, exploitation of resources, and pollution is the main cause of the decline and extinction

51 *Pierce* (n. 1), 33–34.
52 *Ibid.*, 38.
53 See *Mendel* (n. 2).
54 *Pierce* (n. 1), 53–54; 'segregation of alleles', in Henderson's Dictionary of Biology (n. 5), 532.
55 *Pierce* (n. 1), 62–63; see 'independent assortment', in Henderson's Dictionary of Biology (n. 5), 285.
56 *Pierce* (n. 1), 53; see 'dominance', in Henderson's Dictionary of Biology (n. 5), 164.

of species.[57] On the other hand, humans have domesticated and improved animal and plant species for thousands of years.[58] For most of the time, the only method to improve cultivated species was *selective breeding*, which refers to selectively mating strains that possess desired traits such as increased productivity or resistance.[59]

After the principles of genetics were discovered in the early twentieth century, novel breeding techniques such as *hybridization* were developed, which however still relied on utilizing naturally occurring genetic mutations.[60] In the late 1920s, it was discovered that certain mutagenic agents such as radiation and chemicals increase the rate of genetic mutations in an organism, and that these agents can be used to accelerate breeding by creating large amounts of mutants and then selecting individuals with desired characteristics.[61] This technique is today known as *mutation breeding* or *mutagenesis*.[62]

In the following decades, genetic science advanced quickly. Major milestones include the decryption of the chemical structure and molecular functioning of DNA in 1966, the first creation of a transgenic organism in 1973, and the development of the first methods for sequencing DNA in 1977 and multiplying DNA segments in 1983.[63] The first genetically modified crop, an antibiotic-resistant tobacco plant, was produced in 1982.[64] The modification of endogenous genes became possible with the development of *gene targeting* methods based on homologous recombination.[65] More recently, the development of *genome editing* techniques substantially extended the possibilities to modify genetic information.

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57 See *Russell Lande*, Anthropogenic, Ecological and Genetic Factors in Extinction and Conservation, 40 (1998) Researches on Population Ecology 259.

58 On the history of plant breeding, see the extensive monograph by *Kingsbury* (n. 1).

59 *Rolf H. J. Schlegel*, Concise Encyclopedia of Crop Improvement (2007), 5–52; *Kingsbury* (n. 1), 155–186.

60 *Schlegel* (n. 59), 53–135.

61 *Hermann J. Muller*, Artificial Transmutation of the Gene, 66 (1927) Science 84; see *B. S. Ahloowalia* et al., Global Impact of Mutation-Derived Varieties, 135 (2004) Euphytica 187; *Schlegel* (n. 59), 96–101; *Kingsbury* (n. 1), 266–272.

62 Cf. 'mutagenesis' and 'mutation breeding', in Henderson's Dictionary of Biology (n. 5), 371–372.

63 *Pierce* (n. 1), 9–11.

64 *Robert T. Fraley* et al., Expression of Bacterial Genes in Plant Cells, 80 (1983) PNAS 4803.

65 *Wenfang Tan* et al., Gene Targeting, Genome Editing, 25 (2016) Transgenic Research 273, 274–275; *Almudena Fernández* et al., A History of Genome Editing in Mammals, 28 (2017) Mammalian Genome 237, 237.

B. Genome Editing

A central challenge in biotechnology is to induce genetic changes at *specific locations* in the genome, i.e. at a particular site of the DNA sequence within a certain chromosome. If existing genes are to be modified or knocked out, the genetic modification must necessarily take place at the location of the targeted gene. In conventional *mutation breeding* (where random mutations are induced by exposing the organisms to certain chemicals or radiation), the search for an individual bearing a mutation at the desired genomic location or showing the desired traits in its phenotype is a laborious and time-consuming step.

In addition, it is now known that not only the existence of a certain gene but also its position in the genome can be decisive for its phenotypic expression.[66] Hence, when transgenes are to be inserted into an organism, it is not always sufficient to achieve integration of these transgenes at a random location in the genome of the plant, as is the case with earlier genetic engineering methods.[67]

For many years, strategies of efficiently inducing precise, targeted genome alterations were laborious and limited to certain organisms.[68] Furthermore, these techniques often required drug-selectable markers or left behind unwanted DNA sequences associated with the modification method.[69] However, in the last decade, a number of techniques have been developed that allow for the introduction of double-strand breaks at specific locations of an organism's DNA, which can be used to site-specifically insert, delete or replace genetic information. These techniques are commonly denoted as *genome editing* techniques.

The following section outlines the general principles underlying genome editing (I.). Subsequently, the most relevant techniques are described (II.). This is followed by an overview of potential and already existing applications of genome editing techniques (III.) before the technical

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66 See, in particular, *Matthew V. Rockman* et al., Selection at Linked Sites Shapes Heritable Phenotypic Variation in C. Elegans, 330 (2010) Science 372.

67 See *Schlegel* (n. 59), 157–174; *Götz Laible* et al., Improving Livestock for Agriculture, 10 (2015) Biotechnology Journal 109, 112–113; *Katia Pauwels* et al., Engineering Nucleases for Gene Targeting: Safety and Regulatory Considerations, 31 (2014) New Biotechnology 18.

68 *Jeffry D. Sander/J. K. Joung*, CRISPR-Cas Systems for Editing, Regulating and Targeting Genomes, 32 (2014) Nature Biotech. 347, 347; see *Tan* et al. (n. 65), 273–275.

69 *Sander/Joung* (n. 68), 347.

challenges and limitations of these methods (IV.) as well as environmental risks and ethical concerns (V.) are addressed.

I. Functioning of Genome Editing

Most current approaches to genome editing follow the same principles. Firstly, a double-strand break is induced at the location in the genome where the modification is intended. This can be achieved by using *site-directed nucleases*. *Nucleases* are naturally occurring enzymes that can cleave the nucleotide chain of nucleic acid.[70] A *site-directed* nuclease (SDN) can bind to a specific DNA sequence and then cleave the DNA at this location. After such a break has been induced, intra-cellular DNA repair mechanisms will attempt to repair the break. These mechanisms can be harnessed to introduce the intended modification. Generally, genome editing techniques based on SDNs are categorized as follows:[71]

SDN-1: In its most basic form, only the SDN is delivered to the organism without a repair template. The cell will repair the DNA break by *non-homologous end joining* (NHEJ), which means that the two loose ends of DNA are simply joined together.[72] This process tends to add or leave out a small number of nucleotides. Hence, NHEJ often induces small mutations (so-called *indels*) at the cleavage site, which can be used to knock out a specific gene.[73] Alternatively, larger DNA sequences can be 'deleted'

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70 Cf. 'nuclease', in: Henderson's Dictionary of Biology (n. 5), 392; *Albers* et al. (n. 1), 464–465.

71 See *Maria Lusser/Howard V. Davies*, Comparative Regulatory Approaches for Groups of New Plant Breeding Techniques, 30 (2013) New Biotechnology 437; *Thorben Sprink* et al., Regulatory Hurdles for Genome Editing: Process- vs. Product-Based Approaches in Different Regulatory Contexts, 35 (2016) Plant Cell Reports 1493, 1504 and Figure 2 on p. 1498. Note that some publications (e.g. *Motoko Araki* et al., Caution Required for Handling Genome Editing Technology, 32 (2014) Trends in Biotechnology 234, 235; European Commission, New Techniques Working Group (NTWG): Final Report, not officially published (2012), 14–16; *Maria Lusser* et al., New Plant Breeding Techniques: State-of-the-Art and Prospects for Commercial Development (2011), 19) also refer to these methods as ZFN-1, ZFN-2 and ZFN-3, implying the use of ZFN as site-directed nuclease to induce a double-strand break (see *infra* section B.II.1). The editing pathways, however, are identical to those of other SDNs.

72 *Pierce* (n. 1), 575–576; see *supra* section A.II.1.

73 *Thomas Gaj* et al., ZFN, TALEN, and CRISPR/Cas-Based Methods for Genome Engineering, 31 (2013) Trends in Biotechnology 397, 400; *Lusser/Davies* (n. 71), 440; *Sander/Joung* (n. 68), 347; *Pauwels* et al. (n. 67), 19 and Figure 2 on p. 20.

by inducing breaks at either end of the targeted sequence.[74] It is also possible to induce mutations at several locations in one step.[75]

SDN-2: The second option is to direct the DNA repair by providing a 'repair template'. This template consists of a small DNA snippet which is identical (*homologous*) to the target site except for one or a few differing base pairs.[76] When the cell employs *homology-directed repair* (HDR),[77] it relies on the given template to repair the break, which leads to the inclusion of the pre-determined mutation at the target site.[78]

SDN-3: A double-strand break can also be used to introduce larger pieces of new DNA. This can be achieved by supplying a piece of 'donor' DNA which has ends corresponding to the DNA sequence at the intended cleavage site.[79] In between these homologous ends, the donor DNA may contain new genetic information.[80] Similar to SDN-2, the cell will rely on the donor DNA as a template for homology-directed repair, which results in the incorporation of the new sequence at the intended location.[81]

As mentioned above, most cell types and organisms have two pathways to repair DNA double-strand breaks, namely NHEJ and HDR.[82] If the cell relies on NHEJ, a given repair template is ignored and the resulting mutations will be random, as in SDN-1.[83] Hence, for SDN-2 and SDN-3 it is necessary that the damage is repaired by HDR.[84] Since both repair mechanisms operate in different phases of the cell cycle, timed delivery of the SDN and the repair template can influence which repair mechanism

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74 Cf. *Huanbin Zhou* et al., Large Chromosomal Deletions and Heritable Small Genetic Changes Induced by CRISPR/Cas9 in Rice, 42 (2014) Nucleic Acids Res. 10903.

75 See *Le Cong* et al., Multiplex Genome Engineering Using CRISPR/Cas Systems, 339 (2013) Science 819; *An Xiao* et al., Chromosomal Deletions and Inversions Mediated by TALENs and CRISPR/Cas in Zebrafish, 41 (2013) Nucleic Acids Res. e141.

76 *Sprink* et al. (n. 71), 1504.

77 See *supra* section A.II.1.

78 *Sander/Joung* (n. 68), 347; *Lusser/Davies* (n. 71), 440.

79 *Gaj* et al. (n. 73), 400.

80 *Sprink* et al. (n. 71), 1504.

81 *Gaj* et al. (n. 73), 400; *Lusser/Davies* (n. 71), 440; *Sprink* et al. (n. 71), 1504.

82 See *supra* section A.II.1. There are a number of other DNA repair mechanisms, including *single-strand annealing*, *alternative end joining*, and *microhomology-mediated joining*. See *Rodolphe Barrangou/Jennifer A. Doudna*, Applications of CRISPR Technologies in Research and Beyond, 34 (2016) Nature Biotech. 933, 933 for further references.

83 *Sprink* et al. (n. 71), 1504.

84 Cf. *Gaj* et al. (n. 73), 400.

is used.[85] Depending on the particular circumstances, the likelihood of achieving the desired mutation varies between 1 % and, in some cases, over 50 %.[86] Usually, a larger number of individuals need to be treated to identify a small number who carry the desired mutation using screening techniques.[87]

II. Engineered Nuclease Techniques for Site-Specific DNA Cleavage

The mechanisms described above require a DNA double-strand break to be induced at the target site. Hence, the main challenge of genome editing lies not in stimulating the repair, but in cleaving DNA at specific locations. This became first possible in the 1990s with the discovery of so-called *meganucleases,* whose 18 base pair long recognition site could be manipulated to target desired chromosomal sites. With meganucleases, it became possible for the first time to introduce DNA double-strand breaks at *predictable* locations. However, the recognition sites of meganucleases are randomly scattered in the genome and redesigning these recognition sites to target specific genes was very laborious.[88]

More recently, a number of techniques have been developed to engineer site-directed nucleases that can target virtually any DNA sequence. These techniques include engineered *zinc finger nucleases* (1.), synthetic *transcription-activator-like effector nucleases* (2.), and the *CRISPR-Cas* technique (3.).

1. Zinc Finger Nucleases

The first genome editing method that could be virtually universally applied was the *zinc-finger nuclease* (ZFN) technique.[89] Zinc finger nucleases are artificial constructs generated by fusing a non-specific nuclease domain (responsible for cleaving the DNA) to an engineered zinc finger DNA-

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85 *Steven Lin* et al., Enhanced Homology-Directed Human Genome Engineering by Controlled Timing of CRISPR/Cas9 Delivery, 3 (2014) eLife e04766.

86 *Sander/Joung* (n. 68), 347; see *Christopher D. Richardson* et al., Enhancing Homology-Directed Genome Editing by Catalytically Active and Inactive CRISPR-Cas9 Using Asymmetric Donor DNA, 34 (2016) Nature Biotech. 339.

87 *Sander/Joung* (n. 68), 347.

88 *Christian Jung* et al., Recent Developments in Genome Editing and Applications in Plant Breeding, 137 (2018) Plant Breeding 1, 2.

89 Cf. *Gaj* et al. (n. 73), 399; *Fernández* et al. (n. 65), 238–239.

binding domain.[90] Zinc fingers, which are a structural component shared by various DNA-binding proteins, can recognize certain three base pair long DNA sequences.[91] Scientists were able to engineer zinc fingers to recognize almost any of the 64 possible three-base pair combinations that can occur in DNA.[92] Additionally, arrays of multiple zinc fingers can be constructed to increase their specificity; these arrays can recognize DNA sequences of up to 18 base pairs in length.[93] These engineered zinc finger domains are then fused to a nuclease domain in order to create a *zinc finger nuclease* that will cleave DNA at the recognition site programmed in the zinc finger array.

The first ZFN was created and applied *in vitro* in 1996,[94] while the first successful application for targeted mutagenesis was reported in 2002.[95] After that, the ZFN technique has been applied to edit the genome of many plants and animals,[96] including mammals.[97] ZFNs were also applied in clinical trials to cure HIV.[98] For many years, ZFNs were the only available approach for inducing site-specific cuts in nucleic acid. However, the development of custom-made ZFN complexes remained laborious and expensive.[99]

2. Transcription Activator-Like Effector Nucleases

Transcription activator-like effector nucleases (TALENs) are structurally very similar to ZFNs since they also consist of a nuclease domain (responsible for cleaving DNA) and a DNA-binding domain (responsible for at-

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90 *Pierce* (n. 1), 574.
91 *Ibid.*, 472–473; *Gaj* et al. (n. 73), 398.
92 See *C. O. Pabo* et al., Design and Selection of Novel Cys2His2 Zinc Finger Proteins, 70 (2001) Annual Review of Biochemistry 313.
93 *Gaj* et al. (n. 73), 398.
94 *Y. G. Kim* et al., Hybrid Restriction Enzymes, 93 (1996) PNAS 1156.
95 *Marina Bibikova* et al., Targeted Chromosomal Cleavage and Mutagenesis in Drosophila Using Zinc-Finger Nucleases, 161 (2002) Genetics 1169.
96 See *Dana Carroll*, Genome Engineering with Zinc-Finger Nucleases, 188 (2011) Genetics 773, 776.
97 *Fernández* et al. (n. 65), 239.
98 *Pablo Tebas* et al., Gene Editing of CCR5 in Autologous CD4 t Cells of Persons Infected with HIV, 370 (2014) N. Engl. J. Med. 901.
99 *Sander/Joung* (n. 68), 348.

taching to specific DNA sequences).[100] Here, the DNA-binding domain is derived from naturally occurring TALE proteins that are secreted by the *Xanthomonas* bacteria. These proteins possess DNA-binding domains composed of series of *amino-acid repeats* that each recognize a single base pair.[101] Like zinc fingers, several TALE repeats can be linked together to recognize continuous DNA sequences. TALENs are equally efficient as ZFNs but relatively easier to design.[102] Therefore, the new technique was quickly adopted by a broad range of scientists after it had been developed in 2011.[103] Since then, TALENs were applied to edit the genome of numerous organisms.[104]

3. CRISPR-Cas

CRISPR/Cas9 was discovered as a novel technique for genome editing in 2012. CRISPR denotes adaptive immune systems used by prokaryotes (i.e. bacteria and archaea) to defend themselves against viruses and other foreign DNA elements.[105] These mechanisms memorize the genetic characteristics of past invaders and, when they intrude again, recognize and

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100 Cf. *Jens Boch* et al., Breaking the Code of DNA Binding Specificity of TAL-Type III Effectors, 326 (2009) Science 1509; *Matthew J. Moscou/Adam J. Bogdanove*, A Simple Cipher Governs DNA Recognition by TAL Effectors, 326 (2009) Science 1501; see *J. K. Joung/Jeffry D. Sander*, TALENs, 14 (2013) Nature Reviews Molecular Cell Biology 49, 49.

101 *Gaj* et al. (n. 73), 399.

102 *Joung/Sander* (n. 100), 49; *Sander/Joung* (n. 68), 348.

103 *Joung/Sander* (n. 100), 49.

104 See e.g. *Sanyuan Ma* et al., Highly Efficient and Specific Genome Editing in Silkworm Using Custom TALENs, 7 (2012) PLOS ONE e45035; *Xiao* et al. (n. 75); *Kulbhushan Chaudhary* et al., Transcription Activator-like Effector Nucleases (TALENs), 16 (2016) Engineering in Life Sciences 330, 334–335.

105 Approximately 46 % of bacteria and 90 % of archaea carry CRISPR loci in their genomes. Despite their similarity in role and function, there are many different CRISPR systems that are extremely variable in characteristics such as genetic locus, protein composition, RNA processing, and effector complex structure. The variety of natural CRISPR systems can be harnessed for various genome editing purposes. See *Philippe Horvath* et al., Applications of the Versatile CRISPR-Cas Systems, in: Rodolphe Barrangou/John van der Oost (eds.), CRISPR-Cas Systems (2013) 267; *Eugene V. Koonin* et al., Diversity, Classification and Evolution of CRISPR-Cas Systems, 37 (2017) Current Opinion in Microbiology 67.

destroy them.[106] When a prokaryote is first infected by a virus, it integrates short fragments of the viral DNA into special regions of its own genome. These regions are called CRISPR (from *clustered regularly interspaced short palindromic repeats*).[107] The CRISPR array is then continuously transcribed into RNA snippets called crRNA (from *CRISPR RNAs*).[108] These crRNAs combine with CRISPR-associated (*Cas*) proteins that can cleave DNA to form an *effector complex*. If at some point the same virus enters the cell again, the crRNA will immediately bind to its corresponding sequence in the viral DNA. Subsequently, the associated Cas protein will cleave and thereby destroy the viral DNA.[109]

The discovery of CRISPR-Cas as a genome editing tool was preceded by two decades of research into natural CRISPR systems.[110] When the occurrence of CRISPR sequences in prokaryotes was first discovered in the genome of the bacterium *Escherichia coli* in 1987,[111] the function of these sequences was still unclear.[112] In 2005, a systematic analysis of CRISPR arrays revealed that they are derived from foreign genetic elements[113] and that viruses are unable to infect prokaryotes carrying DNA sequences cor-

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106 *Emmanuelle Charpentier* et al., CrRNA Biogenesis, in: Rodolphe Barrangou/John van der Oost (eds.), CRISPR-Cas Systems (2013) 115, 137.

107 *Albers* et al. (n. 1), 434.

108 *Ibid.*

109 *Pierce* (n. 1), 574–575.

110 See *Eric S. Lander*, The Heroes of CRISPR, 164 (2016) Cell 18. Note that this article has been criticized for not adequately representing the share of some researchers in the discovery of CRISPR/Cas9 as a genome editing technique, cf. *Heidi Ledford*, The Unsung Heroes of CRISPR, 535 (2016) Nature News 342; *Tracy Vence*, “Heroes of CRISPR” Disputed, The Scientist, 19 January 2016, available at: https://www.the-scientist.com/?articles.view/articleNo/45119/title/-Heroes-of-CRISPR--Disputed/ (last accessed 28 May 2022).

111 *Yoshizumi Ishino* et al., Nucleotide Sequence of the {i}ap Gene, Responsible for Alkaline Phosphatase Isozyme Conversion in Escherichia Coli, and Identification of the Gene Product, 169 (1987) Journal of Bacteriology 5429.

112 *Patrick D. Hsu* et al., Development and Applications of CRISPR-Cas9 for Genome Engineering, 157 (2014) Cell 1262.

113 *Francisco J. Mojica* et al., Intervening Sequences of Regularly Spaced Prokaryotic Repeats Derive from Foreign Genetic Elements, 60 (2005) Journal of Molecular Evolution 174; *C. Pourcel* et al., CRISPR Elements in Yersinia Pestis Acquire New Repeats by Preferential Uptake of Bacteriophage DNA, and Provide Additional Tools for Evolutionary Studies, 151 (2005) Microbiology 653; *Alexander Bolotin* et al., Clustered Regularly Interspaced Short Palindrome Repeats (CRISPRs) Have Spacers of Extrachromosomal Origin, 151 (2005) Microbiology 2551.

responding to their own genomes.[114] Two years later, experiments showed that CRISPR acts as an adaptive immunity system in which Cas enzymes control both the acquisition of spacers (i.e. the insertion of non-coding viral DNA into the prokaryote's own genome) and the defence against intruding foreign DNA.[115] In the following years, many further details were revealed[116] and the first steps to rebuilding the CRISPR-Cas9 nuclease system were taken.[117] In the course of these efforts, a third essential component of the CRISPR-Cas9 system was discovered: so-called *trans-activating crRNA* (*tracRNA*) facilitates the generation of crRNAs,[118] but it also has an auxiliary role in nuclease activity by keeping the Cas protein active.[119]

In 2012, two research groups made substantial discoveries that led to the use of CRISPR as a genome editing tool. Both groups demonstrated that Cas9 protein derived from bacteria of the *Streptococcus* genus is able to cleave purified DNA *in vitro*. They also showed the Cas9 protein can be 'programmed' to cleave DNA at specific sites by providing an engineered crRNA that contains the target sequence.[120] In addition, one of the groups constructed a single *guide RNA (sgRNA)* by fusing the engineered crRNA with tracrRNA (which, as mentioned above, supports the cleavage of DNA

114 *Mojica* et al. (n. 113), 180.

115 *Rodolphe Barrangou* et al., CRISPR Provides Acquired Resistance Against Viruses in Prokaryotes, 315 (2007) Science 1709.

116 See *Hsu* et al. (n. 112), 1266; *Luciano A. Marraffini*, CRISPR-Cas Immunity in Prokaryotes, 526 (2015) Nature 55. Important publications include: *Hélène Deveau* et al., Phage Response to CRISPR-Encoded Resistance in Streptococcus Thermophilus, 190 (2008) Journal of Bacteriology 1390; *Philippe Horvath* et al., Comparative Analysis of CRISPR Loci in Lactic Acid Bacteria Genomes, 131 (2009) International Journal of Food Microbiology 62; *Andrea Quiberoni* et al., Streptococcus Thermophilus Bacteriophages, 20 (2010) International Dairy Journal 657; *Josiane E. Garneau* et al., The CRISPR/Cas Bacterial Immune System Cleaves Bacteriophage and Plasmid DNA, 468 (2010) Nature 67; *Rimantas Sapranauskas* et al., The Streptococcus Thermophilus CRISPR/Cas System Provides Immunity in Escherichia Coli, 39 (2011) Nucleic Acids Res. 9275.

117 See, *inter alia*, *Garneau* et al. (n. 116); *Elitza Deltcheva* et al., CRISPR RNA Maturation by Trans-Encoded Small RNA and Host Factor RNase III, 471 (2011) Nature 602, 602–603.

118 *Deltcheva* et al. (n. 117), 602–603.

119 *Martin Jinek* et al., A Programmable Dual-RNA–Guided DNA Endonuclease in Adaptive Bacterial Immunity, 337 (2012) Science 816, 816.

120 *Giedrius Gasiunas* et al., Cas9–crRNA Ribonucleoprotein Complex Mediates Specific DNA Cleavage for Adaptive Immunity in Bacteria, 109 (2012) PNAS E2579–86, E2583; *Jinek* et al. (n. 119), 817.

by keeping the Cas protein active).[121] With the development of sgRNAs, only two components were required for genome editing, namely a Cas protein and a customized sgRNA in which the target sequence is 'programmed'. This meant a major breakthrough in harnessing CRISPR-Cas9 for genome editing.[122] Shortly after, two simultaneous studies demonstrated that CRISPR need not be limited to bacteria, but can also be applied to eukaryotes, in particular to mammals such as mice and humans.[123] Furthermore, it was shown that multiple guide RNAs can be used to induce multiple double-strand breaks in one single step.[124]

Since its discovery, the CRISPR/Cas9 genome editing technique was rapidly adopted by many commercial and non-commercial researchers. It widely replaced other genome editing techniques such as TALENs, since CRISPR is said to be more precise, easier to apply and cheaper to prepare.[125] Further refinements of the technique are published constantly at the time of writing. For instance, different Cas proteins can be used to achieve different cleavage characteristics.[126] Another example is the so-called *base editing* approaches, which aim at exchanging single bases in RNA[127] or base pairs in DNA[128] without cleaving the nucleotide chain.[129] In 2020, *Emmanuelle Charpentier* and *Jennifer Doudna* were awarded the Nobel Prize in Chemistry 'for the development of a method for genome editing'.[130]

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121 *Jinek* et al. (n. 119), 819–820.
122 *Heidi Ledford*, CRISPR, the Disruptor, 522 (2015) Nature 20, 23.
123 *Cong* et al. (n. 75); *Prashant Mali* et al., RNA-Guided Human Genome Engineering via Cas9, 339 (2013) Science 823.
124 *Cong* et al. (n. 75); *Mali* et al. (n. 123).
125 *Ledford* (n. 122), 21–22.
126 *Bernd Zetsche* et al., Cpf1 Is a Single RNA-Guided Endonuclease of a Class 2 CRISPR-Cas System, 163 (2015) Cell 759; *Guocai Zhong* et al., Cpf1 Proteins Excise CRISPR RNAs from MRNA Transcripts in Mammalian Cells, 13 (2017) Nature Chemical Biology 839; see also *Heidi Ledford*, Alternative CRISPR System Could Improve Genome Editing, 526 (2015) Nature News 17.
127 *David B. T. Cox* et al., RNA Editing with CRISPR-Cas13, 358 (2017) Science 1019.
128 *Nicole M. Gaudelli* et al., Programmable Base Editing of A•T to G•C in Genomic DNA Without DNA Cleavage, 551 (2017) Nature 464.
129 See *Emily Mullin*, CRISPR 2.0 Is Here, and It's Way More Precise, MIT Technology Review, 25 October 2017, available at: https://www.technologyreview.com/s/609203/crispr-20-is-here-and-its-way-more-precise/ (last accessed 28 May 2022).
130 Royal Swedish Academy of Sciences, The Nobel Prize in Chemistry 2020 (07 October 2020), available at: https://www.kva.se/en/pressrum/pressmeddelanden/nobelpriset-i-kemi-2020 (last accessed 28 May 2022).

III. Applications of Genome Editing Techniques

Genome editing techniques, especially those using the CRISPR-Cas method, are extremely versatile and can be applied in all areas of molecular biology. Prospective and already-existing applications can be found, *inter alia*, in agriculture (1.), basic research and medicine (2.), approaches to modify the human genome (3.), and industrial biotechnology (4.).

1. Agriculture

Like conventional genetic engineering techniques, genome editing is widely used in agriculture, where it can be applied to either directly incorporate heritable mutations or to accelerate conventional breeding. In livestock breeding, for example, genome editing is applied to improve traits relevant to the quality and quantity of animal products such as milk, meat, and wool.[131] It can also be used to increase animal health and welfare, for instance by breeding variants that are resistant to certain diseases.[132] The development of hornless dairy cattle variants could spare calves the pain- and stressful dehorning commonly practised in industrial livestock farming.[133] Moreover, the organs of pigs are modified through genome editing with the aim of making their organs usable for pig-to-human transplantations.[134]

Besides livestock, genome editing is extensively used to improve crop plants.[135] For instance, the genes encoding for *polyphenol oxidase* (PPO), an enzyme that causes browning to fruit and vegetables when cut or bruised,

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131 *Iuri V. Perisse* et al., Improvements in Gene Editing Technology Boost Its Applications in Livestock, 11 (2020) Frontiers in Genetics 614688, 8–11; *Abdul Jabbar* et al., Advances and Perspectives in the Application of CRISPR-Cas9 in Livestock, 63 (2021) Molecular Biotechnology 757, 760–762.

132 *Perisse* et al. (n. 131), 11; cf. *Kristin M. Whitworth* et al., Gene-Edited Pigs Are Protected from Porcine Reproductive and Respiratory Syndrome Virus, 34 (2016) Nature Biotech. 20.

133 Cf. *Daniel F. Carlson* et al., Production of Hornless Dairy Cattle from Genome-Edited Cell Lines, 34 (2016) Nature Biotech. 479; *Felix Schuster* et al., CRISPR/Cas12a Mediated Knock-in of the Polled Celtic Variant to Produce a Polled Genotype in Dairy Cattle, 10 (2020) Sci. Rep. 13570.

134 *Peter J. Cowan* et al., Xenogeneic Transplantation and Tolerance in the Era of CRISPR-Cas9, 24 (2019) Current Opinion in Organ Transplantation 5.

135 *Reema Rani* et al., CRISPR/Cas9, 38 (2016) Biotechnology Letters 1991; *Ming Luo* et al., Applications of CRISPR/Cas9 Technology for Targeted Mutagenesis,

were successfully knocked out in various species.[136] Genome editing also allows to confer or improve the resistance of plants to diseases,[137] insect pests,[138] or drought stress.[139] Another important field of application lies in conferring herbicide resistance to various crop plants.[140] Furthermore, genome editing can serve to improve the nutritious characteristics of food crops.[141] One approach aims to produce bread wheat with lower levels of gluten immunogenicity that can be consumed by people suffering from celiac disease.[142]

Like in conventional genetic engineering, the CRISPR-Cas components can be introduced into the target organism by using vectors such as the plant pest bacterium *Agrobacterium tumefaciens* or viral plasmids that encode them.[143] The use of vectors involves the introduction of foreign genetic elements into the target organism, which either are not incorporated into the plant's genome or can later be removed.[144] In many jurisdictions,

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Gene Replacement and Stacking of Genes in Higher Plants, 35 (2016) Plant Cell Reports 1439.

136 *Norfadilah Hamdan* et al., Prevention of Enzymatic Browning by Natural Extracts and Genome-Editing: A Review on Recent Progress, 27 (2022) Molecules 1101.

137 *Giuseppe Andolfo* et al., Genome-Editing Technologies for Enhancing Plant Disease Resistance, 7 (2016) Front. Plant Sci. 1813; *Naghmeh Nejat* et al., Plant-Pathogen Interactions, 37 (2017) Critical Reviews in Biotechnology 229.

138 *Shaily Tyagi* et al., Genome Editing for Resistance to Insect Pests: An Emerging Tool for Crop Improvement, 5 (2020) ACS Omega 20674.

139 *Damiano Martignago* et al., Drought Resistance by Engineering Plant Tissue-Specific Responses, 10 (2019) Frontiers in Plant Science 1676; *Abdul Sami* et al., CRISPR-Cas9-Based Genetic Engineering for Crop Improvement Under Drought Stress, 12 (2021) Bioengineered 5814.

140 *Huirong Dong* et al., The Development of Herbicide Resistance Crop Plants Using CRISPR/Cas9-Mediated Gene Editing, 12 (2021) Genes 912; *Amjad Hussain* et al., Herbicide Resistance: Another Hot Agronomic Trait for Plant Genome Editing, 10 (2021) Plants 621.

141 *Kathleen L. Hefferon*, Nutritionally Enhanced Food Crops; Progress and Perspectives, 16 (2015) International Journal of Molecular Sciences 3895; *Yongwei Sun* et al., Generation of High-Amylose Rice Through CRISPR/Cas9-Mediated Targeted Mutagenesis of Starch Branching Enzymes, 8 (2017) Front. Plant Sci. 298.

142 *Aurelie Jouanin* et al., CRISPR/Cas9 Gene Editing of Gluten in Wheat to Reduce Gluten Content and Exposure–Reviewing Methods to Screen for Coeliac Safety, 7 (2020) Frontiers in Nutrition 51.

143 See *Zheng Gong* et al., Non-GM Genome Editing Approaches in Crops, 3 (2021) Frontiers in Genome Editing 817279, 2.

144 *Je W. Woo* et al., DNA-Free Genome Editing in Plants with Preassembled CRISPR-Cas9 Ribonucleoproteins, 33 (2015) Nature Biotech. 1162, 1162; *San-*

however, the regulatory regime for GMOs is already triggered by the transient presence of transgenic elements in the organism.[145] Researchers are therefore developing methods for editing plant genomes without introducing foreign DNA.[146] For instance, preassembled gRNA-Cas9 protein complexes (so-called *ribonucleoproteins*) can be delivered to the plant cell by vector-less methods such as direct injection or by transfection.[147] These complexes cleave their chromosomal target sites immediately after entering the cell and rapidly degrade afterwards.[148]

2. Basic Research and Medicine

The CRISPR-Cas technique may also serve as an important tool in basic research and medicine.[149] For instance, CRISPR-Cas can serve as a tool for genome-wide screens, including for genes involved in tumour growth and metastasis.[150] In medical research, genome editing can be used to generate disease models, such as for human lung cancer in mice,[151] which might accelerate the identification of suitable therapies.[152] Researchers were also able to recreate a naturally occurring mutation that provides innate resistance to HIV.[153] Another study successfully corrected an inherited mutation in mice and thus cured the metabolic disease *tyrosinemia*.[154] Moreover, the original function of CRISPR as an immune system could

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wen Huang et al., A Proposed Regulatory Framework for Genome-Edited Crops, 48 (2016) Nature Genetics 109, 109.

145 See chapter 3, sections A.I.1 and A.IV.2.

146 *Chidananda N. Kanchiswamy* et al., Non-GMO Genetically Edited Crop Plants, 33 (2015) Trends in Biotechnology 489; *Gong* et al. (n. 143), 2–8.

147 *Woo* et al. (n. 144); *Gong* et al. (n. 143), 4–6.

148 *Woo* et al. (n. 144), 1162; see *Sojung Kim* et al., Highly Efficient RNA-Guided Genome Editing in Human Cells via Delivery of Purified Cas9 Ribonucleoproteins, 24 (2014) Genome Research 1012.

149 See *Barrangou/Doudna* (n. 82).

150 *Ophir Shalem* et al., High-Throughput Functional Genomics Using CRISPR–Cas9, 16 (2015) Nature Rev. Genet. 299.

151 *Andrea Ventura* et al., In Vivo Engineering of Oncogenic Chromosomal Rearrangements with the CRISPR/Cas9 System, 516 (2014) Nature 423.

152 *Barrangou/Doudna* (n. 82), 936.

153 *Pankaj K. Mandal* et al., Efficient Ablation of Genes in Human Hematopoietic Stem and Effector Cells Using CRISPR/Cas9, 15 (2014) Cell Stem Cell 643.

154 *Hao Yin* et al., Genome Editing with Cas9 in Adult Mice Corrects a Disease Mutation and Phenotype, 32 (2014) Nature Biotech. 551.

also be harnessed to develop new antimicrobial and antiviral applications that might be able to replace conventional drugs such as antibiotics.[155]

Various approaches using genome editing for therapeutic purposes in humans have already advanced to clinical trials.[156] Some studies seek to treat cancer by editing the immune cells of patients *in vitro*, selecting and expanding cells which contain the desired modification, and infusing these cells back into the patient.[157] Another promising application is *gene therapy*, in which genetic disorders are corrected to treat diseases that cannot be cured with conventional therapies.[158] In 2019, CRISPR was successfully used to treat humans suffering from the genetic disorder *sickle-cell anaemia*.[159] In 2020, CRISPR was used for the first time to edit genetic information in a human *in vivo* in an attempt to treat the heritable eye disease *Leber congenital amaurosis*.[160]

155 *Chase L. Beisel* et al., A CRISPR Design for Next-Generation Antimicrobials, 15 (2014) Genome Biology 516; *Robert J. Citorik* et al., Sequence-Specific Antimicrobials Using Efficiently Delivered RNA-Guided Nucleases, 32 (2014) Nature Biotech. 1141; *David Bikard* et al., Exploiting CRISPR-Cas Nucleases to Produce Sequence-Specific Antimicrobials, 32 (2014) Nature Biotech. 1146; *Ahmed A. Gomaa* et al., Programmable Removal of Bacterial Strains by Use of Genome-Targeting CRISPR-Cas Systems, 5 (2014) mBio e00928–13; see generally *Barrangou/Doudna* (n. 82), 937–938.

156 *Barrangou/Doudna* (n. 82), 937; *Filipe V. Jacinto* et al., CRISPR/Cas9-Mediated Genome Editing: From Basic Research to Translational Medicine, 24 (2020) Journal of Cellular and Molecular Medicine 3766; *Matthew P. Hirakawa* et al., Gene Editing and CRISPR in the Clinic: Current and Future Perspectives, 40 (2020) Bioscience Reports.

157 *Hirakawa* et al. (n. 156), 4–11; *Jacinto* et al. (n. 156), 3768–3769.

158 *Jacinto* et al. (n. 156), 3771–3774.

159 *Rob Stein*, In a 1st, Doctors in U.S. Use CRISPR Tool to Treat Patient with Genetic Disorder, NPR, 29 July 2019, available at: https://www.npr.org/sections/health-shots/2019/07/29/744826505/sickle-cell-patient-reveals-why-she-is-volunteering-for-landmark-gene-editing-st?t=1617188222805 (last accessed 28 May 2022); *Heidi Ledford*, CRISPR Gene Therapy Shows Promise Against Blood Diseases, 588 (2020) Nature 383; see *Haydar Frangoul* et al., CRISPR-Cas9 Gene Editing for Sickle Cell Disease and B-Thalassemia, 384 (2021) N. Engl. J. Med. 252; *Erica B. Esrick* et al., Post-Transcriptional Genetic Silencing of BCL11A to Treat Sickle Cell Disease, 384 (2021) N. Engl. J. Med. 205.

160 *Rob Stein*, In a 1st, Scientists Use Revolutionary Gene-Editing Tool to Edit Inside a Patient, NPR, 04 March 2020, available at: https://www.npr.org/sections/health-shots/2020/03/04/811461486/in-a-1st-scientists-use-revolutionary-gene-editing-tool-to-edit-inside-a-patient (last accessed 28 May 2022); *Heidi Ledford*, CRISPR Treatment Inserted Directly into the Body for First Time, 579 (2020) Nature 185.

3. Human Germline Editing

The therapeutic applications mentioned above aim at editing somatic cells, i.e. body cells whose genetic information is not heritable.[161] Basic research studies usually work with embryonic or post-embryonic stem cells that cannot develop into viable organisms.[162] However, genome editing can also be applied to modify the genes of reproductive germline cells or fertilized egg cells (*zygotes*), including early human embryos.[163] Researchers have already demonstrated the use of CRISPR-Cas in human embryos in a number of studies.[164]

In November 2018, it was revealed that a Chinese biophysicist had used CRISPR to edit the genomes of embryos in an attempt to confer genetic resistance to HIV.[165] While the researcher claimed that the babies were born healthy,[166] some contended that the genetic modification could have life-shortening effects.[167] The undertaking was widely condemned[168] and

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161 Cf. *Mali* et al. (n. 123); see *supra* section B.III.2.

162 *Zhao Zhang* et al., CRISPR/Cas9 Genome-Editing System in Human Stem Cells, 9 (2017) Molecular Therapy – Nucleic Acids 230; *Jacinto* et al. (n. 156), 3769–3770.

163 Cf. *R. Vassena* et al., Genome Engineering Through CRISPR/Cas9 Technology in the Human Germline and Pluripotent Stem Cells, 22 (2016) Human Reproduction Update 411.

164 *Puping Liang* et al., CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes, 6 (2015) Protein & Cell 363; *Xiangjin Kang* et al., Introducing Precise Genetic Modifications into Human 3PN Embryos by CRISPR/Cas-Mediated Genome Editing, 33 (2016) Journal of Assisted Reproduction and Genetics 581; *Lichun Tang* et al., CRISPR/Cas9-Mediated Gene Editing in Human Zygotes Using Cas9 Protein, 292 (2017) Molecular Genetics and Genomics 525; *Hong Ma* et al., Correction of a Pathogenic Gene Mutation in Human Embryos, 548 (2017) Nature 413.

165 *Antonio Regalado*, Exclusive: Chinese Scientists Are Creating CRISPR Babies, MIT Technology Review, 25 November 2018, available at: https://www.technologyreview.com/2018/11/25/138962/exclusive-chinese-scientists-are-creating-crispr-babies/ (last accessed 28 May 2022).

166 *He Jiankui*, About Lulu and Nana: Twin Girls Born Healthy After Gene Surgery as Single-Cell Embryos (31 March 2021), available at: https://www.youtube.com/watch?v=th0vnOmFltc (last accessed 28 May 2022).

167 *Jon Cohen*, Did CRISPR Help – Or Harm – The First-Ever Gene-Edited Babies?, Science News, 01 August 2019, available at: https://www.sciencemag.org/news/2019/08/did-crispr-help-or-harm-first-ever-gene-edited-babies (last accessed 28 May 2022).

168 See *Natalie Kofler*, Why Were Scientists Silent over Gene-Edited Babies?, 566 (2019) Nature 427; *Jon Cohen*, Inside the Circle of Trust, 365 (2019) Science 430;

the responsible scientist was later sentenced to prison for ‘illegal medical practice’.[169]

4. Industrial Biotechnology

It is assumed that genome editing based on the CRISPR-Cas technique will have a large impact on all industries related to bacteria, fungi, and yeast.[170] For instance, engineered versions of these organisms may help to produce biofuels[171] or chemicals required for antibiotics.[172] In the food industry, genome editing may be used to improve fermentation-based manufacturing, e.g. by vaccinating useful bacteria against phages or by depleting certain microbial populations while preserving others.[173]

IV. Technical Challenges of CRISPR-Cas Based Genome Editing

Although the CRISPR-Cas technique quickly became the prevalent technique for genome editing, it still involves a number of technical challenges affecting both the efficacy and the safety of the techniques. These challenges include the potential for off-target effects (1.), genetic mosaicism (2.), and the delivery of the CRISPR components into the target organism (3.).

1. Off-Target Effects

A major challenge in the application of CRISPR for genome editing is potential *off-target effects*, i.e. the introduction of double-strand breaks

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Karen M. Meagher et al., Reexamining the Ethics of Human Germline Editing in the Wake of Scandal, 95 (2020) Mayo Clinic Proceedings 330.

169 *David Cyranoski*, What CRISPR-Baby Prison Sentences Mean for Research, 577 (2020) Nature 154.

170 *Barrangou/Doudna* (n. 82), 938.

171 Cf. *Owen W. Ryan* et al., Selection of Chromosomal DNA Libraries Using a Multiplex CRISPR System, 3 (2014) eLife e03703; *Ching-Sung Tsai* et al., Rapid and Marker-free Refactoring of Xylose-fermenting Yeast Strains with Cas9/CRISPR, 112 (2015) Biotechnology and Bioengineering 2406.

172 *He Huang* et al., One-Step High-Efficiency CRISPR/Cas9-Mediated Genome Editing in Streptomyces, 47 (2015) Acta Biochimica et Biophysica Sinica 231.

173 Cf. *Kurt Selle/Rodolphe Barrangou*, CRISPR-Based Technologies and the Future of Food Science, 80 (2015) Journal of Food Science R2367, R2370-R2371.

at other than the desired location, which might lead to unwanted mutations. One reason for this is that Cas proteins have a certain tolerance for mismatches between the introduced guide RNA and the target DNA sequence.[174] Furthermore, complex genomes often contain multiple copies of sequences that are identical or highly similar to the intended DNA target.[175]

The frequency of off-target effects depends on many factors and varies among cell types.[176] Algorithms can help anticipate the locations of off-target mutations.[177] However, there appears to be no scientific consensus about the general likelihood and extent of off-target effects. A publication reporting unexpected mutations in mice after CRISPR-Cas9 was applied to edit their genome *in vivo*[178] was criticized for using an insufficient experimental design and wrongly interpreting data.[179] As noted above, there have also been concerns about the safety of human germline editing using CRISPR-Cas9.[180] In any case, many researchers are seeking to increase the precision of CRISPR,[181] including by identifying alternative

174 *Seung W. Cho* et al., Analysis of Off-Target Effects of CRISPR/Cas-Derived RNA-Guided Endonucleases and Nickases, 24 (2014) Genome Research 132, 134; *Xiao-Hui Zhang* et al., Off-Target Effects in CRISPR/Cas9-Mediated Genome Engineering, 4 (2015) Molecular Therapy – Nucleic Acids e264, 1.

175 *Gaj* et al. (n. 73), 400.

176 *Sander/Joung* (n. 68), 349–350; *Zhang* et al. (n. 174), 3.

177 See *Maximilian Haeussler* et al., Evaluation of Off-Target and On-Target Scoring Algorithms and Integration into the Guide RNA Selection Tool CRISPOR, 17 (2016) Genome Biology 148; *Hong Zhou* et al., Whole Genome Analysis of CRISPR Cas9 SgRNA Off-Target Homologies via an Efficient Computational Algorithm, 18 (2017) BMC Genomics 826.

178 *Kellie A. Schaefer* et al., Unexpected Mutations After CRISPR-Cas9 Editing in Vivo, 14 (2017) Nature Methods 547.

179 *Christopher J. Wilson* et al., Response to "Unexpected Mutations After CRISPR-Cas9 Editing in Vivo", 15 (2018) Nature Methods 236; *Caleb A. Lareau* et al., Response to "Unexpected Mutations After CRISPR-Cas9 Editing in Vivo", 15 (2018) Nature Methods 238.

180 *Michael V. Zuccaro* et al., Allele-Specific Chromosome Removal After Cas9 Cleavage in Human Embryos, 183 (2020) Cell 1650–1664.e15.

181 *Muhammad Naeem* et al., Latest Developed Strategies to Minimize the Off-Target Effects in CRISPR-Cas-Mediated Genome Editing, 9 (2020) Cells, 3–9; *Manuel M. Vicente* et al., The Off-Targets of Clustered Regularly Interspaced Short Palindromic Repeats Gene Editing, 9 (2021) Frontiers in Cell and Developmental Biology 718466; cf. *William T. Garrood* et al., Analysis of Off-Target Effects in CRISPR-Based Gene Drives in the Human Malaria Mosquito, 118 (2021) PNAS.

Cas proteins.[182] Furthermore, researchers work on developing methods to identify off-target mutations more efficiently.[183]

2. Genetic Mosaicism

Another challenge of applying the CRISPR-Cas technique in multicellular embryos or whole organisms lies in the potential creation of *genetic mosaics*, which denotes the simultaneous presence of wild-type cells and modified cells in the resulting organism.[184] The reason for this phenomenon is that CRISPR-Cas is not 100 % efficient, which means that the desired mutation may not occur equally in all cells of the organism.[185] Genetic mosaics may lead to major phenotypic changes or cause the expression of lethal genetic mutations.[186]

3. In Vivo Delivery of CRISPR-Cas Components

There are many different methods for delivering the CRISPR components into the cell, depending on the organism and other particular circumstances.[187] Most methods do not insert the CRISPR components themselves into the organism, but rather genetic elements encoding for sgRNA and a Cas protein.[188] While delivery of these elements into cell cultures *in*

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182 *Naeem* et al. (n. 181), 9–12; see *Zetsche* et al. (n. 126); *Sergey Shmakov* et al., Discovery and Functional Characterization of Diverse Class 2 CRISPR-Cas Systems, 60 (2015) Molecular Cell 385; *Zhong* et al. (n. 126); see also *Barrangou/Doudna* (n. 82), 934.

183 *Zhang* et al. (n. 174), 4–5; *Naeem* et al. (n. 181), 3–6.

184 *Araki* et al. (n. 71), 234; *Maryam Mehravar* et al., Mosaicism in CRISPR/Cas9-Mediated Genome Editing, 445 (2019) Developmental Biology 156, 156–159; see *Shuo-Ting Yen* et al., Somatic Mosaicism and Allele Complexity Induced by CRISPR/Cas9 RNA Injections in Mouse Zygotes, 393 (2014) Developmental Biology 3; *Uros Midic* et al., Quantitative Assessment of Timing, Efficiency, Specificity and Genetic Mosaicism of CRISPR/Cas9-Mediated Gene Editing of Hemoglobin Beta Gene in Rhesus Monkey Embryos, 26 (2017) Human Molecular Genetics 2678.

185 *Pierce* (n. 1), 577.

186 *Hagop Youssoufian/Reed E. Pyeritz*, Human Genetics and Disease, 3 (2002) Nature Rev. Genet. 748; see *Ma* et al. (n. 104), 2–4.

187 *Sander/Joung* (n. 68), 352–353.

188 Cf. *Alexis C. Komor* et al., CRISPR-Based Technologies for the Manipulation of Eukaryotic Genomes, 168 (2017) Cell 20, 27.

vitro is comparatively easy to accomplish, delivery *in vivo*, i.e. the insertion into cells of living host organisms, remains a challenging task.[189] These challenges include the limited carrying capacity of vectors, their immunogenicity (i.e. CRISPR components engaging a response by the host organism's immune system) and the limited efficiency of delivery and editing, which is significantly lower compared to *in vitro* editing.[190] Therefore, other approaches like non-viral vectors[191] and protein-based delivery, in which a preassembled Cas9-sgRNA complex is directly inserted into the organism by various methods,[192] are being developed.

V. Environmental Risks and Ethical Concerns Connected to the Use of Genome Editing

Aside from the aforementioned technical challenges, the use of genome editing faces several other criticism and concerns, particularly in the context of agricultural uses (1.) and when applied to humans (2.).

1. Alleged Environmental Risks of Genome Editing in Agriculture

Regarding commercial applications including in agriculture, critics primarily point to the general limitations of genome editing techniques pointed out above.[193] In particular, it is argued that genome editing techniques are prone to inducing off-target mutations that, similar to conventional genetic engineering methods, might lead to unintended effects including the accumulation of toxins and residues, and an increase in allergens.[194]

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189 *Pierce* (n. 1), 577.

190 *Rubul Mout* et al., In Vivo Delivery of CRISPR/Cas9 for Therapeutic Gene Editing, 28 (2017) Bioconjugate Chemistry 880, 882–883.

191 *Ling Li* et al., Challenges in CRISPR/CAS9 Delivery, 26 (2015) Human Gene Therapy 452; *Sander/Joung* (n. 68), 352.

192 *Mout* et al. (n. 190), 880–882; cf. *Ming Wang* et al., Efficient Delivery of Genome-Editing Proteins Using Bioreducible Lipid Nanoparticles, 113 (2016) PNAS 2868.

193 See *supra* section B.IV.

194 *Sarah Z. Agapito-Tenfen/Odd-Gunnar Wikmark*, Current Status of Emerging Technologies for Plant Breeding: Biosafety and Knowledge Gaps of Site Directed Nucleases and Oligonucleotide-Directed Mutagenesis, Biosafety report 02/2015 (2015), 32; *Ricarda A. Steinbrecher*, Genetic Engineering in Plants and

It is furthermore contended that the primary aim of many efforts was to avoid the existing regulatory processes for GMOs,[195] even though the risks and uncertainties related to genome-edited organisms were similar to those relating to products of conventional genetic engineering, such as increased toxicity of the resulting organism or horizontal gene transfer to native species, which may have unintended consequences for ecosystems and biological diversity.[196] Others claim that organisms containing no transgenic elements did not give rise to any new type of risks that would require governance beyond the existing regulation of new traits.[197]

Notably, many of the potential environmental impacts of conventional GMOs recognized in scientific literature appear to be related to the presence of transgenes in these organisms[198] and would thus not be caused by

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the "New Breeding Techniques (NBTs)" (2015), 3, but see *Miguel A. Sánchez/ Wayne A. Parrott*, Characterization of Scientific Studies Usually Cited as Evidence of Adverse Effects of GM Food/Feed, 15 (2017) Plant Biotechnology Journal 1227.

195 *Steinbrecher* (n. 194), 1; see *Woo* et al. (n. 144), 1162 who assume that: 'Editing plant genomes without introducing foreign DNA into cells may alleviate regulatory concerns related to genetically modified plants.' Also see *Emily Waltz*, Gene-Edited CRISPR Mushroom Escapes US Regulation, 532 (2016) Nature News 293; *Emily Waltz*, CRISPR-Edited Crops Free to Enter Market, Skip Regulation, 34 (2016) Nature Biotech. 582.

196 *Araki* et al. (n. 71), 236; *Christoph Then/Andreas Bauer-Panskus*, Playing Russian Roulette with Biodiversity: Uncontrolled Applications of Gene Editing Threaten Biodiversity, the Rights of Consumers and Farmers, as Well as the Future of Animal and Plant Breeding (2017), 14–21; *Steinbrecher* (n. 194); also see Conseil d'État, Confédération paysanne et autres, 03 October 2016, N° 388649, para. 28; CJEU, Confédération paysanne et al. v. Premier ministre et al., Judgment of 25 July 2018, C-528/16, para. 48; on the questionable statements of the Court regarding the risk of organisms modified through targeted mutagenesis, see *Felix Beck*, All About that Risk? A (Re-)Assessment of the CJEU's Reasoning in the "Genome Editing" Case, 17 (2019) EurUP 246, 250–251.

197 *Robin Fears*, Assessing the Security Implications of Genome Editing Technology: Report of an International Workshop, Herrenhausen, Germany, 11–13 October 2017 (2018), 13 and 19; *Fyodor D. Urnov* et al., A Call for Science-Based Review of the European Court's Decision on Gene-Edited Crops, 36 (2018) Nature Biotech. 800–802; *Rodolphe Barrangou*, CRISPR Craziness: A Response to the EU Court Ruling, 1 (2018) The CRISPR Journal 251; *Martin Wasmer*, Roads Forward for European GMO Policy, 7 (2019) Front. Bioeng. & Biotechnol. 367, 7.

198 Cf. *Aristidis M. Tsatsakis* et al., Environmental Impacts of Genetically Modified Plants: A Review, 156 (2017) Environmental Research 818; also see *José L. Domingo*, Safety Assessment of GM Plants: An Updated Review of the Scientific Literature, 95 (2016) Food and Chemical Toxicology 12. Furthermore, see

transgene-free edited organisms. However, while it is comparatively easy to identify GMOs containing transgenes, it is often difficult or even impossible to conclusively determine whether an organism that only contains one or several point mutations has occurred naturally or has been modified using genome editing techniques.[199]

2. Risks and Ethical Concerns Relating to Human Genome Editing

The advent of genome editing in humans, particularly in the human germline,[200] has re-fuelled pre-existing ethical debates.[201] It has been warned that therapeutic applications of genome editing in the human germline, such as correcting mutations that give rise to hereditary diseases, could have unpredictable consequences on future generations,[202] in particular in light of the still limited knowledge of human genetics, gene-environment interactions and the interplay of various traits and conditions in

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NASEM, Genetically Engineered Crops (2016), 15, which concluded that there was ‘no conclusive evidence of cause-and-effect relationships between GE crops and environmental problems’, even though it was admitted that ‘the complex nature of assessing long-term environmental changes often made it difficult to reach definitive conclusions’.

199 *Lutz Grohmann* et al., Detection and Identification of Genome Editing in Plants: Challenges and Opportunities, 10 (2019) Frontiers in Plant Science 236.

200 See *supra* section B.III.3.

201 Cf. *David Baltimore* et al., Biotechnology. A Prudent Path Forward for Genomic Engineering and Germline Gene Modification, 348 (2015) Science 36; *Edward Lanphier* et al., Don’t Edit the Human Germ Line, 519 (2015) Nature News 410; Leopoldina Nationale Akademie der Wissenschaften et al., The Opportunities and Limits of Genome Editing (2015); *Kelly E. Ormond* et al., Human Germline Genome Editing, 101 (2017) American Journal of Human Genetics 167; German Ethics Council, Intervening in the Human Germline: Opinion (2019); *Sean C. McConnell/Alessandro Blasimme*, Ethics, Values, and Responsibility in Human Genome Editing, 21 (2019) AMA Journal of Ethics E1017–1020; *Seppe Segers/Heidi Mertes*, Does Human Genome Editing Reinforce or Violate Human Dignity?, 34 (2020) Bioethics 33; *Sebastian Schleidgen* et al., Human Germline Editing in the Era of CRISPR-Cas: Risk and Uncertainty, Inter-Generational Responsibility, Therapeutic Legitimacy, 21 (2020) BMC Medical Ethics 87; also see UNESCO General Conference, Universal Declaration on the Human Genome and Human Rights (11 November 1997), Records of the General Conference, 29th session, Vol. 1: Resolutions, p. 41; *Federico Lenzerini*, Biotechnology, Human Dignity and the Human Genome, in: Francesco Francioni/Tullio Scovazzi (eds.), Biotechnology and International Law (2006) 285.

202 *Lanphier* et al. (n. 201), 410.

the human body.[203] Moreover, it was warned that human germline gene editing could pose a substantial risk for aneuploidy.[204]

Beyond that, there are strong concerns of both the scientific community and the general public about non-therapeutic applications, i.e. the theoretical possibility of applying genome editing for human enhancement or eugenic purposes.[205] Therefore, many researchers have called for a global moratorium on human germline editing to discuss the connected scientific, ethical and legal issues.[206] However, there will likely be more instances of genome-edited humans in the future, as shown by a Russian scientist seeking to create a germline modification to prevent a type of hereditary deafness.[207]

In response, the *World Health Organization* (WHO) established a multidisciplinary expert panel which concluded that 'it would be irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing'.[208] The WHO's Director-General stated that 'regulatory authorities in all countries should not allow any further work

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203 *Baltimore* et al. (n. 201), 37; *Ormond* et al. (n. 201), 169–171; Leopoldina Nationale Akademie der Wissenschaften et al. (n. 201), 25–26.

204 *Zuccaro* et al. (n. 180).

205 *Lanphier* et al. (n. 201), 410; *Baltimore* et al. (n. 201), 37; *Ormond* et al. (n. 201), 171–172.

206 Cf. *Baltimore* et al. (n. 201); *Lanphier* et al. (n. 201); Leopoldina Nationale Akademie der Wissenschaften et al. (n. 201), 27; *Francis S. Collins*, Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos (28 April 2015), available at: https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos (last accessed 28 May 2022); European Group on Ethics in Science and New Technologies, Statement on Gene Editing (2016), available at: https://ec.europa.eu/info/sites/default/files/research_and_innovation/ege/gene_editing_ege_statement.pdf (last accessed 28 May 2022).

207 *David Cyranoski*, Russian 'CRISPR-Baby' Scientist Has Started Editing Genes in Human Eggs with Goal of Altering Deaf Gene, 574 (2019) Nature 465; see WHO Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, Human Genome Editing: As We Explore Options for Global Governance, Caution Must Be Our Watchword (08 November 2019), available at: https://www.who.int/news/item/08-11-2019-human-genome-editing-as-we-explore-options-for-global-governance-caution-must-be-our-watchword (last accessed 28 May 2022).

208 WHO Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, Report of the First Meeting (2019), 3.

in this area until its implications have been properly considered'.[209] The WHO also established a *Human Genome Editing Registry* to collect information on clinical trials using human genome editing technologies.[210] The Registry, which covers both somatic and germline clinical trials, lists 133 research projects as of May 2022.[211] In the future, the Registry is planned to also cover research using genome editing technologies on human embryos and germline cells even when there is no attempt to initiate a pregnancy.[212]

C. Engineered Gene Drives

According to the Mendelian *principle of segregation* in sexually reproducing organisms, each of the two parents normally contributes a random half of its genetic information to the genome of their offspring. Consequently, a genetic mutation occurring in only one of the parents is statistically inherited by only half of its offspring. A newly emerged mutation thus spreads rather slowly through a natural population. Whether it can prevail depends on evolutionary factors, particularly on whether it confers a physical or reproductive advantage to the organisms carrying it.[213]

These rules of inheritance and evolution can be circumvented by *gene drives*, which refers to genetic elements that bias inheritance in their favour, resulting in the gene becoming more prevalent in the population over successive generations.[214] In this way, a gene drive can spread through a wild population even if it bears no advantage in evolutionary

209 WHO, Statement on Governance and Oversight of Human Genome Editing (26 July 2019), available at: https://www.who.int/news/item/26-07-2019-statement-on-governance-and-oversight-of-human-genome-editing (last accessed 28 May 2022).

210 WHO, Human Genome Editing Registry, available at: https://www.who.int/groups/expert-advisory-committee-on-developing-global-standards-for-governance-and-oversight-of-human-genome-editing/registry (last accessed 28 May 2022).

211 *Ibid.*

212 *Ibid.*

213 See *supra* section A.II.2.

214 *Luke S. Alphey* et al., Opinion: Standardizing the Definition of Gene Drive, 117 (2020) PNAS 30864.

fitness compared to the wild type allele, hence circumventing the rules of Mendelian inheritance.[215]

While gene drive is a naturally occurring phenomenon (I.), genome editing techniques such as CRISPR-Cas now allow for the development of *engineered* (or *synthetic*) gene drives to genetically modify wild populations of species (II.). Engineered gene drives have a range of prospective applications (III.), although the technique is not without technical limitations and environmental risks (IV.).

I. Natural Gene Drive Mechanisms

Selfish genetic elements are naturally occurring gene drive phenomena that use various molecular mechanisms to bias inheritance in their favour.[216] They typically make use of either of two strategies, namely increasing their own replication (1.) or eliminating competing wild-type gametes or progeny (2.).[217]

1. Over-Replication Mechanisms

Selfish genetic elements relying on *over-replication* bias their transmission to subsequent generations by becoming replicated more often than other genes in the same organism.[218] The most prominent type of over-replication is *transposable elements*, which are DNA elements that are able to change their position within the genome.[219] Their changing presence at random locations in the genome tends to create multiple copies of the

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215 *Jackson Champer* et al., Cheating Evolution, 17 (2016) Nature Rev. Genet. 146, 146–147; *Kevin M. Esvelt* et al., Concerning RNA-Guided Gene Drives for the Alteration of Wild Populations, 3 (2014) eLife e03401, 1.

216 For a detailed account of various natural gene drive systems, see the extensive monograph by *Austin Burt/Robert Trivers*, Genes in Conflict (2006); also see (with reference to research on engineered drive systems) NASEM, Gene Drives on the Horizon (2016), 26–30.

217 *Champer* et al. (n. 215), 147. Note that *Burt/Trivers* (n. 216), 5–7 introduce a third strategy called *gonotaxis,* by which they refer to drive systems that bias inheritance by moving preferentially towards the germline, and away from somatic cells, e.g. by distorting meiosis in females (*ibid*., p. 301–324).

218 *Ibid.*, 4.

219 *Ibid.*, 228–300; see *supra* section A.II.1.

same transposable element in the genome,[220] which results in an increased inheritance compared to Mendelian inheritance patterns.[221] Transposable elements are currently not seen to be a feasible vector for engineered gene drives, mainly because they integrate at random, unpredictable loci when moving across the genome.[222]

Another class of gene drive based on over-replication are *homing endonuclease genes*. These genes encode sequence-specific endonucleases that cleave the corresponding DNA sequence in chromosomes lacking them.[223] This triggers the activity of the intra-cellular DNA repair mechanisms that are also utilised for genome editing.[224] If the cut is repaired by *homology-direct repair*, the intact chromosome inhibiting the drive will be used as a template, and the drive components will be copied onto the damaged chromosome along with any genes.[225] However, the application of other repair mechanisms such as *non-homologous end joining* can lead to the formation of resistances against the drive mechanism.[226]

2. Interference Mechanisms

Natural gene drives relying on *interference* increase the frequency in which they are inherited by disrupting the transmission of the alternative, 'wild type' allele.[227] There are various molecular pathways to achieve this. Many systems gain a fitness advantage over the wild type allele by either impeding the viability of the wild-type gametes or by killing progeny that carries the wild type allele.[228] Other mechanisms, called *Meiotic Drive*, bias the

220 *Ibid.*, 231–232.
221 *B. Charlesworth/C. H. Langley*, The Population Genetics of Drosophila Transposable Elements, 23 (1989) Annual Review of Genetics 251.
222 *Malcolm J. Fraser*, Insect Transgenesis, 57 (2012) Annual Review of Entomology 267, 272–273; NASEM, Gene Drives on the Horizon (n. 216), 27.
223 *Austin Burt/Vassiliki Koufopanou*, Homing Endonuclease Genes, 14 (2004) Current Opinion in Genetics & Development 609, 609; NASEM, Gene Drives on the Horizon (n. 216), 27.
224 See *supra* section A.II.1.
225 *Champer* et al. (n. 215), 151.
226 *Ibid.*
227 *Burt/Trivers* (n. 216), 4.
228 *Ibid.; Champer* et al. (n. 215), 147.

transmission of alleles during the segregation of chromosomes in meiosis (i.e. the formation of gametes).[229]

Interference mechanisms can be classified by their goal. So-called *selfish sex chromosomes* distort the sex ratios of the progeny in favour of one of the sexes. For instance, the so-called *X-shredder* mechanism is composed of endonucleases that cleave the female-determining X chromosome during spermatogenesis, leading to a bias towards male progeny.[230] It has been proposed that the X-shredder mechanism could be used to employ gene drives for population suppression, for instance in disease vector and pest control.[231] Other drive elements reverse the sex of their host by converting XY males into females.[232]

The second class of interference mechanisms is *autosomal killers*, which propagate genetic elements located on non-sex-determining (i.e. *autosomal*) chromosomes and have no direct influence on sex ratios. This includes the *Maternal-Effect Dominant Embryonic Arrest* (*Medea*) mechanism found in flour beetles, which is a combination of a maternally-expressed toxin and an antidote expressed by those zygotes that carry the Medea element, leading to the survival of only those zygotes.[233] Other examples are the

229 Note that the term *Meiotic Drive* appears to be used inconsistently. Some authors refer to it as *any* drive mechanism that distorts the rules of Mendelian inheritance (e.g. NASEM, Gene Drives on the Horizon (n. 216), 28; *Shannon R. McDermott/Mohamed A. F. Noor*, The Role of Meiotic Drive in Hybrid Male Sterility, 365 (2010) Philos. Trans. R. Soc. B 1265), while others use the term more narrowly as referring only to those mechanisms that interfere with the process of *meiosis*, i.e. the formation of gametes (*Terence W. Lyttle*, Cheaters Sometimes Prosper, 9 (1993) Trends in Genetics 205; *Champer* et al. (n. 215), 152; 'meiotic drive', in: Henderson's Dictionary of Biology (n. 5), 340).

230 *Burt/Trivers* (n. 216), 60–73; *Austin Burt*, Site-Specific Selfish Genes as Tools for the Control and Genetic Engineering of Natural Populations, 270 (2003) Proc. R. Soc. B 921, 926.

231 *Anne Deredec* et al., The Population Genetics of Using Homing Endonuclease Genes in Vector and Pest Management, 179 (2008) Genetics 2013; *Roberto Galizi* et al., A Synthetic Sex Ratio Distortion System for the Control of the Human Malaria Mosquito, 5 (2014) Nature Comms. 3977.

232 *Burt/Trivers* (n. 216), 78–91.

233 Cf. *R. W. Beeman* et al., Maternal-Effect Selfish Genes in Flour Beetles, 256 (1992) Science 89; *Chun-Hong Chen* et al., A Synthetic Maternal-Effect Selfish Genetic Element Drives Population Replacement in Drosophila, 316 (2007) Science 597; see *Champer* et al. (n. 215), 152–154; *Austin Burt/Andrea Crisanti*, Gene Drive, 13 (2018) ACS Chemical Biology 343, 344.

t-haplotype in mice[234] and the *Segregation Distorter* system in the fruit fly species *Drosophila melanogaster*,[235] which both drive through populations by disabling sperm cells not containing their elements. Similar mechanisms also exist in plants, fungi, and nematodes.[236]

Maternal-effect toxin-antidote systems might be applied as a method to create *underdominance* gene drives.[237] Underdominance, or *heterozygous disadvantage*, denotes a genetic condition in which heterozygotes (or their progeny) have a lower relative fitness compared to (parental) homozygotes.[238] Drive systems based on underdominance have the potential to be both spatially self-limiting and reversible to the original genetic state, and might therefore be used in developing safe methods for propagating desired genetic changes in natural populations.[239]

II. Development of Engineered Gene Drives

The idea of using naturally occurring gene drives to suppress species that are vectors of human diseases like yellow fever and malaria has been discussed since 1960.[240] *Austin Burt* first proposed the idea of using homing endonuclease genes to propagate genetic modifications to natural

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234 *Lee M. Silver*, The Peculiar Journey of a Selfish Chromosome, 9 (1993) Trends in Genetics 250; *K. G. Ardlie*, Putting the Brake on Drive, 14 (1998) Trends in Genetics 189; see *Burt/Trivers* (n. 216), 21–37.

235 Cf. *Yuichiro. Hiraizumi/James F. Crow*, Heterozygous Effects on Viability, Fertility, Rate of Development, and Longevity of Drosophila Chromosomes that Are Lethal When Homozygous, 45 (1960) Genetics 1071; *Amanda M. Larracuente/Daven C. Presgraves*, The Selfish Segregation Distorter Gene Complex of Drosophila Melanogaster, 192 (2012) Genetics 33; see *Burt/Trivers* (n. 216), 38–45.

236 Cf. NASEM, Gene Drives on the Horizon (n. 216), 28; *Burt/Trivers* (n. 216), 20–21.

237 The use of underdominance as a method to achieve gene drives was suggested by *Omar S. Akbari* et al., Novel Synthetic Medea Selfish Genetic Elements Drive Population Replacement in Drosophila; a Theoretical Exploration of Medea-Dependent Population Suppression, 3 (2014) ACS Synthetic Biology 915.

238 *Pierce* (n. 1), 786.

239 *R. Guy Reeves* et al., First Steps Towards Underdominant Genetic Transformation of Insect Populations, 9 (2014) PLOS ONE e97557; *Omar S. Akbari* et al., A Synthetic Gene Drive System for Local, Reversible Modification and Suppression of Insect Populations, 23 (2013) Current Biology 671.

240 *G. B. Craig* et al., An Inherited Male-Producing Factor in Aedes Aegypti, 132 (1960) Science 1887.

populations in 2003.[241] The first successful creation of a gene drive in mosquitoes with HEGs was reported in 2011.[242] However, the difficulty in engineering HEGs to cut new target sequences posed a major obstacle to the development of universal gene drive techniques.[243] Therefore, attempts were made to build 'synthetic' HEGs using engineered nucleases like ZFN and TALENs.[244] Besides the disadvantages of these nucleases known from genome editing, namely their laborious and expensive construction and limited specificity,[245] they also suffered from evolutionary instability due to off-target cleavage.[246]

The discovery of the CRISPR-Cas technique for genome editing has enhanced the capabilities of gene drive research.[247] In principle, gene drives can be engineered by introducing DNA encoding for the CRISPR-Cas component into the host organism along with any desired payload gene. The cell expresses the components which then cleave the host's DNA at the target sequence in the wild-type chromosome. After that, the mechanism relies on the intra-cellular homology-directed repair mechanism, which remedies the break and copies the gene drive elements from the mutant chromosome.[248]

In 2015, researchers reported the first successful developments of gene drives based on the CRISPR-Cas technique in fruit and vinegar flies,[249]

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241 See *Burt* (n. 230).
242 *Nikolai Windbichler* et al., A Synthetic Homing Endonuclease-Based Gene Drive System in the Human Malaria Mosquito, 473 (2011) Nature 212.
243 Cf. *Ryo Takeuchi* et al., Redesign of Extensive Protein–DNA Interfaces of Meganucleases Using Iterative Cycles of in Vitro Compartmentalization, 111 (2014) PNAS 4061; *Summer B. Thyme* et al., Reprogramming Homing Endonuclease Specificity Through Computational Design and Directed Evolution, 42 (2014) Nucleic Acids Res. 2564, 2574.
244 *Alekos Simoni* et al., Development of Synthetic Selfish Elements Based on Modular Nucleases in Drosophila Melanogaster, 42 (2014) Nucleic Acids Res. 7461.
245 See *supra* sections B.II.1 and B.II.2.
246 *Simoni* et al. (n. 244), 7471; *Esvelt* et al. (n. 215), 2; *John M. Marshall/Omar S. Akbari*, Gene Drive Strategies for Population Replacement, in: Zach N. Adelman (ed.), Genetic Control of Malaria and Dengue (2015) 169, 179.
247 *Robyn R. Raban* et al., Progress Towards Engineering Gene Drives for Population Control, 223 (2020) Journal of Experimental Biology, 1.
248 See *Esvelt* et al. (n. 215), 4–8; NASEM, Gene Drives on the Horizon (n. 216), 32; *Raban* et al. (n. 247), 4.
249 *Valentino M. Gantz/Ethan Bier*, The Mutagenic Chain Reaction: A Method for Converting Heterozygous to Homozygous Mutations, 348 (2015) Science 442; *Fang Li/Maxwell J. Scott*, CRISPR/Cas9-Mediated Mutagenesis of the White and

yeast,[250] and two mosquito species.[251] Since then, CRISPR-based gene drives have been developed in a number of other species, demonstrating its potential to drive genetic changes at virtually any genomic location through natural populations.[252]

III. Potential Applications of Engineered Gene Drives

The application of engineered gene drives is currently being discussed in several different areas and for various purposes, including the management of infectious diseases (1.), the protection of biological diversity (2.), and agriculture (3.).

Generally, gene drives can either be employed to propagate desirable genetic changes to a target population (*modification drive*), reduce the abundance of a target species, or exterminate it locally or globally (*suppression drive*).[253] Depending on the desired outcome, different drive strategies might be preferable. They are generally classified by several attributes relating to their efficiency, specificity and stability.[254] Some systems, called *low-threshold* or *invasive drives*, are fast-spreading and require a comparatively low number of initial releases. In contrast, *high-threshold* or *local drives* spread more slowly and need higher numbers of initial releases relative to the size of the target population, which could allow for locally confined releases.[255] In any case, the pace at which a gene drive spreads also depends

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Sex Lethal Loci in the Invasive Pest, Drosophila Suzukii, 469 (2016) Biochemical and Biophysical Research Communications 911.

250 *James E. DiCarlo* et al., Safeguarding CRISPR-Cas9 Gene Drives in Yeast, 33 (2015) Nature Biotech. 1250.

251 *Valentino M. Gantz* et al., Highly Efficient Cas9-Mediated Gene Drive for Population Modification of the Malaria Vector Mosquito Anopheles Stephensi, 112 (2015) PNAS E6736–43; *Roberto Galizi* et al., A CRISPR-Cas9 Sex-Ratio Distortion System for Genetic Control, 6 (2016) Sci. Rep. 31139.

252 *Champer* et al. (n. 215), 151; *Marshall/Akbari* (n. 246), 180; *John Min* et al., Harnessing Gene Drive, 5 (2018) Journal of Responsible Innovation S40, S43–S45; *Ethan Bier*, Gene Drives Gaining Speed, 23 (2022) Nature Rev. Genet. 5, 5.

253 *Esvelt* et al. (n. 215).

254 *Champer* et al. (n. 215), 147.

255 *Ibid.*, 148; *Min* et al. (n. 252), S41; cf. *Sumit Dhole* et al., Invasion and Migration of Spatially Self-limiting Gene Drives, 11 (2018) Evolutionary Applications 794, 800–802. Other authors distinguish between *localized* and *non-localized drives*, depending on the potential of drive systems to spread beyond their initial release site, cf. *Raban* et al. (n. 247).

on characteristics of the target population such as mating dynamics and generation time.[256]

1. Control of Vector-Borne Diseases

The use of gene drives in the fight against vector-borne diseases has been discussed since 1960[257] and is their most prominent application.[258] In particular, the fight against human *malaria* has attracted much attention. Malaria is an infection caused by parasitic microorganisms of the *Plasmodium* genus, which are transmitted by mosquitoes of the *Anopheles* genus.[259] Malaria occurs in tropical and subtropical regions and caused approximately 627,000 deaths in 2020, predominantly in Africa.[260] Besides malaria, several other severe diseases are transmitted by insects, including *Dengue* and *Yellow Fever*.[261]

a) Modification Drives

Gene drives could be used to genetically modify populations of disease vector species in order to reduce their ability to transmit a given pathogen.[262] For instance, it was shown that CRISPR-Cas9 can be used to engineer a gene drive that spreads a resistance gene against the malaria pathogen *Plasmodium* to populations of the malaria vector mosquito *Anopheles stephensi*.[263]

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256 *Esvelt* et al. (n. 215), 3.
257 See *Craig* et al. (n. 240).
258 See *Stephanie James/Karen Tountas*, Using Gene Drive Technologies to Control Vector-Borne Infectious Diseases, 10 (2018) Sustainability 4789.
259 Cf. *Austin Burt* et al., Gene Drive to Reduce Malaria Transmission in Sub-Saharan Africa, 5 (2018) Journal of Responsible Innovation S80, S66–S67.
260 WHO, World Malaria Report 2021 (2021), 24; also see *Burt* et al. (n. 259), S66–S67.
261 See, *inter alia*, *Galizi* et al. (n. 231).
262 See generally *John M. Marshall/Charles E. Taylor*, Malaria Control with Transgenic Mosquitoes, 6 (2009) PLOS Medicine e1000020; NASEM, Gene Drives on the Horizon (n. 216), 50–54; *H. C. J. Godfray* et al., How Driving Endonuclease Genes Can Be Used to Combat Pests and Disease Vectors, 15 (2017) BMC Biology 81, 4–6; *Burt* et al. (n. 259), S70–S72; *Bier* (n. 252), 9–12.
263 Cf. *Gantz* et al. (n. 251); *Astrid Hoermann* et al., Converting Endogenous Genes of the Malaria Mosquito into Simple Non-Autonomous Gene Drives for Popula-

b) Suppression Drives

Alternatively, a gene drive could be employed as a 'genetic equivalent of insecticides', i.e. to suppress or even eradicate the vector species.[264] This could be achieved by either biasing the sex ratio of the progeny[265] or by propagating a mutation that confers sterility.[266] Researchers have already used CRISPR-Cas9 to develop a gene drive system that causes sterility in female *Anopheles gambiae* mosquitoes.[267] A major challenge is genetic mutations which arise after a number of generations and confer resistance to the drive.[268] However, in 2018 a drive system targeting the *doublesex* gene in *Anopheles gambiae* reportedly reached a 100 % prevalence among mosquitos after 7–11 generations, which caused the population to collapse in a small-scale cage trial.[269] In 2020, a male-biased sex-distorter gene drive was developed as an additional, complementary approach.[270]

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tion Replacement, 10 (2021) eLife e58791; also see *Junitsu Ito* et al., Transgenic Anopheline Mosquitoes Impaired in Transmission of a Malaria Parasite, 417 (2002) Nature 452; *Esvelt* et al. (n. 215), 12; for an overview of other approaches, see *John M. Marshall*, The Cartagena Protocol and Releases of Transgenic Mosquitoes, in: Brij K. Tyagi (ed.), Training Manual: Biosafety for Human Health and the Environment in the Context of the Potential Use of Genetically Modified Mosquitoes (GMMs) (2015) 163, 165.

264 *Bier* (n. 252), 7; see *Anne Deredec* et al., Requirements for Effective Malaria Control with Homing Endonuclease Genes, 108 (2011) PNAS E874–80; *Burt* et al. (n. 259), 570–571.

265 Cf. *Nikolai Windbichler* et al., Targeting the X Chromosome During Spermatogenesis Induces Y Chromosome Transmission Ratio Distortion and Early Dominant Embryo Lethality in Anopheles Gambiae, 4 (2008) PLOS Genetics e1000291.

266 Cf. *T. A. Klein* et al., Infertility Resulting from Transgenic I-PpoI Male Anopheles Gambiae in Large Cage Trials, 106 (2012) Pathogens and Global Health 20; see *Marshall* (n. 263), 164; *Bier* (n. 252), 8–9.

267 *Andrew Hammond* et al., A CRISPR-Cas9 Gene Drive System Targeting Female Reproduction in the Malaria Mosquito Vector *Anopheles Gambiae*, 34 (2016) Nature Biotech. 78.

268 *Andrew M. Hammond* et al., The Creation and Selection of Mutations Resistant to a Gene Drive over Multiple Generations in the Malaria Mosquito, 13 (2017) PLOS Genetics e1007039; *Bier* (n. 252), 7.

269 *Kyros Kyrou* et al., A CRISPR–Cas9 Gene Drive Targeting *Doublesex* Causes Complete Population Suppression in Caged *Anopheles Gambiae* Mosquitoes, 36 (2018) Nature Biotech. 1062.

270 *Alekos Simoni* et al., A Male-Biased Sex-Distorter Gene Drive for the Human Malaria Vector Anopheles Gambiae, 38 (2020) Nature Biotech. 1054.

c) Current State of Development

While genetically modified insects were already released into the environment in a number of instances,[271] there have so far been no reported environmental releases of organisms carrying a synthetic gene drive.[272] Instead, experiments are confined to cage trials,[273] and computational models are used to evaluate various gene drive methods and release strategies by simulating simplified field settings including circumstances such as seasonal weather.[274] Altering, reducing or eliminating a mosquito species may have various ecological effects on other species that they interact with as prey, predator, competitor or disease vector, and may also open ecological niches that may be colonized by other species.[275] It has also been suggested that species could be reintroduced from sheltered laboratories or island populations once disease eradication is complete.[276]

A research consortium named *Target Malaria* is currently exploring the use of engineered gene drives to bias the sex ratio or reduce the female fertility in the mosquitoe species *Anopheles gambiae*.[277] In September 2018, regulators in Burkina Faso granted permission to Target Malaria for the

271 *R. Guy Reeves* et al., Scientific Standards and the Regulation of Genetically Modified Insects, 6 (2012) PLOS Neglected Tropical Diseases e1502; see *infra* section E.III.
272 Cf. *Burt* et al. (n. 259), S75–S76.
273 *Andrew Hammond* et al., Gene-Drive Suppression of Mosquito Populations in Large Cages as a Bridge Between Lab and Field, 12 (2021) Nature Comms. 4589.
274 Cf. *Philip A. Eckhoff* et al., Impact of Mosquito Gene Drive on Malaria Elimination in a Computational Model with Explicit Spatial and Temporal Dynamics, 114 (2017) PNAS E255–E264; *Ace R. North* et al., Modelling the Suppression of a Malaria Vector Using a CRISPR-Cas9 Gene Drive to Reduce Female Fertility, 18 (2020) BMC Biology 98; *Paola Pollegioni* et al., Detecting the Population Dynamics of an Autosomal Sex Ratio Distorter Transgene in Malaria Vector Mosquitoes, 57 (2020) The Journal of Applied Ecology 2086.
275 *Godfray* et al. (n. 262), 6 and additional file 1, note 11; see *Aaron S. David* et al., Release of Genetically Engineered Insects: A Framework to Identify Potential Ecological Effects, 3 (2013) Ecology and Evolution 4000; *Andrew Roberts* et al., Results from the Workshop "Problem Formulation for the Use of Gene Drive in Mosquitoes", 96 (2017) Am. J. Trop. Med. Hyg. 530. Also see *infra* section C.IV.3.
276 *Esvelt* et al. (n. 215), 14.
277 See Target Malaria, Male Bias and Female Fertility, available at: https://targetmalaria.org/what-we-do/our-approach/male-bias-and-female-fertility/ (last accessed 28 May 2022).

experimental release of up to 10,000 genetically modified mosquitoes.[278] The mosquitoes did not contain a gene drive, but were modified to be sterile (i.e. incapable of sexual reproduction) and to carry fluorescent markers, which allows the identification of modified individuals.[279] The mosquitoes were generated in the United Kingdom and tested in containment in Italy before they were imported to Burkina Faso in the form of eggs in November 2016.[280] Following cage trials in Burkina Faso, approximately 6,400 genetically modified male (i.e. non-biting) mosquitoes were experimentally released in a village in Burkina Faso in July 2019.[281] The release was followed by a 20-day 'recapture period' and a monitoring period to verify the disappearance of the transgene from the environment.[282] In the next project phase, Target Malaria plans to release non-drive mosquitoes with a male bias.[283]

278 Cf. Target Malaria, Target Malaria Welcomes the Decision of the National Biosafety Agency of Burkina Faso to Approve a Small-Scale Release of Genetically Modified Sterile Male Mosquitoes (n.d.), available at: https://targetmalaria.org/wp-content/uploads/2021/07/statement_authorisation_nba_bf-1.pdf (last accessed 28 May 2022); *Keith R. Hayes* et al., Risk Assessment for Controlling Mosquito Vectors with Engineered Nucleases: Controlled Field Release for Sterile Male Construct: Risk Assessment Final Report (2018); *Ike Swetlitz*, Researchers to Release First-Ever Genetically Engineered Mosquitoes in Africa, STAT, 05 September 2018, available at: https://www.statnews.com/2018/09/05/release-genetically-engineered-mosquitoes-africa/ (last accessed 28 May 2022). The decision appears to be unpublished, nor was it notified to the Biosafety Clearing-House, see chapter 3, section A.II.3. On non-drive applications of genetically modified insects generally, see *infra* section E.II.

279 Target Malaria, Results of the Small-Scale Release of Non Gene Drive Genetically Modified Sterile Male Mosquitoes in Burkina Faso (2021), 1–2; *Franck A. Yao* et al., Mark-Release-Recapture Experiment in Burkina Faso Demonstrates Reduced Fitness and Dispersal of Genetically-Modified Sterile Malaria Mosquitoes, 13 (2022) Nature Comms. 796, 2; cf. *Hayes* et al. (n. 278), 14; *Windbichler* et al. (n. 265), 2.

280 Target Malaria was criticized for not having notified the import of the mosquitoes into Burkina Faso in line the pertinent international regulations, but claimed that these rules did not apply because the mosquitoes were first tested in containment before being released; see chapter 3, section A.II.1.g).

281 Target Malaria (n. 279), 2–3.

282 *Ibid.*, 3; *Yao* et al. (n. 279), 6–7.

283 Target Malaria (n. 279), 3.

2. Control of Invasive Species

Invasive species often cause severe damage to the local environment up to the extinction of local species, as well as substantial economic losses, particularly on islands.[284] It has been suggested that suppression drives could be employed to control or eradicate these species from islands or continents[285] or even to cause their global extinction.[286]

The application of suppression drives has been proposed to eradicate non-indigenous rodents such as rats and mice species.[287] Gene drives could constitute a more efficient, more species-specific and non-toxic alternative to conventional methods to suppress invasive species.[288] In theory, gene drives might also be used to aid threatened species by genetically enhancing them or by increasing their ecological niches.[289]

The application of gene drives to control invasive species is currently investigated by several universities, government and not-for-profit organizations that have established a joint program on *Genetic Biocontrol of Invasive Rodents*.[290] Furthermore, New Zealand's *Predator Free 2050* program, which aims at eliminating all rats, possums and stoats by 2050, is sometimes associated with suppression drives,[291] but there appear to exist no concrete plans to actually employ gene drive techniques as part of the program.[292]

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284 *S. L. Goldson* et al., New Zealand Pest Management, 45 (2015) Journal of the Royal Society of New Zealand 31, 32–35; *Min* et al. (n. 252), S47.

285 *Esvelt* et al. (n. 215), 15; NASEM, Gene Drives on the Horizon (n. 216), 54–56.

286 *Bruce L. Webber* et al., Opinion, 112 (2015) PNAS 10565, 10565.

287 *Karl J. Campbell* et al., The Next Generation of Rodent Eradications, 185 (2015) Biological Conservation 47, 51–52.

288 *Ibid.*

289 *Esvelt* et al. (n. 215), 15; see *Kent H. Redford* et al., Genetic Frontiers for Conservation (2019); *Jesse L. Reynolds*, Engineering Biological Diversity: The International Governance of Synthetic Biology, Gene Drives, and De-Extinction for Conservation, 49 (2021) Current Opinion in Environmental Sustainability 1, 2.

290 Island Conservation, The Genetic Biocontrol of Invasive Rodents (GBIRd) Program, available at: http://www.geneticbiocontrol.org/ (last accessed 28 May 2022).

291 See *Kevin M. Esvelt/Neil J. Gemmell*, Conservation Demands Safe Gene Drive, 15 (2017) PLOS Biology e2003850, 1–2; *Brian Owens*, Behind New Zealand's Wild Plan to Purge All Pests, 541 (2017) Nature News 148.

292 Cf. Predator Free 2050 Limited, Current Research Projects, available at: https://pf2050.co.nz/current-research-projects/ (last accessed 28 May 2022).

3. Agriculture

In agriculture, gene drives might be applied to fight plant pests in various ways. One study suggested that a suppression drive might be applied in the fruit crop pest *Drosophila suzukii*, which poses an economic threat to soft summer fruits such as blueberries and strawberries.[293] Another approach is to use *sensitizing drives* to remove herbicide or pesticide resistances that pest species have developed over time,[294] such as the western corn rootworm's resistance to *Bacillus thuringiensis* toxins[295] or the mutations allowing horseweed and pigweed to resist the herbicide glyphosate.[296] Alternatively, *sensitizing drives* might be used to render pest populations vulnerable to substances that have not affected them before; this would potentially allow for the development of less toxic and more species-specific pest control agents.[297] Finally, gene drives could be applied to render pest species less harmful without impeding their viability, for instance by reprogramming insects to avoid human crops or by disabling the desert locust's capacity to form large, damaging swarms.[298]

IV. Limitations and Risks of Applying Engineered Gene Drives

Engineered gene drive techniques are still subject to several limitations (1.) and risks (2.). In addition, concerns arise from the potential ecological effects of suppressing target species (3.) as well as from the potential transboundary effects of gene drives (4.).

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293 Cf. *Li/Scott* (n. 249), 916; *Anna Buchman* et al., Synthetically Engineered Medea Gene Drive System in the Worldwide Crop Pest Drosophila Suzukii (2018) PNAS 201713139; see also NASEM, Gene Drives on the Horizon (n. 216), 58.

294 *Ibid.*, 57–58.

295 *Aaron J. Gassmann* et al., Field-Evolved Resistance by Western Corn Rootworm to Multiple Bacillus Thuringiensis Toxins in Transgenic Maize, 111 (2014) PNAS 5141.

296 *Todd A. Gaines* et al., Gene Amplification Confers Glyphosate Resistance in Amaranthus Palmeri, 107 (2010) PNAS 1029; *Xia Ge* et al., Rapid Vacuolar Sequestration, 66 (2010) Pest Management Science 345; NASEM, Gene Drives on the Horizon (n. 216), 57–58.

297 *Esvelt* et al. (n. 215), 15; *Min* et al. (n. 252), S46–S47.

298 *Min* et al. (n. 252); see *Ryohei Sugahara* et al., Knockdown of the Corazonin Gene Reveals Its Critical Role in the Control of Gregarious Characteristics in the Desert Locust, 79 (2015) Journal of Insect Physiology 80.

1. Limitations of Current Gene Drive Techniques

Current gene drive techniques are subject to four major challenges. First of all, gene drives only work in organisms that reproduce sexually, since they rely on biasing the inheritance of genetic information from both parents.[299] Therefore, gene drive systems will not function in organisms that reproduce asexually, including viruses and bacteria.[300] Organisms that employ a mix of sexual and asexual reproduction, including many plants,[301] are expected to be highly resistant to gene drives.[302]

Secondly, depending on the number of initial releases, gene drives require many generations to spread through a population. Hence, they are an unsuitable means to address species that have long generation times compared to human-relevant time frames.[303]

The third group of challenges concerns the potential formation of resistances.[304] When the cell repairs the drive-induced DNA break not by homology-directed repair but by joining together the 'loose ends' of DNA (non-homologous end joining), small mutations will alter the target sequence and hence inactivate the drive components.[305] One approach to solve this is to address only genes that are important for fitness so that any resistant organism will not reproduce.[306] However, there is no scientific certainty yet about the degree to which evolving resistances inhibit gene drives.[307] While some studies reported that mutations inevitably arise,[308]

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299 *Esvelt* et al. (n. 215), 9; NASEM, Gene Drives on the Horizon (n. 216), 49; *Min* et al. (n. 252), S48.

300 *Esvelt* et al. (n. 215), 9.

301 See NASEM, Gene Drives on the Horizon (n. 216), 50.

302 *Min* et al. (n. 252), S48; *Esvelt* et al. (n. 215), 9; see *Douglas W. Drury* et al., CRISPR/Cas9 Gene Drives in Genetically Variable and Nonrandomly Mating Wild Populations, 3 (2017) Science Advances e1601910.

303 *Esvelt* et al. (n. 215), 9; NASEM, Gene Drives on the Horizon (n. 216), 49; *Min* et al. (n. 252), S48.

304 See *J. J. Bull*, Evolutionary Decay and the Prospects for Long-Term Disease Intervention Using Engineered Insect Vectors, 2015 (2015) Evolution, Medicine, and Public Health 152.

305 *Champer* et al. (n. 215), 151; *John M. Marshall* et al., Overcoming Evolved Resistance to Population-Suppressing Homing-Based Gene Drives, 7 (2017) Sci. Rep. 3776, 2; *Charleston Noble* et al., Evolutionary Dynamics of CRISPR Gene Drives, 3 (2017) Science Advances e1601964.

306 *Esvelt* et al. (n. 215), 14.

307 *Raban* et al. (n. 247), 5.

308 Cf. *Robert L. Unckless* et al., Evolution of Resistance Against CRISPR/Cas9 Gene Drive, 205 (2017) Genetics 827; *Jackson Champer* et al., Novel CRISPR/Cas9

another study demonstrated with mathematical models that CRISPR-Cas drive systems are likely to be highly invasive.[309]

The fourth limitation of engineered gene drives is that their evolutionary stability can be limited.[310] This depends on the particular circumstances and whether the drive decreases the organism's fitness. Especially when the drive imposes a fitness cost on the organism, drive-bearing individuals might be outcompeted by wild-types that have higher evolutionary fitness.[311] This might require repeated releases of altered organisms, which can be included in containment strategies.[312]

2. Risks Related to Gene Drive Applications

The application of gene drives also imposes a number of (potential) risks. Some of these risks are shared with other genetic engineering techniques, such as that payload genes delivered with a gene drive may have unanticipated detrimental effects.[313] Furthermore, the drive might evolve into a harmful construct after being released.[314] For instance, the drive construct might produce off-target mutations in the target genome which continue to spread as long as the mutation does not render the drive construct itself inoperative.[315] The use of gene drives could also pose risks to human health, for example by increasing the organism's capacity to transmit pathogens.[316] In addition, several risks originate from the functioning of gene drives and their potential effects.

Gene Drive Constructs Reveal Insights into Mechanisms of Resistance Allele Formation and Drive Efficiency in Genetically Diverse Populations, 13 (2017) PLOS Genetics e1006796.

309 Cf. *Charleston Noble* et al., Current CRISPR Gene Drive Systems Are Likely to Be Highly Invasive in Wild Populations, 7 (2018) eLife e33423.

310 See NASEM, Gene Drives on the Horizon (n. 216), 34–36.

311 *Esvelt* et al. (n. 215), 9; *Min* et al. (n. 252), S49.

312 NASEM, Gene Drives on the Horizon (n. 216), 36.

313 *Champer* et al. (n. 215), 156; see *supra* section B.V.

314 *Fears* (n. 197), 14.

315 *Webber* et al. (n. 286), 10566.

316 Cf. *Fears* (n. 197), 14; *Roberts* et al. (n. 275), 531; *John L. Teem* et al., Problem Formulation for Gene Drive Mosquitoes Designed to Reduce Malaria Transmission in Africa: Results from Four Regional Consultations 2016–2018, 18 (2019) Malaria Journal 347, 7–8.

a) Unintended Geographic Spread

Gene drives might spread beyond their intended target population. Even if not intended to alter or eradicate a species globally, gene flow enabled by human activity or disruptive events, or simply movement of individuals from one population to another,[317] may enable a gene drive to spread beyond its intended geographical range.[318] Thus, invasive gene drives in principle have the potential to spread transgenes globally throughout an entire species.[319] Furthermore, there is a potential risk that invasive gene drives might accidentally escape from laboratories, which requires the adoption of adequate safeguards.[320]

b) Intended but Unauthorized Spread

A gene drive might also be spread through deliberate unauthorized transport and release. When a gene drive system offers substantial economic benefits, such as suppressing an agricultural pest species, previous exam-

317 In this context, one study showed that the t-haplotype, a selfish genetic element in house mice which might also be used for synthetic gene drives (see the references in n. 234), manipulates host behaviour and increases the propensity of mice carrying it to migrate into foreign populations, cf. *Jan-Niklas Runge/Anna K. Lindholm*, Carrying a Selfish Genetic Element Predicts Increased Migration Propensity in Free-Living Wild House Mice, 285 (2018) Proc. R. Soc. B 1333.

318 NASEM, Gene Drives on the Horizon (n. 216), 37–38; *Kenneth A. Oye* et al., Regulating Gene Drives, 345 (2014) Science 626, 627; *Webber* et al. (n. 286), 10556. This problem has been acknowledged before the arrival of synthetic gene drive techniques, in particular with regard to the release of genetically modified viruses for pest control, cf. *Elena Angulo/B. Cooke*, First Synthesize New Viruses Then Regulate Their Release? The Case of the Wild Rabbit, 11 (2002) Molecular Ecology 2703, 2706.

319 *John M. Marshall*, The Cartagena Protocol and Genetically Modified Mosquitoes, 28 (2010) Nature Biotech. 896, 897; *Marshall* (n. 263), 167; also see *Yehonatan Alcalay* et al., The Potential for a Released Autosomal X-Shredder Becoming a Driving-Y Chromosome and Invasively Suppressing Wild Populations of Malaria Mosquitoes, 9 (2021) Front. Bioeng. & Biotechnol. 752253, proposing that it was 'unlikely' that a self-limiting autosomal X-shredder gene drive would become invasive after being released into the environment.

320 Cf. *Burt* (n. 230), 927, noting that 'the ease and rapidity with which these selfish genes can invade a population applies not just to planned releases, but also to unintentional releases of laboratory escapees'. Also see *Omar S. Akbari* et al., Safeguarding Gene Drive Experiments in the Laboratory, 349 (2015) Science 927 and chapter 5, section C.III.

ples from conventional biocontrol[321] suggest that individuals will likely seek advantage by moving drive-equipped organisms to other locations, even when such movement is illegal.[322] Whether a gene drive can persist and continue to spread in other locations depends on the characteristics of both the target organism and the drive and includes factors such as fitness, conversion rate, population structure and ecological interactions with other species.[323] In some cases, gene drives might be confined to certain (sub-)populations by employing highly specific 'precision drives'.[324]

c) Undesired Spread to Non-Target Species

Gene drives, or parts of it, could spread into non-target species through *horizontal gene transfer*, which denotes the movement of genes between distinct species.[325] There are mechanisms that allow for horizontal gene transfer between unrelated bacterial species,[326] between bacteria and plants (e.g., through *Agrobacterium tumefaciens*[327]), between bacteria and animals,[328] and between plants through hybridization.[329] The potential for horizontal gene transfer must therefore be evaluated for any species targeted by a gene drive in order to avoid an undesired spread into non-target species.[330]

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321 Cf. *Angulo/Cooke* (n. 318), 2704–2705; *Peter O'Hara*, The Illegal Introduction of Rabbit Haemorrhagic Disease Virus in New Zealand, 25 (2006) Revue scientifique et technique (International Office of Epizootics) 119.
322 *Esvelt/Gemmell* (n. 291), 2; *Min* et al. (n. 252), S48.
323 NASEM, Gene Drives on the Horizon (n. 216), 39.
324 Cf. *Esvelt* et al. (n. 215), 10–11; *Oye* et al. (n. 318), 627.
325 Horizontal gene transfer is also referred to as 'lateral gene transfer', cf. Henderson's Dictionary of Biology (n. 5), 268.
326 *Pierce* (n. 1), 271.
327 Cf. *Pavel Krenek* et al., Transient Plant Transformation Mediated by Agrobacterium Tumefaciens, 33 (2015) Biotechnology Advances 1024.
328 *Julie C. Dunning Hotopp*, Horizontal Gene Transfer Between Bacteria and Animals, 27 (2011) Trends in Genetics 157.
329 *Pierce* (n. 1), 818; NASEM, Gene Drives on the Horizon (n. 216), 39–40.
330 NASEM, Gene Drives on the Horizon (n. 216), 39; *Webber* et al. (n. 286), 10566; *Virginie Courtier-Orgogozo* et al., Agricultural Pest Control with CRISPR-based Gene Drive, 18 (2017) EMBO Reports 878; *Fears* (n. 197), 14.

d) Dual Use of Gene Drive Techniques

The advent of gene drive techniques also raised concerns over biosecurity and potential dual-use applications.[331] In theory, mosquitoes might be engineered to transmit a pathogen that is normally not vector-borne or even to deliver a toxin.[332] Other scenarios involve the use of gene drives for targeted attacks on crop plants.[333] Currently, the malicious use of gene drive techniques appears unlikely due to its high engineering complexity compared to other potential biohazards.[334] Nevertheless, the potential of gene drives for dual-use applications cannot be discounted[335] and resembles previous instances of so-called *Dual Use Research of Concern*, e.g. studies that increased the transmissibility of the highly pathogenic avian influenza virus H5N1.[336]

3. Potential Ecological Effects of Suppressing a Target Species

The potential removal of a target species or its substantial reduction in abundance in its native habitat range raises ethical[337] as well as ecological

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331 Cf. *Min* et al. (n. 252), S57–S58.
332 *David Gurwitz*, Gene Drives Raise Dual-Use Concerns, 345 (2014) Science 1010; NASEM, Gene Drives on the Horizon (n. 216), 160–161; see *Jeffrey A. Lockwood*, Insects as Weapons of War, Terror, and Torture, 57 (2012) Annual Review of Entomology 205, 221–222.
333 *Gurwitz* (n. 332); *Oye* et al. (n. 318), 627.
334 NASEM, Gene Drives on the Horizon (n. 216), 160; on the low feasibility of using gene drives to modify the he human genome, see Committee on Strategies for Identifying and Addressing Potential Biodefense Vulnerabilities Posed by Synthetic Biology et al., Biodefense in the Age of Synthetic Biology (2018), 79.
335 See *Jim Thomas*, The National Academies' Gene Drive Study Has Ignored Important and Obvious Issues, The Guardian, 09 June 2016, available at: https://www.theguardian.com/science/political-science/2016/jun/09/the-national-academies-gene-drive-study-has-ignored-important-and-obvious-issues (last accessed 28 May 2022).
336 NASEM, Gene Drives on the Horizon (n. 216), 159; cf. *Sander Herfst* et al., Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets, 336 (2012) Science 1534.
337 Cf. *Jonathan Pugh*, Driven to Extinction? The Ethics of Eradicating Mosquitoes with Gene-Drive Technologies, 42 (2016) Journal of Medical Ethics 578; *Axel Hochkirch* et al., License to Kill?, 11 (2018) Conservation Letters e12370; *Tina Rulli*, CRISPR and the Ethics of Gene Drive in Mosquitoes, in: David Boonin (ed.), The Palgrave Handbook of Philosophy and Public Policy (2018) 509;

concerns.[338] Since most species are embedded in complex ecosystems, in which they are connected to other species through food webs or as competitors for ecological niches, removing a certain species might lead to unintended environmental effects.[339] This could include the disruption of food webs as well as the facilitation of other, possibly invasive species or undesired negative effects for non-target species.[340] Hence, targeting one species can potentially produce cascade effects on several other species or destabilize entire ecosystems.[341] Since the ecological trophic networks are highly complex, these effects can be difficult to predict.[342]

Until now, research on ecological consequences of gene drives has mostly focused on mosquito species that transmit malaria, in particular *Anopheles gambiae*.[343] Some argue that the removal of this species was unlikely to cause ecological harm since it did not represent a keystone species and sufficient alternatives, especially from within the *Anopheles* genus were available.[344] Others warn that the removal of *Anopheles gambiae* could cause cascading community effects, disrupt food webs and potentially lead to a loss of diversity in the affected community.[345] Besides natural ecosystems, gene drive applications may also pose risks to agriculture, e.g. when the dominance of a pest species is enhanced, which may cause damage to crops or livestock.[346]

Swiss Federal Ethics Committee on Non-Human Biotechnology, Gene Drives: Ethical Considerations on the Use of Gene Drives in the Environment (2019), 5; see chapter 3, section B.VIII.

338 See *Teem* et al. (n. 316), 8–9; *John B. Connolly* et al., Systematic Identification of Plausible Pathways to Potential Harm via Problem Formulation for Investigational Releases of a Population Suppression Gene Drive to Control the Human Malaria Vector Anopheles Gambiae in West Africa, 20 (2021) Malaria Journal 170.

339 *Oye* et al. (n. 318), 627; NASEM, Gene Drives on the Horizon (n. 216), 40–41; *Webber* et al. (n. 286), 10556; *Bier* (n. 252), 7.

340 *Webber* et al. (n. 286), 10566; NASEM, Gene Drives on the Horizon (n. 216), 40.

341 *David* et al. (n. 275), 4010.

342 NASEM, Gene Drives on the Horizon (n. 216), 40.

343 *Esvelt* et al. (n. 215), 10; see *David* et al. (n. 275); *C. M. Collins* et al., Effects of the Removal or Reduction in Density of the Malaria Mosquito, Anopheles Gambiae S.L., on Interacting Predators and Competitors in Local Ecosystems, 33 (2019) Medical and Veterinary Entomology 1.

344 NASEM, Gene Drives on the Horizon (n. 216), 41; *Roberts* et al. (n. 275), 531–532; *Min* et al. (n. 252), S47–S48.

345 *David* et al. (n. 275), 4010.

346 Cf. *Fears* (n. 197), 14.

In general, it can be concluded that the risks and ecological effects of employing gene drives in wild populations have not yet been sufficiently scrutinized,[347] and it is generally acknowledged that further studies examining the ecological consequences of applying gene drives in specific species and environments are needed.[348] In October 2018, Target Malaria launched a four-year project to study the ecology of *Anopheles gambiae* and to analyse their position in local ecological foods webs.[349] Reportedly, this involves the use of *DNA barcoding*, where excretions of predators are analysed for traces of DNA originating from *Anopheles gambiae*.[350] Scientists also seek to develop drive-neutralizing systems such as 'reversal drives' to halt or undo the spread of a gene drive if it is found to cause unintended effects.[351]

4. Potential Transboundary Effects of Gene Drives

It appears to be undisputed that engineered gene drives, especially invasive drive systems, have the potential to cause transboundary effects. Most importantly, a gene drive might move into foreign territories – either by natural gene flow or intentionally or unintentionally aided by human action – and continue to spread to local populations there.[352] This also means that the risks associated with an unintentional release of a gene

347 Cf. NASEM, Gene Drives on the Horizon (n. 216), 113; also see *David* et al. (n. 275); *Esvelt* et al. (n. 215), 9–10.

348 Cf. *T. Kuiken* et al., Shaping Ecological Risk Research for Synthetic Biology, 4 (2014) Journal of Environmental Studies and Sciences 191; *Esvelt* et al. (n. 215), 10; *Oye* et al. (n. 318), 627; *Webber* et al. (n. 286), 10556; NASEM, Gene Drives on the Horizon (n. 216), 40–41.

349 University of Oxford, Department of Zoology, New Project Led by Oxford University's Zoology Department to Study the Community Ecology of the African Mosquito Vectors of Malaria (15 June 2017), available at: https://www.zoo.ox.ac.uk/article/new-project-led-oxford-universitys-zoology-department-study-community-ecology-african (last accessed 28 May 2022); cf. *Sarah Zhang*, No One Knows Exactly What Would Happen If Mosquitoes Were to Disappear, The Atlantic, 24 September 2018, available at: https://www.theatlantic.com/science/archive/2018/09/mosquito-target-malaria/570937/ (last accessed 28 May 2022).

350 Cf. *ibid.*

351 *Esvelt* et al. (n. 215), 10; *Bier* (n. 252), 15–17.

352 NASEM, Gene Drives on the Horizon (n. 216), 157; *Marshall* (n. 319), 896; *Oye* et al. (n. 318), 628; *Redford* et al. (n. 289), 41; *Connolly* et al. (n. 338), 61; *Raban* et al. (n. 247), 1–4.

drive are higher than with other genetically modified organisms.[353] In theory, a gene drive could also have transboundary effects without actually crossing a boundary. For instance, the gene drive-based removal of a certain predator species could facilitate the dominance of a non-altered invasive species and subsequently its spread into a neighbouring state's territory.

With regard to proposed gene drive applications in the mosquito species *Anopheles gambiae*, it has been argued that their removal from a particular environment was unlikely to cause ecological harm, particularly because the species is not known to be the sole or primary food source for any other species.[354] Others have warned that 'ecosystems are connected in myriad ways and that a handful of organisms introduced in 1 [sic] country may have ramifications well beyond its own borders'.[355] Previous releases of genetically modified insects have also raised concerns about their compliance with the Cartagena Protocol,[356] scientific standards on risk assessments,[357] and impacts on organic farmers.[358]

If a gene drive has transboundary effects, the environment of the foreign state, in particular its biological diversity, will be primarily affected.[359] However, it also appears possible that individual goods might be impaired, e.g. by the loss of ecosystem services or due to contamination of farmland with drive-equipped organisms. Depending on the circumstances, individual damage could take the form of personal injury, property damage, or economic loss.

D. Horizontal Environmental Genetic Alteration Agents (HEGAAs)

As shown in the previous section, engineered gene drives can be used to increase the probability that a certain genetic modification is passed on

353 NASEM, Gene Drives on the Horizon (n. 216), 149.
354 *Roberts* et al. (n. 275), 531–532; *Collins* et al. (n. 343), 10–11.
355 *Esvelt/Gemmell* (n. 291), 5.
356 Cf. *Marshall* (n. 319); *Marshall* (n. 263), 165–167.
357 Cf. *Reeves* et al. (n. 271).
358 Cf. *R. Guy Reeves/Martin Phillipson*, Mass Releases of Genetically Modified Insects in Area-Wide Pest Control Programs and Their Impact on Organic Farmers, 9 (2017) Sustainability 59.
359 *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 75–76.

to subsequent generations. Hence, gene drives aim at achieving a *vertical* propagation of genetic modifications. A different approach is so-called *horizontal environmental genetic alteration agents* (HEGAAs), which perform the same genetic modification in a multitude of individuals of the same generation.[360] HEGAAs are biological agents that can spread through horizontal transmission, such as pathogens or symbionts, and have been engineered to alter the genome of their target organism by using sequence-specific genome editing techniques.[361] In contrast to gene drives, HEGAAs are not necessarily aimed at increasing the rate of transmission of a genetic modification to subsequent generations but rather at modifying large amounts of already-living organisms. However, by targeting germline cells, HEGAAs can also be used to confer heritable alterations.[362]

In 2016, the United States' *Defense Advanced Research Projects Agency* (DARPA) launched a research program funding the development of HEGAAs to genetically modify already-growing crop plants in the field.[363] The program, called *Insect Allies*, proposed to use insects to transmit viral HEGAAs to mature crop plants in order to genetically modify these plants within the same growing season.[364] The most prospective approach is to integrate a CRISPR system into a benign virus that would modify the genetic material of the crop plant in cells infected by the virus.[365] According to DARPA's call for proposals, at least three transgenes should be expressed by the virus to result in a *gain of function* phenotype (i.e. a phenotype that possesses new functions compared to the wild type[366]) in the crop plants.[367] The call required a 'large greenhouse demo' to be performed at the end of the four-year project term.[368]

According to recipients of grants from the Insect Allies program, traits of interest predominantly include resistance to disease, drought or insects,

360 *R. Guy Reeves* et al., Agricultural Research, or a New Bioweapon System?, 362 (2018) Science 35.
361 See *supra* section B.II.
362 *Evan E. Ellison* et al., Multiplexed Heritable Gene Editing Using RNA Viruses and Mobile Single Guide RNAs, 6 (2020) Nature Plants 620, 620.
363 DARPA, Broad Agency Announcement: Insect Allies: HR001117S000 (2016), 4–6.
364 *Ibid.*, 6.
365 *Reeves* et al. (n. 360); see *Ellison* et al. (n. 362).
366 Cf. 'gain-of-function', in: Henderson's Dictionary of Biology (n. 5), 219.
367 Cf. DARPA (n. 363), 8.
368 *Ibid.*, 6.

all of which are of value to farmers.[369] However, the technique might equally be used to confer *detrimental* traits to crops, and thus result in the generation of a new class of biological weapons.[370] Furthermore, the approach faces multiple technical challenges,[371] such as that the envisaged application will almost invariably generate a mixture of the intended edit, along with random mutations at the target chromosomal site (where each individual plant has the potential to gain a unique set of mutations), unintended off-target mutations and individual plants that remain unaltered.[372] Infected insects could also disperse beyond their intended geographical scope and lead to the infection of untargeted plants. It has therefore been argued that the approach was 'beyond any risk assessment ever performed in the field of biotechnology'.[373]

E. Self-Spreading Biotechnology Not Involving Genetic Alteration of the Target Organism

While synthetic gene drives and HEGAAs are aimed at conferring permanent genetic modifications to their target organisms, other instances of

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369 Cf. Boyce Thompson Institute, BTI Receives DARPA "Insect Allies" Award to Develop Viruses and Insects for Maize Improvement (27 July 2017), available at: https://btiscience.org/explore-bti/news/post/bti-receives-darpa-insect-allies-award-to-develop-viruses-and-insects-for-maize-improvement/ (last accessed 28 May 2022); Ohio State University, College of Food, Agricultural, and Environmental Sciences, Insect Allies: How the Enemies of Corn May Someday Save It (16 October 2017), available at: https://cfaes.osu.edu/news/articles/insect-allies-how-the-enemies-corn-may-someday-save-it (last accessed 28 May 2022); Pennsylvania State University, Penn State Team Receives $7M Award to Enlist Insects as Allies for Food Security (20 November 2017), available at: http://news.psu.edu/story/495037/2017/11/20/research/penn-state-team-receives-7m-award-enlist-insects-allies-food (last accessed 28 May 2022), 36.

370 *Todd Kuiken*, DARPA's Synthetic Biology Initiatives Could Militarize the Environment: Is that Something We're Comfortable with? (28 March 2018), available at: http://www.slate.com/articles/technology/future_tense/2017/05/what_happens_if_darpa_uses_synthetic_biology_to_manipulate_mother_nature.html (last accessed 28 May 2022); *Reeves* et al. (n. 360).

371 See *Kevin Pfeifer* et al., Insect Allies – Assessment of a Viral Approach to Plant Genome Editing, 18 (2022) Integrated Environmental Assessment and Management.

372 *Reeves* et al. (n. 360), 36.

373 *Samson Simon* et al., Scan the Horizon for Unprecedented Risks, 362 (2018) Science 1007.

self-spreading biotechnology pursue different goals. For instance, genetically modified viruses can be used to control agricultural pests (I.) or as self-disseminating vaccines (II.). Another example is the suppression of insect populations by releasing large numbers of individuals genetically modified to be sterile (III.). Moreover, the heritable *Wolbachia* bacterium is used to suppress infectious diseases transmitted by mosquitoes (IV.).

I. Use of Genetically Modified Viruses in Plant Pest Control

Genetically modified viruses can be used to control plant pests such as insects or bacteria.[374] For instance, a commercial enterprise located in the United States has developed a genome-edited virus to control the so-called *citrus greening disease* (also known as *Huanglongbing*), which is a bacterial disease that infects citrus fruit trees.[375] In the United States alone, this bacterial disease has caused billions of US dollars in losses since it was first detected in 2005.[376]

To render citrus trees resistant to this disease, genes derived from spinach that encode for antibacterial proteins were added to a harmless strain of the *citrus tristeza* virus.[377] The trees are then artificially infected with the virus, where it triggers the production of *defensin* proteins that kill the bacterium responsible for the disease.[378] The genetic material encoding defensins is not inserted into the citrus chromosome, but only transiently expressed as long as the virus is present in the plant.[379] According to an environmental impact statement produced during the authorization procedure, no adverse impacts on the environment or human health are expected by the use of the modified virus.[380] However, the virus may be

374 Cf. *Jennifer S. Cory* et al., Field Trial of a Genetically Improved Baculovirus Insecticide, 370 (1994) Nature 138.

375 Cf. *Heidi Ledford*, Geneticists Enlist Engineered Virus and CRISPR to Battle Citrus Disease, 545 (2017) Nature News 277; APHIS, Southern Gardens Citrus Nursery, LLC Permit to Release Genetically Engineered Citrus Tristeza Virus: Draft Environmental Impact Statement (2018).

376 *Ledford* (n. 375), 277.

377 APHIS, Draft Environmental Impact Statement on Release of Engineered Citrus tristeza virus (n. 375), 33–34.

378 *Ibid.*

379 *Ibid.*, 33.

380 *Ibid.*, 33–39.

present in products derived from crops that are susceptible to the virus.[381] Moreover, the virus might be delivered to untargeted plants by insects.[382]

II. Self-Disseminating Vaccines

Scientists have proposed to harness the self-propagating capabilities of viruses to develop self-disseminating vaccines.[383] This could be achieved either by modifying a pathogenic wild-type virus not to cause illness or by inserting gene sequences from the target pathogen into a benign but quickly-dispersing virus.[384] Once released, this modified virus would move through its target populations but confer immunity rather than causing disease.[385] According to scientists, self-disseminating vaccines could be designed to be either indefinitely 'transmissible' or merely 'transferable', meaning that only individuals to which the vaccine is administered would be able to pass it on to other individuals.[386] A different study suggested using transgenic mosquitoes as 'flying vaccinators' to deliver vaccines via blood-feeding.[387]

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381 It was concluded that this posed no health risk because the citrus tristeza virus was not pathogenic to humans and, since virtually all citrus produced in Florida was infected with the virus, the virus likely was already 'consumed on a regular basis', cf. *ibid.*, 10–11.

382 Cf. *Michelle Heck*, Insect Transmission of Plant Pathogens: A Systems Biology Perspective, 3 (2018) mSystems e00168–17; but note that the modified virus strains reportedly are either not transmissible or have extremely low transmissibility by insects, see APHIS, Draft Environmental Impact Statement on Release of Engineered Citrus tristeza virus (n. 375), 8. There appear to be no independent or peer-reviewed studies available on the questions of transmissibility and hazardousness to human health.

383 See *Crystal Watson* et al., Technologies to Address Global Catastrophic Biological Risks (2018), 45–47.

384 *James J. Bull* et al., Transmissible Viral Vaccines, 26 (2018) Trends in Microbiology 6.

385 *Filippa Lentzos/R. Guy Reeves*, Scientists Are Working on Vaccines that Spread Like a Disease. What Could Possibly Go Wrong?, Bulletin of the Atomic Scientists, 18 September 2020, available at: https://thebulletin.org/2020/09/scientists-are-working-on-vaccines-that-spread-like-a-disease-what-could-possibly-go-wrong/ (last accessed 28 May 2022); *Filippa Lentzos* et al., Eroding Norms over Release of Self-Spreading Viruses, 375 (2022) Science 31, 32.

386 *Scott L. Nuismer/James J. Bull*, Self-Disseminating Vaccines to Suppress Zoonoses, 4 (2020) Nature Ecology & Evolution 1168, 1169.

387 *D. S. Yamamoto* et al., Flying Vaccinator; a Transgenic Mosquito Delivers a Leishmania Vaccine via Blood Feeding, 19 (2010) Insect Molecular Biology 391.

The first known field trial of a transmissible vaccine was carried out by Spanish researchers in 2001, targeting two infectious diseases threatening the European rabbit population.[388] In light of the COVID-19 pandemic, efforts to develop self-disseminating vaccines have received renewed attention.[389] To date, they are primarily discussed as a means to control the spread of *zoonoses*, i.e. pathogens of animal origin that can be transmitted to humans,[390] such as Ebola,[391] MERS, and SARS-CoV-2.[392] Currently, about 10 institutions worldwide are known to do significant work on self-disseminating vaccines.[393] A research project funded by DARPA aims at 'creating the world's first prototype of a self-disseminating vaccine designed to induce a high level of herd immunity (wildlife population level protection) against Lassa virus […] and Ebola'.[394]

Outside of experiments, the deployment of self-disseminating vaccines will likely face considerable technical challenges, such as identifying appropriate targets for intervention and ensuring that the immunity is maintained in the long term.[395] The approach also raises dual-use concerns, because the research could be repurposed to develop self-spreading,

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388 *Juan M. Torres* et al., First Field Trial of a Transmissible Recombinant Vaccine Against Myxomatosis and Rabbit Hemorrhagic Disease, 19 (2001) Vaccine 4536.

389 Cf. *Michael Cogley*, Could Self-Spreading Vaccines Stop a Coronavirus Pandemic?, The Telegraph, 31 January 2020, available at: https://www.telegraph.co.uk/technology/2020/01/28/could-self-spreading-vaccines-stop-global-coronavirus-pandemic/ (last accessed 28 May 2022); *Nuismer/Bull* (n. 386); *Rodrigo Pérez Ortega*, Can Vaccines for Wildlife Prevent Human Pandemics?, Quanta Magazine, 24 August 2020, available at: https://www.quantamagazine.org/can-vaccines-for-wildlife-prevent-human-pandemics-20200824/ (last accessed 28 May 2022); *Lentzos/Reeves* (n. 385).

390 Cf. 'zoonosis', in: Henderson's Dictionary of Biology (n. 5), 638.

391 *Yoshimi Tsuda* et al., A Replicating Cytomegalovirus-Based Vaccine Encoding a Single Ebola Virus Nucleoprotein CTL Epitope Confers Protection Against Ebola Virus, 5 (2011) PLoS Neglected Tropical Diseases e1275.

392 *Nuismer/Bull* (n. 386); *Scott L. Nuismer* et al., Eradicating Infectious Disease Using Weakly Transmissible Vaccines, 283 (2016) Proc. R. Soc. B; *Aisling A. Murphy* et al., Self-Disseminating Vaccines for Emerging Infectious Diseases, 15 (2016) Expert Review of Vaccines 31.

393 *Lentzos/Reeves* (n. 385).

394 UC Davis, Big Win: New Countermeasures to Eliminate Pandemic Risk, available at: https://www.preemptproject.org/s/BIG-WIN-New-Countermeasures.pdf (last accessed 28 May 2022); see DARPA, PREventing EMerging Pathogenic Threats (PREEMPT) (17 November 2020), available at: https://www.darpa.mil/program/preventing-emerging-pathogenic-threats (last accessed 28 May 2022).

395 *Lentzos/Reeves* (n. 385); *Lentzos* et al. (n. 385), 31–32; see *Bull* et al. (n. 384), 9–14.

potentially irreversible biological weapons.[396] Theoretically, transmissible vaccines could even be applied to humans,[397] although this would raise serious ethical and human rights-related concerns.[398]

III. Mass Releases of Sterile Genetically Modified Insects

Another strategy to suppress populations of insect species that are plant pests or disease vectors is to release masses of individuals genetically modified to be sterile.[399] This builds upon the conventional *sterile insect technique*, in which male insects are sterilized by irradiation.[400] The use of genetically modified insects seeks to increase the efficiency and flexibility of these programs, as conventional approaches offer limited ways to separate the sterilized males wanted for release from females, which are undesired for release because they still can lay eggs and transmit diseases through biting.[401]

In contrast to gene drive applications, the use of non-drive sterile insects for population suppression requires continuous releases of large numbers of modified individuals. The use of genetically modified sterile insects can thus be seen as a 'precursor' to gene drive applications, where additional genetic components are used to disseminate the genetic modification conferring sterility within the target population.[402] In the past, genetically modified insects have already been released in a number of cases in various countries.[403]

396 *Lentzos/Reeves* (n. 385); *Lentzos* et al. (n. 385), 33.
397 *Murphy* et al. (n. 392); *Bull* et al. (n. 384), 14; see *Lentzos/Reeves* (n. 385), noting that 'there is no clear evidence that anybody is actively working' on self-spreading vaccines for humans.
398 *Watson* et al. (n. 383), 46–47.
399 *Marshall* (n. 263), 164.
400 Cf. *W. Klassen/C. F. Curtis*, History of the Sterile Insect Technique, in: Victor A. Dyck/J. Hendrichs/A. S. Robinson (eds.), Sterile Insect Technique (2005) 3.
401 Cf. *Reeves/Phillipson* (n. 358), 4–5.
402 See *supra* section C.III.1.b).
403 Cf. *Reeves* et al. (n. 271), 1.

IV. Use of Wolbachia to Suppress Mosquito-Vectored Infectious Diseases

An alternative approach to suppress certain infectious diseases not necessarily involving genetic modification is to introduce strains of *Wolbachia* into the *Aedes aegypti* mosquito.[404] Wolbachia is a heritable, intra-cellular bacterium that naturally occurs in many insect species.[405] Its presence within *Aedes aegypti* shortens the lifespan of these mosquitoes[406] and reduces their ability to spread viruses such as *Dengue fever*[407] and *Zika*.[408]

An initiative called *World Mosquito Program* has announced plans to release *Wolbachia*-carrying mosquitoes in a number of countries, claiming that their approach neither suppressed mosquito populations nor involved genetic modification.[409] Deployments of Wolbachia-infected mosquitoes in *Townsville* in Australia[410] as well as in *Yogyakarta* in Indonesia[411] were reported to effectively reduce the local transmission of Dengue to humans.

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404 See *Marshall* (n. 263), 163–164.

405 Cf. *Laura R. Serbus* et al., The Genetics and Cell Biology of Wolbachia-Host Interactions, 42 (2008) Annual Review of Genetics 683.

406 *Conor J. McMeniman* et al., Stable Introduction of a Life-Shortening Wolbachia Infection into the Mosquito Aedes Aegypti, 323 (2009) Science 141; *Luciano A. Moreira* et al., Human Probing Behavior of Aedes Aegypti When Infected with a Life-Shortening Strain of Wolbachia, 3 (2009) PLoS Neglected Tropical Diseases e568.

407 *T. Walker* et al., The WMel *Wolbachia* Strain Blocks Dengue and Invades Caged *Aedes Aegypti* Populations, 476 (2011) Nature 450.

408 *Luciano A. Moreira* et al., A Wolbachia Symbiont in Aedes Aegypti Limits Infection with Dengue, Chikungunya, and Plasmodium, 139 (2009) Cell 1268; *Heverton L. Carneiro Dutra* et al., Wolbachia Blocks Currently Circulating Zika Virus Isolates in Brazilian Aedes Aegypti Mosquitoes, 19 (2016) Cell Host & Microbe 771; see *Champer* et al. (n. 215), 156.

409 See World Mosquito Program, Our Wolbachia Method, available at: https://www.worldmosquitoprogram.org/en/work/wolbachia-method (last accessed 28 May 2022).

410 *Scott L. O'Neill* et al., Scaled Deployment of *Wolbachia* to Protect the Community from Dengue and Other *Aedes* Transmitted Arboviruses, 2 (2018) Gates Open Research 36.

411 *Ewen Callaway*, The Mosquito Strategy that Could Eliminate Dengue, Nature News, 20 August 2020, available at: https://www.nature.com/articles/d41586-020-02492-1 (last accessed 28 May 2022).

F. Summary

Genetic change is a natural phenomenon that has been influenced by humankind for a long time. However, modern biotechnology has made significant advancements in the last decade. Especially the discovery of the CRISPR system and its development as a versatile tool for genome editing has vastly enlarged the 'molecular toolbox'. Applications of these new possibilities already exist and can be expected to arise in many areas including agriculture, basic and medical research (including gene therapy and genome editing in the human germline) and industrial biotechnology.

However, the probably most significant advancement is the development of engineered gene drives and other self-spreading techniques, which can either bias the Mendelian rules of inheritance or even spread horizontally within the same generation of organisms. This potentially allows one to confer new traits to natural populations of species or crop plants within a single generation. But it also makes it possible to inhibit the reproductivity of organisms and thereby suppress populations of species, potentially to the point of extinction.

The technological leap made with self-spreading biotechnology cannot be overestimated: while conventional GMOs are developed in the laboratory and can be thoroughly tested before being released into the environment, self-spreading techniques inherit the 'molecular toolbox' itself and the genetic modification is carried out in the target organism and without direct human intervention. Thus, the advent of self-spreading biotechnology means that 'the laboratory moves into the environment'.[412] However, the ecological effects of these techniques have not yet been sufficiently scrutinized, and there is a substantial likelihood that they are released into the environment before their risks are fully understood. This poses considerable challenges to existing scientific conventions but, as will be discussed in the subsequent chapters, also to international law.

412 *Samson Simon* et al., Synthetic Gene Drive: Between Continuity and Novelty (2018) EMBO Reports e45760, 2.

Chapter 2: Concepts and Terms Relevant to Transboundary Harm Caused by Biotechnology

The first chapter has shown that recent advances in biotechnology open up many new possibilities, but also pose challenges to the law, including at the international level. While the environmental and ethical implications of genome editing techniques remain controversial, it seems undisputed that techniques aimed at self-propagation, such as engineered gene drives, involve considerable environmental risks. In contrast to conventional applications of genetic engineering, these techniques also entail a considerable likelihood of uncontrolled transboundary effects. This raises the question of how international law addresses potential transboundary damage caused by the application of biotechnology.

Before we embark on a detailed analysis of the applicable rules and gaps in international law, the present chapter sets the scene by introducing a number of key terms which are fundamental to the topic and will be frequently used in the following chapters. To begin with, the terms 'living' and 'genetically' modified organisms are defined and the differences between both terms will be explained (A.). The ensuing section provides an overview of the different types of damage which may result from LMOs (B.). Moreover, the terms 'responsibility' and 'liability' must be distinguished (C.).

The imposition of liability for damage caused by LMOs is mandated by the 'polluter-pays' principle, although it is questionable whether liability should be imposed on states or on private operators (D.). Although liability is normally attached to proof of fault, this may be inappropriate in the case of hazardous activities, which may justify the imposition of 'strict' liability (E.). While international law focuses on interactions between states, it may also need to provide for harmonized rules on civil liability in a transboundary context (F.). Finally, a recent trend of international law-making is to provide for 'administrative liability' to complement the conventional 'civil liability' of operators (G.).

A. 'Genetically Modified' and 'Living Modified' Organisms

To denote organisms whose genome was engineered through molecular biotechnology, most national and regional regimes refer to 'genetically modified organisms' or GMOs.[1] In contrast, many treaties and instruments at the global level instead refer to 'living modified organisms' or LMOs.[2] This term was first used in the *Convention on Biological Diversity* (CBD) of 1992,[3] because it was assumed that many of the concerns directed at GMOs – such as the risk of invasiveness or uncontrolled spread, selection for resistant organisms from biopesticides, and the production of toxic by-products – were, in some circumstances, equally applicable to traditionally developed or bred organisms.[4] However, when the parties to the CBD mandated the negotiations of the *Cartagena Protocol on Biosafety*, the scope was restricted to LMOs 'resulting from *modern* biotechnology', which was meant to exclude conventional breeding methods.[5]

It is widely assumed that the terms 'genetically modified' and 'living modified' organisms are largely synonymous,[6] although the latter excludes processed materials derived from modified organisms.[7] However, as will be shown in chapter 3, more recent genome editing techniques challenge

1 Cf. *David Hamburger*, Comparative Analysis: The Regulation of Plants Derived from Genome Editing in Argentina, Australia, Canada, the European Union, Japan and the United States, in: Hans-Georg Dederer/David Hamburger (eds.), Regulation of Genome Editing in Plant Biotechnology (2019) 313, 327–336.

2 See chapter 3, sections A.I.1, B.III, D, E, and H.

3 Convention on Biological Diversity (05 June 1992; effective 29 December 1993), 1760 UNTS 79, Article 8g(g).

4 *Lyle Glowka* et al., A Guide to the Convention on Biological Diversity (1994), 45.

5 CBD COP, Decision II/5. Consideration of the Need for and Modalities of a Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms, UN Doc. UNEP/CBD/COP/2/19, p. 49 (1995), operative para. 1 (emphasis added); cf. *Ruth Mackenzie* et al., An Explanatory Guide to the Cartagena Protocol on Biosafety (2003), MN. 46.

6 See Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council on the Transboundary Movement of Genetically Modified Organisms, Explanatory Memorandum (25 June 2002), COM(2002) 85 final – 2002/0046(COD); *Jan Husby*, Definitions of GMO/LMO and Modern Biotechnology, in: Terje Traavik/Li C. Lim (eds.), Biosafety First (2009) 365; *Piet van der Meer* et al., The Status Under EU Law of Organisms Developed Through Novel Genomic Techniques (2021) European Journal of Risk Regulation 1, 15.

7 *Husby* (n. 6), 370–371.

the existing definitions of both terms under the various instruments.[8] A major source of controversy seems to be the contention that the definitions presume that the resulting organisms contain *transgenes*, i.e. genetic information from a different, sexually incompatible species.[9]

Except where stated otherwise, the present study uses the terms LMO and GMO synonymously. When referring to a particular instrument, the term employed by that instrument is used. This is without prejudice to the question of applicability, which will have to be assessed individually for each organism and each instrument, but which is presumed here in some instances to avoid repetition.

B. Types of Damage Potentially Caused by LMOs

The development and use of LMOs are considered to involve risks for various legally protected rights and interests. On the one hand, LMOs may cause damage to the rights and interests of individual persons. These types of damage are usually categorized into three sub-categories: personal injury, property damage and economic loss.

Firstly, *personal injury* denotes bodily or mental injury to a human person or any invasion of a personal right.[10] Such injury may be caused by direct interaction between the LMO and an individual, for instance by (intentional or unintentional) ingestion, or by stinging or biting by insects. This includes the infection of humans with a genetically modified virus.[11] Personal injury may also be suffered as a consequence of human rights violations.

Secondly, *property damage* or *material injury* refers to the destruction or devaluation of material or intellectual property.[12] The scope of this second

8 See chapter 3, sections A.I.1 and A.IV.

9 Cf. *Motoko Araki* et al., Caution Required for Handling Genome Editing Technology, 32 (2014) Trends in Biotechnology 234, 234–235 and the references in chapter 3; see 'transgene', in: *Eleanor Lawrence* (ed.), Henderson's Dictionary of Biology (16th ed. 2016), 595.

10 Cf. 'personal injury', in: *Bryan A. Garner* (ed.), Black's Law Dictionary (11th ed. 2019), 939.

11 *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 76.

12 See *Drew L. Kershen*, Legal Liability Issues in Agricultural Biotechnology, 44 (2004) Crop Science 456, 459–460.

category essentially depends on the scope of protection awarded to such interests by domestic law.[13] Thirdly, *economic loss* refers to a monetary loss, such as lost wages or profits that would have been earned had the undesired event not occurred.[14]

In the context of international environmental law, these types of damage are sometimes referred to as 'traditional damage' because their compensability is generally recognised and established in most jurisdictions.[15] A frequent example of traditional damage caused by LMOs is the contamination of organic or conventionally grown crops with LMOs.[16] Claims for such damage have been brought in many jurisdictions, including the United States, Canada, and the European Union.[17] Notably, contamination may not only originate from genetically modified seeds but also from other applications such as genetically modified insects.[18]

On the other hand, damage caused by LMOs may also take the form of injury caused to *common goods* and *public interests*. This includes damage to the environment, such as to biological diversity, which may be caused by the loss of a certain species or the spread of an invasive species as a consequence of the release of an LMO. Such damage may include the costs of response measures taken to prevent further loss or to restore the loss,

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13 See chapter 6, section D.I.1.

14 Cf. 'economic loss', in: Black's Law Dictionary (n. 10), 649; see *Kershen* (n. 12), 460–461.

15 The notion of 'traditional damage' seems to stem from the development of the Environmental Liability Directive in the then European Communities (now European Union), cf. European Commission, White Paper on Environmental Liability, COM(2000) 66 final (2000), 16–17; Directive 2004/35/CE on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage (21 April 2004), OJ L 143, p. 56 (hereinafter 'EU Environmental Liability Directive'), Preamble, Recitals 11 and 14; see *Armelle Gouritin*, EU Environmental Law, International Environmental Law, and Human Rights Law (2016), 39–40.

16 *Kershen* (n. 12), 456.

17 See *A. B. Endres*, "GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union, 22 (2000) Loyola of Los Angeles International and Comparative Law Review 453; *Kershen* (n. 12); *Stuart J. Smyth/Drew L. Kershen*, Agricultural Biotechnology, 6 (2006) Global Jurist Advances 1; *Bernhard A. Koch/Bjarte Askeland* (eds.), Economic Loss Caused by Genetically Modified Organisms (2008); *Odile J. Lim Tung*, Genetically Modified Organisms and Transboundary Damage, 38 (2013) SAYIL 67, 72–74.

18 *R. Guy Reeves/Martin Phillipson*, Mass Releases of Genetically Modified Insects in Area-Wide Pest Control Programs and Their Impact on Organic Farmers, 9 (2017) Sustainability 59.

or public health costs for medical screening or vaccination. However, it is controversial whether environmental damage is compensable beyond the reimbursement of such *incidental expenses*, i.e. expenses which become necessary as a result of the damage but do not repair the actual damage sustained.[19] Besides, it is also controversial whether adverse effects of LMOs on wider socio-economic considerations, such as cultural, social and spiritual values, food security, agricultural biodiversity and economic competitiveness, can be considered as damage. Usually, a major obstacle to making successful claims for such effects will be the requirement to establish a causal link with the required degree of certainty.[20]

Finally, there are two groups of cases in which the adverse effects described above may materialize in a transboundary setting. In the first scenario, an LMO uncontrolledly spreads in the territory of another state and causes adverse effects there.[21] This includes both situations of an uncontrolled natural spread (either through natural migration of the LMO or when carried by animals, pollen or seed) and situations where an LMO is inadvertently carried across the border by humans (e.g. through contaminated cargo or baggage) and subsequently released.

In the second scenario, an LMO causes adverse effects after being deliberately imported into the receiving state (be it lawfully or unlawfully) and subsequently released into the environment (be it intentionally or unintentionally).[22] This distinction is also relevant to the question of liability and responsibility. In the first scenario, the LMO enters the affected state without the latter's consent. The situation thus resembles the occurrence of transboundary pollution and other forms of environmental interference. In the second group of cases, damage is caused by a series of events involving the state where the LMO originates, the state where the damage occurs, and possibly also other states involved in the transboundary movement of the LMO, making it harder to identify the party (or parties) liable.

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19 See chapter 11, section B.I.

20 See *Gouritin* (n. 15), 157–158. On socio-economic considerations in the Cartagena Protocol, see chapter 3, section A.II.1.e).

21 *Susanne Förster*, Internationale Haftungsregeln für schädliche Folgewirkungen gentechnisch veränderter Organismen (2007), 161.

22 *Ibid.*

C. The Distinction Between 'Responsibility' and 'Liability'

In literature dealing with transboundary damage in international law, a distinction is usually made between 'responsibility' and 'liability'. However, there are major differences in how this distinction is made and, consequently, how both terms are used. According to one school of thought, the terms denote two mutually exclusive concepts, with 'responsibility' meaning the legal consequences of *wrongful* conduct and 'liability' referring to an obligation to remedy damage caused by *lawful* acts.[23] This appears to be in line with the terminology used by the *International Law Commission* (ILC), which has distinguished between '*responsibility* for internationally wrongful acts'[24] and '*liability* for damage resulting from acts not prohibited by international law'.[25]

A different view also understands 'responsibility' as the legal consequences of unlawful conduct (i.e. the breach of a 'primary obligation'), whereas 'liability' largely denotes a legal obligation to make reparation regardless of whether it results from the responsibility for wrongful conduct (as a 'secondary obligation'[26]) or as a separate 'primary' obligation that applies regardless of whether there was a legal wrongdoing.[27] The latter

23 *N.L.J.T. Horbach*, The Confusion About State Responsibility and International Liability, 4 (1991) Leiden J. Int'l L. 47, 52–53; *Julio Barboza*, The Environment, Risk and Liability in International Law (2011), 22–24; *Alexandre Kiss/Dinah Shelton*, Guide to International Environmental Law (2007), 19; *Attila Tanzi*, Liability for Lawful Acts, in: Wolfrum/Peters (ed.), MPEPIL, MN. 2; *Ulrich Beyerlin/Thilo Marauhn*, International Environmental Law (2011), 361.

24 Cf. ILC, Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries (2001), YBILC 2001, vol. II(2), p. 31 (hereinafter 'ARSIWA') (emphasis added).

25 Cf. UNGA, Resolution 32/151. Report of the International Law Commission, UN Doc. A/RES/32/151 (1977) (emphasis added); also see *Robert Q. Quentin-Baxter*, Preliminary Report on International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law, YBILC 1980, Vol. II, Pt. 1, p. 247 (1980), 250–252; *Barboza* (n. 23), 75–81.

26 In this sense ITLOS, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, Advisory Opinion of 01 November 2011, Case No. 17, 2011 ITLOS Rep. 10, para. 66.

27 *L.F.E. Goldie*, Concepts of Strict and Absolute Liability and the Ranking of Liability in Terms of Relative Exposure to Risk, 16 (1985) NYL 175, 180; *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 15; *Johan G. Lammers*, International Responsibility and Liability for Damage Caused by Environmental Interferences, 31 (2001) Environmental Policy and Law 42–50 and 94–105, 42; *Hanqin Xue*, Transboundary Damage in International Law (2003), 75–76; *Alena Douhan*, Liability for Environmental

view finds support in a number of international treaties that use 'liability' to denote obligations to compensate for damage resulting from either lawful activities[28] or wrongful conduct.[29]

Notably, both views accept that international law may also provide for 'liability' in situations where damage has been caused by *lawful* conduct. Such liability, which arises whenever damage results from a certain activity, is usually referred to as 'strict liability' or 'absolute liability'.[30] Thus, it could be assumed that the differences are only of a terminological nature. At the same time, the confusion over the meaning and scope of 'responsi-

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Damage, in: Wolfrum/Peters (ed.), MPEPIL, MN. 11–13; *Barbara Saxler* et al., International Liability for Transboundary Damage Arising from Stratospheric Aerosol Injections, 7 (2015) Law, Innovation and Technology 112, 117.

28 See Vienna Convention on Civil Liability for Nuclear Damage (25 May 1963; effective 12 September 1997), 1063 UNTS 358, as amended by the Protocol of 12 September 1997 (effective 4 October 2003), IAEA Doc. INFCIRC/566 (hereinafter '1997 Vienna Convention on Civil Liability for Nuclear Damage'); International Convention on Civil Liability for Oil Pollution Damage (29 November 1969; effective 19 June 1975), 973 UNTS 3, as amended by the Protocol of 27 November 1992 (effective 30 May 1996), 1956 UNTS 255 (hereinafter '1992 Oil Pollution Convention'); Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty: Liability Arising from Environmental Emergencies (14 June 2005; not yet in force), ATCM Measure 1 (2005) (hereinafter 'Antarctic Liability Annex'); Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64 (hereinafter 'Supplementary Protocol').

29 Cf. Article 91 of the Protocol Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflicts (Protocol I) (08 June 1977; effective 07 December 1978), 1125 UNTS 3, which is titled 'Responsibility' and reads: 'A Party to the conflict which violates the provisions of the Conventions or of this Protocol shall, if the case demands, be *liable* to pay compensation. It shall be *responsible* for all acts committed by persons forming part of its armed forces' (emphasis added); further cf. Article 139(2) of the United Nations Convention on the Law of the Sea (10 December 1982; effective 16 November 1994), 1833 UNTS 3, which reads: '[…] damage caused by the failure of a State Party or international organization to carry out its *responsibility* under this Part shall entail *liability*' (emphasis added; see *Silja Vöneky/Anja Höfelmeier*, Article 139 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017) 968, MN. 9–16), also see Art. 4(4) of Annex III to UNCLOS.

30 *Louise A. de La Fayette*, International Liability for Damage to the Environment, in: Malgosia A. Fitzmaurice/David Ong/Panos Merkouris (eds.), Research Handbook on International Environmental Law (2010) 320, 325–326; see *infra* section E.

bility' and 'liability' may have contributed significantly to the deadlock that the whole issue of accountability for transboundary harm has faced for many years (and perhaps still does).[31]

For the purposes of the present study, it shall suffice to assume that 'responsibility' denotes the consequences arising from unlawful conduct, while 'liability' refers to a legal obligation to rectify damage, which may either result from responsibility or from a legal provision providing for liability independently from legal wrongdoing. In that sense, the present study follows the latter of the aforementioned views.

D. *The 'Polluter-Pays' Principle: State or Operator Liability?*

According to the so-called 'polluter-pays principle', the costs of pollution or environmental damage shall be *internalized*, i.e. allocated to the actor who causes the harm and draws the benefits from the polluting activity.[32] From the perspective of international law, however, it is not entirely clear whether the principle directs liability only to the individual(s) in control of the activity or also to the state under whose jurisdiction the activity is conducted.[33]

States are generally reluctant to accept liability for hazardous conduct carried out by private actors within their jurisdiction. Therefore, international law on liability for environmental damage often refers to *operator liability*, which means the liability of private actors when their hazardous activities or substances cause transboundary harm.[34] As private actors are no subjects of public international law, their liability is usually implemented under national law adopted in accordance with international treaty

31 Cf. *Jutta Brunnée*, Of Sense and Sensibility: Reflections on International Liability Regimes as Tools for Environmental Protection, 53 (2004) ICLQ 351; *Günther Handl*, International Accountability for Transboundary Environmental Harm Revisited: What Role for State Liability?, 37 (2007) Environmental Policy and Law 117.

32 Rio Declaration on Environment and Development (14 June 1992), UN Doc. A/CONF.151/26/Rev.1 (Vol. I) (hereinafter 'Rio Declaration 1992'), Principle 16; see *Priscilla Schwartz*, Principle 16, in: Jorge E. Viñuales (ed.), The Rio Declaration on Environment and Development: A Commentary (2015) 429, 441–442.

33 *Caroline E. Foster*, The ILC Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, 14 (2005) RECIEL 265, 270–275; *Lefeber* (n. 11), 76; *de La Fayette* (n. 30), 329–330.

34 *Xue* (n. 27), 75–76.

obligations and enforced by national judicial and administrative systems.[35] In the context of damage caused by LMOs in a transboundary setting, the relevant international instrument providing for operator liability is the *Nagoya – Kuala Lumpur Supplementary Protocol*.[36] Moreover, the *Biodiversity Compact* is a private law instrument by which biotechnology providers have voluntarily assumed liability for potential biodiversity damage caused by their products.[37] But beyond these instruments, it is questionable whether states are generally required to ensure that operators within their jurisdiction are liable for transboundary harm caused by their activities.[38]

Apart from the operator, accountability for transboundary harm may also be imposed on the so-called *state of origin* (or *source state*), which refers to the state under whose jurisdiction the activity that has caused the damage is carried out. As will be shown below, there now is a large body of conventional[39] and customary[40] international law under which states must take steps to ensure that products of biotechnology do not cause harm to other states and the 'global commons'. In principle, it is undisputed that a state is internationally responsible for transboundary harm that results from a breach of its obligations aimed at preventing such harm.[41] However such breaches are often difficult to establish, mainly because the obligations of prevention are cast as obligations 'of conduct' rather than 'of result', which means that the causation of damage does not necessarily indicate a breach of the obligation to prevent such damage.[42]

Arguably, international responsibility may also result from a failure to implement international obligations to provide for the liability of the respective operators which have caused the damage.[43] As phrased by the *Institut de Droit International*, international responsibility can be also be incurred for a

> *'failure of the State to comply with the obligation to establish and implement civil liability mechanisms under national law, including insurance*

35 Cf. *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 735.
36 Supplementary Protocol (n. 28); see chapter 6.
37 See chapter 7.
38 See chapter 8.
39 See chapter 3.
40 See chapter 4.
41 See chapter 9.
42 See chapter 4, sections C and E.
43 See chapter 9, section A.III.1.

schemes, compensation funds and other remedies and safeguards, as provided for under such regimes'.[44]

Beyond that, however, it is controversial whether the state should also be *liable* for transboundary harm for which it is not *responsible*.[45] According to some authors, the polluter-pays principle could be interpreted extensively to include a residual liability for costs which cannot be imposed on the respective operator.[46]

E. Standards of Liability: Fault-Based, Objective, Strict, and Absolute Liability

Virtually all legal systems recognize that it is 'just' to provide for liability in the case that one person causes injury to another. However, the conditions under which such liability arises vary considerably.[47] In most cases, liability is premised on the injury to be caused by some sort of 'fault', which usually involves a breach of a primary obligation or a duty of care, either by an intentional act or by an act of negligence.[48] This type of liability is commonly referred to as 'tort', 'fault-based', or 'delictual' liability.[49]

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44 Institut de Droit International, Responsibility and Liability Under International Law for Environmental Damage: Resolution Adopted on September 4, 1997, 37 ILM 1474, Article 6(2).

45 In the ILC's parlance, these cases were long referred as 'injurious consequences arising out of acts not prohibited by international law'. This term was later given up in favour of 'liability for loss from transboundary harm arising out of hazardous activities' (and, even later, 'allocation of loss') after the ILC had concluded its work on state responsibility (cf. ARSIWA (n. 24)) and on prevention of transboundary harm, cf. ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148 (hereinafter 'ILC, Articles on Prevention').

46 See *de La Fayette* (n. 30), 329; and see chapter 10.

47 Cf. *Robert Jennings/Arthur Watts*, Oppenheim's International Law (9th ed. 1992), 509, noting that there was 'probably no single basis of international responsibility, applicable in all circumstances, but rather several, the nature of which depends on the particular obligation in question'. Also see *André Tunc* (ed.), International Encyclopedia of Comparative Law, Vol. XI: Torts (1986).

48 *Sanford E. Gaines*, International Principles for Transnational Environmental Liability: Can Developments in Municipal Law Help Break the Impasse?, 30 (1989) Harv. Int'l L. J. 311, 333–335; *Xue* (n. 27), 296; *Kershen* (n. 12), 456–459; *de La Fayette* (n. 30), 325; *Barboza* (n. 23), 24.

49 Cf. *Horbach* (n. 23), 49; *Xue* (n. 27), 295–298; *Giuseppe Palmisano*, Fault, in: Wolfrum/Peters (ed.), MPEPIL, MN. 5; *de La Fayette* (n. 30), 324–325; see 'fault liability', in Black's Law Dictionary (n. 10), 1098. Note that besides negligence,

The requirement to prove intent or culpable negligence on the part of the defendant may create unjust results, in particular where the defendant has engaged in a dangerous activity that, albeit lawful or even deemed socially desirable, exposed the victim to an increased risk of harm.[50] In these situations, harm may arise from the inherent risk involved in the activity even when the defendant acted without intent or culpable negligence, or when such fault would be very difficult to prove for the injured party. In order to achieve a just allocation of the risk incurred by operating hazardous activities,[51] many legal systems have adopted 'strict liability' for such activities.[52] Strict liability denotes liability which is incurred regardless of whether the liable actor acted culpably.[53] Hence, in order to obtain compensation, a plaintiff must only prove a causal relationship between the damage he suffered and the hazardous activity of the defendant.[54] Most international treaties on operator liability for environmental damage provide for strict liability as the relevant standard.[55]

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tort law systems usually also provide for a range of other forms of liability, such as *trespass* and *nuisance*, see *Michael G. Faure/Andri Wibisana*, Liability for Damage Caused by GMOs: An Economic Perspective, 23 (2010) Geo. Int'l Envtl. L. Rev. 1, 10–17; *Kershen* (n. 12), 456–459.

50 *Goldie* (n. 27), 204–213; *de La Fayette* (n. 30), 327; *Alan E. Boyle*, Globalising Environmental Liability: The Interplay of National and International Law, 17 (2005) J. Envt'l L. 3, 13.

51 But see *Lucas Bergkamp*, Liability and Environment (2001), 160–164, arguing that regimes providing for strict liability were 'unnecessary, inefficient and ultimately rather pointless' since they did not contribute to an optimal risk allocation, created over-deterrence, imposed unnecessary costs, and inhibited innovation.

52 Cf. ILC, Survey of Liability Regimes Relevant to the Topic of International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law (International Liability in Case of Loss from Transboundary Harm Arising Out of Hazardous Activities): Prepared by the Secretariat, UN Doc. A/CN.4/543 (2004), paras. 29–112; *Xue* (n. 27), 299–302; *Gaines* (n. 48), 330–333.

53 Cf. 'strict liability', in Black's Law Dictionary (n. 10), 1099.

54 *Horbach* (n. 23), 49; *Xue* (n. 27), 300; *de La Fayette* (n. 30), 326; *Barboza* (n. 23), 25.

55 Note that strict liability is rarely expressly provided for, but usually rather follows from the absence of a requirement of fault, see 1992 Oil Pollution Convention (n. 28), Article III(1); Convention on Third Party Liability in the Field of Nuclear Energy (29 July 1960; effective 01 April 1968), 956 UNTS 251, as amended by the Additional Protocol of 28 January 1964 and the Protocol of 16 November 1982 (effective 7 October 1988), 1519 UNTS 329 (hereinafter 'Paris Convention'), Article III(a); Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal (10 December 1999; not yet in force), UNEP/CHW.5/29, p. 88 (hereinafter 'Basel Protocol on Liability for Hazardous Wastes'), Article IV; Kiev Protocol on Civil

While strict liability does not require an element of fault, the defendant may still rely on a number of extenuating circumstances that 'exonerate' him from liability.[56] Exonerations from strict liability commonly include *force majeure* (i.e. an event that could neither be anticipated nor controlled[57]), intervening acts by third parties,[58] actions by public authorities (called 'act of state' defence),[59] and fault of the injured party (or 'contributory negligence').[60] Liability that allows for no such (or only a few) exonerations is called 'absolute liability'.[61] A prominent example of an international treaty providing for absolute liability is the *Space Liability Convention*.[62]

Notably, the responsibility of states for breaches of international law does usually not require an element of fault or negligence, unless expressly provided for by a particular rule.[63] For instance, breaches of the obligation

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Liability and Compensation for Damage Caused by the Transboundary Effects of Industrial Accidents on Transboundary Waters (21 May 2003; not yet in force), UN Doc. ECE/MP.WAT/11-ECE/CP.TEIA/9 (hereinafter 'Kiev Liability Protocol'), Article IV. Strict liability is expressly required by the Antarctic Liability Annex (n. 28), Article VI(3). For a comprehensive overview of international agreements providing for strict liability, see ILC, Survey of liability regimes (n. 52), paras. 117–181.

56 *De La Fayette* (n. 30), 326; see e.g. 1992 Oil Pollution Convention (n. 28), Articles III(3) and V(2).

57 Cf. 'force majeure', in Black's Law Dictionary (n. 10), 788; see, e.g., Basel Protocol on Liability for Hazardous Wastes (n. 55), Article IV(5).

58 See, e.g., 1992 Oil Pollution Convention (n. 28), Articles III(3); see *Boyle* (n. 50), 13.

59 It is sometimes argued that when damage is caused by a party which has adhered to the pertinent regulations and authorization of the noxious activity, this party should be exempted from liability (so-called 'regulatory compliance defence'), cf. *Bergkamp* (n. 51), 239–258; also see *André Nollkaemper*, Cluster-Litigation in Cases of Transboundary Environmental Harm, in: Michael G. Faure/Ying Song (eds.), China and International Environmental Liability (2008) 11, 26.

60 *De La Fayette* (n. 30), 326.

61 *Goldie* (n. 27); *Horbach* (n. 23), 50; *Barboza* (n. 23), 26; cf. 'absolute liability', in: Black's Law Dictionary (n. 10), 1097.

62 Cf. Convention on International Liability for Damage Caused by Space Objects (29 March 1972; effective 01 September 1972), 961 UNTS 187, Article II, which provides: 'A launching State shall be absolutely liable to pay compensation for the damage caused by its space object on the surface of the earth or to aircraft in flight.' Also see 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 28), Article IV(1), which provides for absolute liability of the operator a of nuclear installations.

63 Cf. ARSIWA (n. 24), Commentary to Article 2, para. 3; *Xue* (n. 27), 295–298; see *Palmisano* (n. 49), MN. 17; chapter 9, section A.III.3.

to prevent significant transboundary harm are assessed against the standard of *due diligence*, which does not rely on whether the responsible state acted negligently but rather on what could reasonably be expected from the state in the individual circumstances.[64] Therefore, the responsibility of states for breaches of international obligations is sometimes characterized as 'objective'.[65] Some authors have referred to the legal consequences of state responsibility as 'liability *ex delicto*' as opposed to 'liability *sine delicto*', by which they refer to liability arising regardless of any breach.[66] However, the more common distinction is made between 'state responsibility' and '(strict) state liability'.[67]

F. Procedural Issues in Enforcing Civil Liability in a Transboundary Context

In typical scenarios of transboundary harm, such as in the *Trail Smelter* and *Pulp Mills* cases, hazardous or noxious activities carried out by private actors under the jurisdiction of one state cause injury to persons situated in the jurisdiction of another state. While public international law tends to view these situations exclusively from the perspective of disputes between sovereign states, in many cases the victims of such harm may first attempt to obtain compensation through litigation against the (mostly) private actor that has actually caused the damage.[68] This involves questions relating to the choice of forum, applicable law, and recognition and enforcement of judgments.

Depending on the applicable national law, claims may be brought either in the courts of the state where the damage is caused, where it materializes, or where the defendant is domiciled.[69] In most continental law systems,

64 See chapter 4, section C.

65 Cf. *Barboza* (n. 23), 24–25; *James Crawford*, State Responsibility: The General Part (2013), 60–62.

66 Cf. *Lefeber* (n. 27), 47–53; *Barboza* (n. 23), 25–26.

67 See e.g. *Alan E. Boyle*, State Responsibility and International Liability for Injurious Consequences of Acts Not Prohibited by International Law: A Necessary Distinction?, 39 (1990) ICLQ 1; *Horbach* (n. 23); *Brunnée* (n. 31); *Kiss/Shelton* (n. 23), 19; see *supra* section C.

68 *Nollkaemper* (n. 59), 14. Private victims of transboundary harm may even be required to first exhaust any available local remedies, see chapter 9, section C.II.

69 Cf. *Boyle* (n. 50), 11; *Burkhardt Hess*, International Civil Litigation, in: Wolfrum/Peters (ed.), MPEPIL, MN. 25–26; *Sufian Jusoh*, Harmonisation of Liability Rules in Transboundary Movement of Biotechnology Crops (2012), 78–87; see Kiev Liability Protocol (n. 55), Article 13.

the latter is the standard case.[70] For instance, in the European Union, the so-called *Brussels I Regulation* provides that 'persons domiciled in a Member State shall, whatever their nationality, be sued in the courts of that Member State'.[71] Alternatively, these persons may also be sued in another Member State 'in matters relating to tort, delict or quasi-delict, in the courts for the place where the harmful event occurred or may occur'.[72] According to the *Court of Justice of the European Union*, this means that the 'plaintiff has an option to commence proceedings either at the place where the damage occurred or the place of the event giving rise to it'.[73]

Once a court has established that it has jurisdiction to adjudicate a case of transboundary harm, the question arises as to which law applies to the dispute. This is usually governed by the laws of the forum, i.e. the state in which the claim is adjudicated. Laws applied to cases of transboundary damage include the *lex fori* (i.e. the law of the forum), *lex loci delicti* (i.e. the law of the place where the tort was committed), *lex domicilii* (i.e. the law of the domicile either of the defendant or the plaintiff),[74] or the law which is most favourable to the plaintiff.[75] In the European Union, the law applicable to non-contractual obligations is determined by the *Rome II Regulation*.[76] Unless the parties to a dispute have agreed on a law of their

70 *Lucas Bergkamp*, Liability and Redress: Existing Legal Solutions for Traditional Damage, in: CropLife International (ed.), Compilation of Expert Papers Concerning Liability and Redress and Living Modified Organisms (2004) 21, 23–24; *Hess* (n. 69), MN. 25–26.

71 Regulation (EU) No 1215/2012 on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (12 December 2012), OJ L 351, p. 1 (hereinafter 'Brussels Ia Regulation'), Article 4(1); also see Convention on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (30 October 2007; effective 01 October 2010), 2658 UNTS 197, which extends the Brussels regime to Iceland, Switzerland, Norway, and Denmark; also see *Thomas Kadner Graziano/Matthias Erhardt*, Cross-Broder Damage Caused by Genetically Modified Organisms: Jurisdiction and Applicable Law, in: Bernhard A. Koch (ed.), Damage Caused by Genetically Modified Organisms (2010) 784, MN. 15–21.

72 Brussels Ia Regulation (n. 71), Article 7(2).

73 CJEU, Bier v. Mines de Potasse d'Alsace, Judgment of 30 November 1976, Case 21/76, 1976 ECR 1735, para. 19.

74 See *Aaron X. Fellmeth/Maurice Horwitz*, Guide to Latin in International Law (2011), 167–168.

75 *Bergkamp* (n. 70), 27–28; *Boyle* (n. 50), 11.

76 Regulation (EC) No 864/2007 on the Law Applicable to Non-Contractual Obligations (11 July 2007), OJ L 199, p. 40 (hereinafter 'Rome II Regulation').

choice,[77] transboundary damage caused by LMOs may be governed either by the rules relating to product liability,[78] environmental damage,[79] or obligations arising out of a tort or delict.[80] In most cases, the applicable law will be that of the country where the damage occurred.[81]

From a choice of forum perspective, it seems most convenient for victims to litigate against a foreign defendant in their 'own' courts, or in a jurisdiction where there is the greatest likelihood of success.[82] However, in common law systems, in particular in the United States, the concept of *forum non conveniens*[83] may create obstacles to bringing claims for an injury suffered abroad.[84] According to this doctrine, a court has the discretion to refuse jurisdiction and dismiss a case if it finds that the case may be heard more appropriately in another court.[85] But even where a court finds that it has jurisdiction, the benefits of litigating in the most convenient forum may be offset by the problems involved with enforcing a judgment obtained there, which becomes relevant when the defendant (or its assets) are not situated in the state where the judgment is obtained.[86]

Under general international law, states are under no obligation to recognize and/or enforce foreign judgments.[87] Although many countries recognize and enforce foreign judgments under some conditions, differences are vast.[88] In the European Union, the aforementioned *Brussels I Regulation* provides that, subject to certain conditions, a judgment given in a Member State shall be recognized and enforceable in all other Member States without any special procedure of recognition or declaration of enforce-

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77 *Ibid.*, Article 14.
78 *Ibid.*, Article 5.
79 *Ibid.*, Article 7.
80 *Ibid.*, Article 4.
81 See *Kadner Graziano/Erhardt* (n. 71), MN. 48–110; *Jusoh* (n. 69), 78–94; *Albert A. Ehrenzweig*, Products Liability in the Conflict of Laws–Toward a Theory of Enterprise Liability Under Foreseeable and Insurable Laws, 69 (1960) Yale L.J. 794; also see Convention on the Law Applicable to Products Liability (02 October 1973; effective 01 October 1977), 1056 UNTS 187.
82 *Boyle* (n. 50), 11; *Nollkaemper* (n. 59), 16.
83 See 'Forum non conveniens', in: *Fellmeth/Horwitz* (n. 74), 112.
84 *Boyle* (n. 50), 11.
85 See generally *Ronald A. Brand*, Forum Non Conveniens, in: Wolfrum/Peters (ed.), MPEPIL.
86 *Nollkaemper* (n. 59), 16.
87 *Jan Michaels*, Recognition and Enforcement of Foreign Judgments, in: Wolfrum/Peters (ed.), MPEPIL, MN. 11.
88 *Ibid.*; see *Jusoh* (n. 69), 95–98.

ability being required.[89] Apart from the European Union and the wider *European Economic Area*,[90] comparable regimes exist on regional levels,[91] but attempts to elaborate a global treaty have so far not been successful.[92] Some international agreements on civil operator liability contain special rules on jurisdiction, applicable law, and the recognition and enforcement of judgments.[93] But in the absence of such harmonized rules, the victim will often be required to bring his claim before the courts of the state where the defendant resides and/or where the damage has been caused. This may incur problems relating to equal access and non-discriminatory treatment of foreign plaintiffs. Both the international community[94] and the ILC[95] have repeatedly recognized that victims of transboundary damage should have a right to non-discriminatory access to justice in the state of origin, which has led to the assumption that it 'already reflects existing international law'.[96]

89 Brussels Ia Regulation (n. 71), Articles 36 and 39.
90 See *supra* n. 71.
91 See, e.g., Inter-American Convention on Extraterritorial Validity of Foreign Judgments and Arbitral Awards (08 May 1979; effective 14 June 1980), 1439 UNTS 87.
92 See *Michaels* (n. 87), MN. 15.
93 Cf. e.g. 1992 Oil Pollution Convention (n. 28), Article X; Convention on Civil Liability for Damage Caused During Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels (10 October 1989; not yet in force), UN Doc. ECE/TRANS/79, Article 20; Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment (21 June 1993; not yet in force), 32 ILM 1228, XXIII; International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea (03 May 1996; not yet in force), 25 ILM 1406, as amended by the Protocol of 30 April 2010, IMO Doc. LEG/CONF.17/DC/1 (hereinafter 'HNS Convention'), Article 40; 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 28), Article XII; Basel Protocol on Liability for Hazardous Wastes (n. 55), Article 21; see *Lammers* (n. 27), 104–105; *Worku D. Yifru* et al., Review of Issues, Instruments and Practices Relevant to Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms (2012), 20. On the issue generally, see *Jusoh* (n. 69), 78–99.
94 UNGA, World Charter for Nature, UN Doc. A/RES/37/7, Annex (1982), Principle 23; Rio Declaration 1992 (n. 32), Principle 10; Convention on the Law of the Non-Navigational Uses of International Watercourses (21 May 1997; effective 17 August 2014), UN Doc. A/RES/51/229, Article 32.
95 ILC, Articles on Prevention (n. 45), Article 15 and commentary thereto, para. 3; ILC, Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, with Commentaries (2006), YBILC 2006, vol. II(2), p. 56 (hereinafter 'ILC, Allocation of Loss Principles'), Principle 6 and commentary thereto, para. 3.
96 *Boyle* (n. 50), 9; similarly *Nollkaemper* (n. 59), 16; see chapter 8, section F.

G. Civil Liability and 'Administrative Liability' for Damage to the Environment

Most existing international agreements on operator liability for environmental damage seek to harmonize the rules on *civil liability*, which denotes the obligation of the operator of a hazardous activity to make reparation for the damage caused by this activity to the health, property or income of other persons.[97] In most cases, civil liability is governed by rules of national law, which may be harmonized by international treaties on civil liability,[98] and implemented by domestic courts in proceedings initiated by the person who suffered an injury.[99] Depending on the circumstances, the available remedy is either monetary compensation or injunctive relief.[100]

While this approach is appropriate to address 'traditional damage', such as to persons or property, it often faces challenges in adequately accommodating damage to common goods, such as biological diversity. In these cases, there will often be no plaintiff who can establish a legal interest in the subject matter, which is required to have *standing* to make claims in many jurisdictions.[101] Moreover, it will often be difficult or even impossible

97 *Sands* et al. (n. 35), 735.

98 For treaties providing for the harmonization of civil liability, see, e.g., 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 28); Paris Convention (n. 55); Convention on Civil Liability for Oil Pollution Damage Resulting from Exploration for and Exploitation of Seabed Mineral Resources (01 May 1977; not yet in force), 16 ILM 1451; HNS Convention (n. 93); Basel Protocol on Liability for Hazardous Wastes (n. 55); International Convention on Civil Liability for Bunker Oil Pollution Damage (23 March 2001; effective 21 November 2008), IMO Doc. LEG/CONF.12/19.

99 *Sands* et al. (n. 35), 735; *Gurdial S. Nijar*, Civil Liability in the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 111, 111.

100 *Nijar* (n. 99), 111.

101 See chapter 9, section C.I; also see *Gurdial S. Nijar*, The Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges, 13 (2013) Int. Environ. Agreements 271, 274; *Alejandro Lago Candeira*, Administrative Approach to Liability: Its Origin, Negotiation and Outcome, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 92, 98; and *Lefeber* (n. 11), 44–45, who argues that the administrative approach could also be used for other activities and/or types of damages, e.g. damage to biological diversity caused by the transboundary movement of invasive alien species, or public health costs resulting from unexpected negative effects of the introduction of medicines.

to express environmental damage in financial terms.[102] This significantly limits the use of civil liability for addressing environmental damage. Many international civil liability treaties even exclude compensation for damage to the environment *per se* by providing that compensation in such cases shall be limited to the costs of reinstatement measures actually undertaken.[103]

To address environmental damage that cannot be reasonably compensated by financial payments, a number of more recent instruments have adopted a so-called 'administrative approach' to environmental liability.[104] *Administrative liability* is characterized by the fact that instead of paying monetary compensation to injured individuals, the operator is required to actively take 'response measures' to mitigate and remediate the damage.[105] Depending on the type of damage, this can result in measures to mitigate the spread of damage, such as containing an escaped LMO, measures to clean up contaminated parts of the environment or measures to reinstate the impaired environment to its unharmed state.[106] If the operator does not implement the necessary response measures itself, it must reimburse the expenses incurred by other operators or states in taking them on its behalf.[107] The approach is termed 'administrative' liability because the obligations of the liable operator are not determined through civil litigation but by an administrative authority empowered to assess the damage and to determine the measures the operator must take.[108]

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102 Cf. *Joachim Wolf*, Gibt es im Völkerrecht einen einheitlichen Schadensbegriff?, 49 (1989) ZaöRV 403, 429–432; *Lefeber* (n. 27), 136–138; *Bergkamp* (n. 51), 332–338; see chapter 11, section B.II.

103 See, e.g., 1992 Oil Pollution Convention (n. 28), Article 1(6); 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 28), Article 1(1)(k); Basel Protocol on Liability for Hazardous Wastes (n. 55), Article II(2)(c)(iv); see chapter 11, section B.I.1.

104 Kiev Liability Protocol (n. 55), Article 6; EU Environmental Liability Directive (n. 15), Article 6; Antarctic Liability Annex (n. 28), Article V; ILC, Allocation of Loss Principles (n. 95), Principle 5(b).

105 *Lago Candeira* (n. 101), 96–99.

106 Supplementary Protocol (n. 28), Article 2(2)(d); see chapter 6, section C.I.

107 EU Environmental Liability Directive (n. 15), Article 8; Antarctic Liability Annex (n. 28), Article VI; Supplementary Protocol (n. 28), Article 5(5).

108 See *G. Winter* et al., Weighing up the EC Environmental Liability Directive, 20 (2008) J. Envt'l L. 163, 167–171; *Akiho Shibata*, A New Dimension in International Environmental Liability Regimes: A Prelude to the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 17, 35–38; also see *Valerie Fogleman*, Enforcing the Environmen-

At the international level, the administrative approach has been implemented – albeit in varying forms – in the 2003 *Kiev Protocol on Civil Liability*,[109] the 2004 *Environmental Liability Directive* of the European Union,[110] the 2005 *Antarctic Liability Annex*[111] and the ILC's *Articles on Allocation of Loss* of 2006.[112] In the context of the present study, the *Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress* primarily provides for administrative liability.[113]

The administrative approach is particularly valuable for dealing with damage to global commons (such as biodiversity), as such damage often does not (only) affect the legally protected rights and interests of individuals.[114] In these cases, there will be no plaintiff who can establish a legal interest in the subject matter, which is required in many jurisdictions in order to have *legal standing*.[115] Hence, a key merit of the administrative approach is that it allows addressing so-called 'orphan damage' that would otherwise remain unaddressed.[116] Moreover, by providing for tangible action rather than financial compensation, it seeks to ensure that environmental damage is actually redressed and not merely written off.[117]

By empowering the administrative organs of a state to pursue the liability of private operators for damage they have caused to common goods, administrative liability thus fills a significant *lacuna* left open by conventional civil liability regimes. Furthermore, administrative liability is generally *strict* which, as shown above, means it does not depend on whether the operator caused the damage culpably (and whether such fault

tal Liability Directive: Duties, Powers and Self-Executing Provisions, 4 (2006) Environmental Liability 127, 127–129.

109 Kiev Liability Protocol (n. 55), Article 6.

110 EU Environmental Liability Directive (n. 15), Article 6; see *Edward H. P. Brans/ Dorith H. Dongelmans*, The Supplementary Protocol and the EU Environmental Liability Directive, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 180.

111 Antarctic Liability Annex (n. 28), Article 5.

112 ILC, Allocation of Loss Principles (n. 95), Article 5; see chapter 8, section C.

113 Supplementary Protocol (n. 28), Article 5; see chapter 6, section C.

114 See chapter 4, section B.II.3.

115 See chapter 9, section C.I; also see *Nijar* (n. 101), 274; *Lago Candeira* (n. 101), 98; and *Lefeber* (n. 11), 44–45, who argues that the administrative approach could also be used for other activities and/or types of damages, e.g. damage to biological diversity caused by the transboundary movement of invasive alien species, or public health costs resulting from unexpected negative effects of the introduction of medicines.

116 *Lago Candeira* (n. 101), 98.

117 Cf. *ibid.*

can be proven), but rather attaches to the mere fact that a certain activity – or in the case of the *Supplementary Protocol*, a certain LMO – led to the occurrence of damage to the environment.[118] In this sense, the administrative approach also contributes to a coherent implementation of the 'polluter pays' principle.[119] Furthermore, the administrative approach has a preventive dimension, because it provides for response measures already when there is an immediate threat of damage even though such damage has not yet materialized.[120]

In sum, civil liability and administrative liability are two complementary approaches that, taken together, aim to ensure that no form of damage remains unredressed. Personal injury, property damage, and economic loss – so-called 'traditional damage' – can be redressed through civil liability by ensuring that the plaintiffs can effectively hold the operator liable through domestic or international adjudication. Environmental damage, such as adverse effects on biodiversity, can be more adequately redressed through administrative liability, i.e. by ensuring that clean-up and remediation measures are taken either by the responsible operator or by other actors who are then reimbursed by the operator.

H. Summary and Outlook

This chapter has elucidated fundamental terms and concepts in the area of international law on responsibility and liability relevant to transboundary harm caused by the development and use of biotechnology. Such harm may take the form of *traditional damage* as well as *environmental damage*. 'Traditional damage' refers to types of damage recognized in most national jurisdictions and international instruments on liability, namely *personal injury*, *property damage*, and *economic loss*. Damage may also be caused to common goods, such as the environment. It is widely accepted that expenses incurred to mitigate environmental damage are subject to liability. However, it is controversial whether permanent, unrestorable damage to the environment *per se* is subject to financial compensation.

In the present context of transboundary harm caused by products of biotechnology, the aforementioned types of harm can occur in various scenarios. An important distinction must be made between harm that

118 Cf. *Nijar* (n. 101), 274; *Lago Candeira* (n. 101), 98–99.
119 *Lim Tung* (n. 17), 76.
120 *Lago Candeira* (n. 101), 98.

involves an uncontrolled movement of an organism from one state into another, and harm that occurs after an organism was deliberately imported into the receiving state and subsequently released there. The former scenario may arise, for instance, when self-spreading GMOs (such as engineered gene drives) spread beyond their intended target range.

The terms *responsibility* and *liability* are used inconsistently in international law dealing with the consequences of transboundary harm. The present study will refer to 'responsibility' as the legal consequences that arise from unlawful conduct. 'Liability' means an obligation to rectify damage, regardless of whether this obligation results from responsibility or a legal rule providing for liability regardless of any wrongdoing.

From a perspective of international law, liability for transboundary harm may be placed either on the *operator* or the *state*. '*Operator liability*' means the liability of the person or entity whose hazardous activity or substance causes harm. Since private operators are no subjects of public international law, operator liability must usually be implemented and enforced by states through their domestic legal systems. However, holding private operators liable for transboundary harm is often difficult because states bear no general obligation to recognize and enforce judgments rendered by the courts of other states.

Against this background, many international instruments on environmental liability seek to harmonize the rules of 'civil liability', which means a legal obligation of the operator to pay monetary compensation for the damage caused by its activity. In contrast, 'administrative liability' refers to measures imposed by an administrative authority of a state requiring the operator to take 'response measures', which means tangible action to contain, mitigate and remediate the damage. Although there are vast differences in terminology, most liability regimes distinguish between 'fault-based liability', which attaches to some form of wrongful or negligent conduct, and 'strict liability', which arises regardless of such fault and is often imposed because of the inherent hazardousness of an activity or substance.

'*State responsibility*' refers to the answerability of a state for conduct that constitutes a breach of international law. Such breaches may result from a failure to implement and enforce rules of international law relating to the prevention of transboundary harm, which are discussed in the second part of this study. Furthermore, state responsibility may follow from a failure to implement and enforce international law relating to the provision of operator liability, assessed in the third part. The requirements and consequences of responsibility in case of a breach will be discussed in the fourth part, which will also address the controversial question of whether states incur '(strict) state liability' for transboundary harm in cases where they do not bear 'state responsibility' for such harm.

Part Two:
Prevention of Transboundary Harm

Chapter 3: The Regulation of Biotechnology in International Law

This chapter analyses the international regulation of biotechnology and genetically modified organisms at the global level. The principal instrument in this context is the *Cartagena Protocol on Biosafety*, which has been developed under the *Convention on Biological Diversity* (A.). Although the Protocol's provisions are much more detailed, the pertinent rules contained in the Convention have not become irrelevant due to its broader, near-universal membership (B.).

Besides, a number of other international agreements also contain relevant obligations in the context of regulating risks resulting from the application of biotechnology. In particular, international trade law under the auspices of the *World Trade Organization* might considerably limit the liberty of states to restrict international trade of LMOs (C.). The *International Plant Protection Convention* and the measures adopted within its framework seek to prevent the spread of plant pests, which under certain circumstances may include LMOs (D.). The *World Organisation for Animal Health* serves a similar objective with respect to animal diseases (E.). The *Codex Alimentarius* is a set of standards on food safety and also addresses foods obtained from modern biotechnology (F.). The *United Nations Convention on the Law of the Sea* is relevant with regard to the protection of the high seas beyond the limits of national jurisdiction (G.). International regulations on the transport of hazardous goods and substances also address safeguarding measures for LMOs (H.). When a biotechnology product causes a transmissible disease in humans, international health law becomes relevant (I.). Finally, certain applications of biotechnology may also fall within the scope of the *Biological Weapons Convention* and rules of humanitarian international law (J.).

The instruments analysed in the present chapter primarily address the *prevention of damage*, but they are also relevant for questions relating to *liability for damage* in a number of aspects. First and foremost, the Cartagena Protocol prejudices the scope of application of the *Supplementary Protocol on Redress and Liability*, which was developed to complement the Cartagena Protocol with rules on operator liability and which is analysed further below.[1] Moreover, the Cartagena Protocol, as well as the other relevant instruments, create binding legal obligations for their respective parties, breaches of which may give rise to the accountability of these states under the law of state responsibility.[2]

A. *The Cartagena Protocol on Biosafety*

The *Cartagena Protocol on Biosafety* of 2000[3] is the only global multilateral agreement specifically dealing with molecular biotechnology.[4] It was negotiated within the framework of Article 19(3) of the *Convention on Biological Diversity* of 1992 (CBD),[5] which committed its parties to consider the need for, and modalities of, a protocol relating to the products of modern biotechnology. The Protocol entered into force in 2003 and has 173 parties including the European Union.[6] However, a number of states that play key roles in biotechnology have not ratified the Protocol, including Argentina, Australia, Canada, Israel, Singapore, and the United States.[7]

1 See chapter 6.

2 See chapter 9.

3 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 January 2000; effective 11 September 2003), 2226 UNTS 208 (hereinafter 'Cartagena Protocol' or 'CP').

4 For general discussions of the Cartagena Protocol, see *Riccardo Pavoni*, Assessing and Managing Biotechnology Risk Under the Cartagena Protocol on Biosafety, 10 (2000) Italian YBIL 113; *Robert Falkner*, Regulating Biotech Trade: The Cartagena Protocol on Biosafety, 76 (2000) International Affairs 299; *Barbara Eggers/Ruth Mackenzie*, The Cartagena Protocol on Biosafety, 3 (2000) J. Int. Econ. L. 525; *Terence P. Stewart/David S. Johanson*, A Nexus of Trade and the Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization, 14 (2003) Colorado Journal of International Environmental Law and Policy 1; *Ruth Mackenzie* et al., An Explanatory Guide to the Cartagena Protocol on Biosafety (2003); *Catherine Redgwell*, Biotechnology, Biodiversity and International Law, 58 (2005) Current Legal Problems 543; *Marie-Claire Cordonier Segger/Frederic Perron-Welch* et al. (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013).

5 Convention on Biological Diversity (05 June 1992; effective 29 December 1993), 1760 UNTS 79 (hereinafter 'CBD').

6 UN OLA, Status of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, United Nations Treaty Collection, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-a&chapter=27&clang=_en (last accessed 28 May 2022).

7 For a ranking of 54 countries based on innovation potential in biotechnology, see *Jeremy Abbate* et al., Scientific American Worldview: A Global Biotechnology

Pursuant to its Article 1, the objective of the Protocol is

> '*to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology*'.

The subject matter regulated by the Cartagena Protocol is 'living modified organisms resulting from modern biotechnology'. The recent advances in modern biotechnology set out in the first chapter, particularly genome editing techniques and engineered gene drives, raise questions as to the exact scope of the Protocol (I.). Substantively, most of the Protocol's provisions concern the 'transboundary movement' of LMOs, which denotes the importation, but also unintentional movements of LMOs from one party's territory into that of another. In addition, some of the Cartagena Protocol's provisions also apply to domestic uses (II.).

I. Scope

According to its Article 4, the Cartagena Protocol applies to

> '*the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health*'.

This provision can be divided into three separate elements: Firstly, the *subject matter* covered by the Protocol is 'living modified organisms' (LMOs), which is a technical term defined in Article 3 of the Protocol (1.). Secondly, Article 4 CP refers to LMOs 'that may have adverse effects', which raises the question of whether the Cartagena Protocol only applies to hazardous LMOs (2.). Thirdly, Article 4 specifies the *activities* to which the Cartagena Protocol applies, namely 'transboundary movement, transit, handling, and use' of LMOs (3.). Moreover, under Article 5 CP the 'trans-

Perspective (2016), 26–28. For an overview of the commercial use of GM crops, see International Service for the Acquisition of Agri-biotech Applications, Global Status of Commercialized Biotech/GM Crops in 2019, ISAAA Brief 55 (2019). Data on international trade in genetically modified organisms and products thereof seem not to be available, but see *Vargas M. Xanat* et al., International Trade of GMO-Related Agricultural Products, 52 (2018) Quality & Quantity 565.

boundary movement of LMOs which are pharmaceuticals for humans' is exempted from the scope of the Cartagena Protocol (4.).

1. Subject Matter: Living Modified Organisms Obtained Through Modern Biotechnology

The Cartagena Protocol applies to 'living modified organisms', which is defined in Article 3(g) as

> *'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'.*

As noted earlier, the Cartagena Protocol uses this term instead of the more common phrases 'genetically modified organism' (GMO) and 'genetically engineered organism', which are used in most national and regional biosafety regimes.[8] Most of these regimes were developed in the light of conventional techniques of genetic engineering, which commonly involve the insertion of genetic material from another species. However, as set out in the first chapter, more recently developed genome editing techniques allow to genetically modify an organism with much higher precision than before and, in some instances, without permanently introducing exogenous genetic material.[9]

Against this background, there have been fierce debates about whether organisms modified with these new techniques fall within the scope of the existing regulatory frameworks for GMOs. Currently, genome-edited organisms are regulated like conventional GMOs in some jurisdictions but are exempt from regulation in others.[10] It is also controversial whether

8 See chapter 2, section A; also see *Markus Böckenförde*, Biological Safety, in: Wolfrum/Peters (ed.), MPEPIL, MN. 6.

9 See chapter 1, section B.

10 See *Maria Lusser/Howard V. Davies*, Comparative Regulatory Approaches for Groups of New Plant Breeding Techniques, 30 (2013) New Biotechnology 437; *Dennis Eriksson* et al., A Comparison of the EU Regulatory Approach to Directed Mutagenesis with that of Other Jurisdictions, Consequences for International Trade and Potential Steps Forward, 222 (2019) New Phytologist 1673; *Steffi Friedrichs* et al., An Overview of Regulatory Approaches to Genome Editing in Agriculture, 3 (2019) Biotechnology Research and Innovation 208; *Hans-Georg Dederer/David Hamburger* (eds.), Regulation of Genome Editing in Plant Biotechnology (2019).

genome-edited organisms fall within the scope of the Cartagena Protocol.[11]

According to the aforementioned definition in Article 3(g), the Cartagena Protocol applies to any living organism (a)) the genetic material (b)) of which has a novel combination (c)) that was obtained through the use of modern biotechnology (d)). It is therefore submitted that most genome editing techniques, as well as all current techniques involving engineered gene drives, fall within the scope of the Cartagena Protocol (e)).

a) Living Organism

The term 'living organism' is defined in Article 3(h) CP as

> '*any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids*'.

This definition takes a central role in determining the meaning of a 'living modified organism'. When both definitions are read together, the Protocol applies to any biological entity capable of transferring or replicating genetic material (i.e. a *living organism*) that possesses a novel combination of genetic material obtained through the use of modern biotechnology (i.e. a living *modified* organism). The term 'biological entity' is unspecific and may refer to any being.[12] The decisive criterion is whether such an entity is 'capable of transferring or replicating genetic material'.[13] This excludes, most importantly, products derived from LMOs which are no longer

11 Cf. AHTEG on Synthetic Biology, Report of the Ad Hoc Technical Expert Group on Synthetic Biology: Montreal, Canada, 4–7 June 2019, UN Doc. CBD/SYNBIO/AHTEG/2019/1/3 (2019), para. 17; *Felicity Keiper/Ana Atanassova*, Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols, 8 (2020) Front. Bioeng. & Biotechnol. 310, 16; see *Motoko Araki* et al., Caution Required for Handling Genome Editing Technology, 32 (2014) Trends in Biotechnology 234, 234–235; *Sam O. Callebaut*, New Developments in Modern Biotechnology: A Survey and Analysis of the Regulatory Status of Plants Produced Through New Breeding Techniques, Master Thesis (2015), 46–50; *Eva Sirinathsinghji*, Why Genome Edited Organisms Are Not Excluded from the Cartagena Protocol on Biosafety, TWN Biosafety Briefing (2020).

12 Cf. 'entity', in: *James Murray* et al., Oxford English Dictionary, Online Edition, available at: http://www.oed.com/ (last accessed 28 May 2022).

13 Cf. *Piet van der Meer*, Definitions, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 281, 284.

able to transfer or replicate genetic material.[14] Viruses and viroids, which by themselves cannot actively replicate genetic material,[15] are expressly included in the definition.[16]

b) Genetic Material

The term 'genetic material' is of particular relevance for the scope of the Protocol, as it is used in the definitions of both a *living organism* (which is characterized by its capability to transfer or replicate genetic material) and a *living modified organism* (which possesses a novel combination of genetic material). While the Protocol itself does define this term, a definition of 'genetic material' is included in Article 2 CBD. Although the Cartagena Protocol does not expressly incorporate the definitions contained in the CBD,[17] they can still be referred to as part of the 'relevant rules of interna-

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14 *Eggers/Mackenzie* (n. 4), 529; *Sean D. Murphy*, Biotechnology and International Law, 42 (2001) Harv. Int'l L. J. 47, 77; *Jan Husby*, Definitions of GMO/LMO and Modern Biotechnology, in: Terje Traavik/Li C. Lim (eds.), Biosafety First (2009) 365, 370–371. The Cartagena Protocol refers to LMOs and 'products thereof', see Article 23(3)(c) CP. The inclusion of 'products thereof' into the scope of the Cartagena Protocol was highly contentious during the negotiations, see *Helen Marquard*, Scope, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 289, 297–298. Note that three of the Protocol's provisions on risk assessment, namely Article 23(3)(c), Annex I(i) and Annex III(5), explicitly address LMOs and products thereof, which are defined as 'processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology', see *Mackenzie* et al., IUCN Guide (n. 4), MN. 85. During the negotiations of the Supplementary Protocol, the inclusion of 'products thereof' was discussed again, see chapter 6, section B.1.2.

15 *Bruce Albers* et al., Molecular Biology of the Cell (6th ed. 2015), 18.

16 *Mackenzie* et al., IUCN Guide (n. 4), MN. 204.

17 Most protocols to framework instruments expressly provide that the definitions contained in the framework instrument also apply for the purposes of the respective protocol, see, e.g., Article 2(1) Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64; Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (29 October 2010; effective 12 October 2014), UN Doc. UNEP/CBD/COP/DEC/X/1; Kyoto Protocol to the United Nations Framework Convention on Climate Change (11 December 1997; effective 16 February 2005), 2303 UNTS 162.

tional law applicable in the relations between the parties' in the sense of Article 31(3)(c) of the *Vienna Convention on the Law of Treaties* (VCLT).[18]

According to the definition in Article 2 CBD, 'genetic material' means

> '*any material of plant, animal, microbial or other origin containing functional units of heredity*'.

The central element of this definition is 'functional units of heredity', which is defined neither in the Cartagena Protocol nor elsewhere in the international biodiversity regime.[19] It also seems not to be an established term in scientific literature.

In biology, the term 'heredity' denotes the transmission of genetically based characteristics from parents to offspring.[20] The basic unit of heredity is the gene, which is a sequence of nucleic acid that exerts its influence on the organism's form and function by encoding and directing the synthesis of a protein or certain forms of RNA.[21]

The definition requires that these units of heredity must be 'functional'. This appears to be introduced to distinguish genes from non-coding DNA sequences (also called 'junk DNA'), which were, at the time when the CBD was adopted, believed to have no specific function.[22] However, it is now assumed that non-coding DNA contains genetic information essential for important biological functions such as gene expression, replication and transmission.[23] For this reason, there are currently no units of heredity

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18 Vienna Convention on the Law of Treaties (23 May 1969; effective 27 January 1980), 1155 UNTS 331 (hereinafter 'VCLT'); cf. *Oliver Dörr*, Article 31 VCLT, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 95–96; see *Mackenzie* et al., IUCN Guide (n. 4), MN. 198.

19 The term resembles the notion of 'heritable material' used in the legislation of the European Union on Genetically Modified Organisms. On the relationship between the Cartagena Protocol and EU legislation, see *infra* section A.IV.

20 Cf. 'heredity', in: *Eleanor Lawrence* (ed.), Henderson's Dictionary of Biology (16th ed. 2016), 256; similarly *B. Fedder*, Marine Genetic Resources, Access and Benefit Sharing (2013), 35; *Albers* et al. (n. 15), 2.

21 Cf. 'gene', in: Henderson's Dictionary of Biology (n. 20), 224; *Albers* et al. (n. 15), 182; see *Fedder* (n. 20), 35.

22 *Morten W. Tvedt/Peter J. Schei*, "Genetic Resources" in the CBD: The Wording, the Past, the Present and the Future, UN Doc. UNEP/CBD/WG-ABS/9/INF/1, Annex (2010); cf. *L. E. Orgel/F. H. C. Crick*, Selfish DNA, 284 (1980) Nature 604; but see *James A. Shapiro*, Revisiting the Central Dogma in the 21st Century, 1178 (2009) Annals of the New York Academy of Sciences 6, 12.

23 *James A. Shapiro/Richard* von *Sternberg*, Why Repetitive DNA Is Essential to Genome Function, 80 (2005) Biological Reviews of the Cambridge Philosophical

(or DNA sequences) that can be characterized with scientific certainty as 'non-functional'.[24] Hence, 'functional units of heredity' denote any kind of genetic information stored in nucleic acid.[25] Consequently, 'genetic material' encompasses any biological material that contains nucleic acid, including living cells in any appearance and parts of organisms, as well as isolated DNA or RNA in the form of chromosomes, plasmids or parts thereof.[26]

c) 'Novel Combination' of Genetic Material

The Cartagena Protocol covers living organisms that possess a 'novel combination of genetic material'. Again, the term 'novel combination' is not defined by the Protocol. It is questionable whether it covers any change to the genetic material or whether the change must be of a certain quality. In particular, it could be argued that the term 'novel combination' refers to 'recombinant DNA', which is generally understood as DNA that has been modified *in vitro* to introduce foreign genetic information.[27] According to this understanding, point mutations and other changes not including the insertion of foreign genetic material would be excluded from the Protocol's scope.

However, the *travaux préparatoires* of the Protocol, which can be relied upon as a subsidiary means of interpretation,[28] show that the presence of foreign genetic material in the resulting organism was rejected as a criterion for the LMO definition. During the negotiations, representatives of the so-called *Miami Group* – consisting of the United States, Canada, Australia, Argentina, Chile and Uruguay – proposed to include that the

Society 227; *Shapiro* (n. 22), 12; *ENCODE Project Consortium*, An Integrated Encyclopedia of DNA Elements in the Human Genome, 489 (2012) Nature 57.

24 Cf. *Tvedt/Schei* (n. 22), 16; *Benjamin A. Pierce*, Genetics (7th ed. 2020), 637–638.

25 *Morten W. Tvedt/Tomme R. Young*, Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD, ABS Series No. 2 (2007), 55.

26 *Mackenzie* et al., IUCN Guide (n. 4), MN. 199–200 and Box 14 on p. 44; *Tvedt/Schei* (n. 22), 21; *Fedder* (n. 20), 36.

27 Cf. 'recombinant DNA', in: Henderson's Dictionary of Biology (n. 20), 500–501.

28 Cf. Article 32(a) VCLT (n. 18), see *Oliver Dörr*, Article 32 VCLT, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 11–21.

resulting organism should be 'unlikely to occur in nature'.[29] Others, including representatives from developing and Nordic countries, suggested defining 'novel' as 'not known to occur in nature'.[30] According to a third proposal, the resulting organism should have 'traits novel to the species in the receiving country'[31] or the 'receiving environment'.[32]

Ultimately, however, all these proposals were rejected in favour of the phrase 'novel combination of genetic material', which was understood to be more comprehensive.[33] Notably, suggestions that an LMO should contain 'foreign' or 'transgenic' genetic material were also rejected.[34] The negotiating history of the Cartagena Protocol thus clearly indicates that the presence of foreign genetic material in the resulting organism is not a constitutive criterion for what constitutes an LMO.

Consequently, the term 'novel combination' should be construed in a broad sense as simply referring to any change in the composition of genetic material, regardless of its origin. Whether the resulting genotype or phenotype could have also arisen naturally is irrelevant to whether an organism is an LMO under the Protocol.[35] What is decisive is less the quality of the change but rather that this change is 'obtained through the use of modern biotechnology'. In this sense, a novel combination could arise from a change to even a single nucleotide in a nucleotide sequence.[36]

29 *Aarti Gupta*, Framing "Biosafety" in an International Context: The Biosafety Protocol Negotiations, ENRP Discussion Paper E-99–10 (1999), 23; cf. BSWG, Report of the Third Meeting, UN Doc. UNEP/CBD/BSWG/3/6 (1997), 39; BSWG, Revised Consolidated Text of the Draft Articles (From the Fourth Meeting), UN Doc. UNEP/CBD/BSWG/5/Inf.1 (1998), 11; BSWG, Compilation of Definitions and Terms Relevant to a Biosafety Protocol, UN Doc. UNEP/CBD/BSWG/3/Inf.1 (1997), 19.

30 *Gupta* (n. 29), 23; cf. BSWG, Consolidated Text from Fourth Meeting (n. 29), 11.

31 BSWG, Compilation of Definitions (n. 29), 19; BSWG, Report of the Third Meeting (n. 29), 39.

32 BSWG, Consolidated Text from Fourth Meeting (n. 29), 11.

33 Cf. IISD, Report of the Fourth Session of the Ad Hoc Working Group on Biosafety: 5–13 February 1998, ENB Vol. 9 No. 85 (1998), 5; *Gupta* (n. 29), 23.

34 Cf. BSWG, Consolidated Text from Fourth Meeting (n. 29), 11; ENB Summary of BSWG-4 (n. 33), 5.

35 *Mackenzie* et al., IUCN Guide (n. 4), MN. 214; also see *Sirinathsinghji* (n. 11), 3.

36 *Mackenzie* et al., IUCN Guide (n. 4), MN. 212.

d) Obtained Through the Use of Modern Biotechnology

In order to qualify as an LMO, the organism must possess a novel combination of genetic material which has been 'obtained through the use of modern biotechnology'. The notion of 'modern biotechnology' is defined in Article 3(i) CP as

> *'the application of*
> *a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
> *b. Fusion of cells beyond the taxonomic family,*
> *that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection'.*

This definition consists of three elements that must be fulfilled cumulatively: The first element describes the techniques that are encompassed, i.e., *in vitro* nucleic acid techniques and cell fusion (aa)). The second element provides that these techniques need to overcome natural physiological reproductive or recombination barriers (bb)). Thirdly, these techniques must not be techniques used in traditional breeding and selection (cc)).

aa) 'Application of in vitro nucleic acid techniques…'

The first element of the definition specifies the laboratory techniques encompassed by the definition of modern biotechnology, namely '*in vitro* nucleic acid techniques' and 'fusion of cells beyond the taxonomic family'. The latter, *cell fusion*, means the process of merging two different cells into a single hybrid cell.[37] Since genome editing does not involve cell fusion, this element can be left aside for the purposes of the present study. The only relevant criterion is whether genome editing techniques can be regarded as '*in vitro* nucleic acid techniques'. In this regard, the Protocol provides two examples of what constitutes such a technique, namely 'recombinant deoxyribonucleic acid (DNA)' and 'direct injection of nucleic acid into cells or organelles'.

As to the first example, the term 'recombinant DNA' denotes the insertion of foreign DNA into the genome of the target organism.[38] While

37 Cf. 'Cell fusion', in: *Richard Cammack/Teresa K. Attwood* et al. (eds.), Oxford Dictionary of Biochemistry and Molecular Biology (2[nd] ed. 2006), 107.
38 Cf. 'recombinant DNA', in: Henderson's Dictionary of Biology (n. 20), 500–501.

this has been possible by conventional genetic engineering techniques, it can be achieved with higher precision through more recent *genome editing* techniques.[39] The development of engineered gene drives will usually involve the insertion of foreign DNA and thus constitute a recombinant DNA technique.[40] On the other hand, genome editing techniques used to produce endogenous changes to the genome without inserting foreign DNA, such as targeted point mutations, cannot be regarded as recombinant DNA techniques.

The second example of techniques provided by the definition is 'direct injection of nucleic acid into cells'. In the case of CRISPR/Cas, the *guide RNA* (one of the components prepared *in vitro*) constitutes nucleic acid, and direct injection is one of the available means to insert the guide RNA into the target organism (besides direct injection, a frequently used approach is transfection).[41] Hence, depending on the specific approach, the CRISPR/Cas technique may involve 'direct injection of nucleic acid' in the sense of Article 3(i) CP.

In any case, the notion '*in vitro* nucleic acid techniques' is not limited to the examples mentioned in the definition, as the term 'including' indicates that the examples are not meant to be exhaustive. During the negotiations of the Protocol, it was expressly recognized that the definition of 'modern biotechnology' should be phrased in a manner that would cover new techniques which were not yet envisaged at that time.[42] Therefore, it was deliberately left open whether, besides the two existing examples, new techniques would constitute '*in vitro* nucleic acid techniques'.[43] Hence, the phrase 'in vitro nucleic acid techniques' refers to any technique that

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39 It is undisputed that any technique that involves the insertion of foreign DNA into the organism, including ZFN-3, is covered by the protocol, cf. European Commission, New Techniques Working Group (NTWG): Final Report, not officially published (2012), 19–20; *Jens Kahrmann* et al., Aged GMO Legislation Meets New Genome Editing Techniques, 15 (2017) EurUP 176, 177 n. 11; Dutch Commission on Genetic Modification (COGEM), The Status of Oligonucleotides Within the Context of Site-Directed Mutagenesis: 100701–03 (2010), 10; *Thorben Sprink* et al., Regulatory Hurdles for Genome Editing: Process- vs. Product-Based Approaches in Different Regulatory Contexts, 35 (2016) Plant Cell Reports 1493, 1497.

40 See chapter 1, section C.II.

41 See chapter 1, section B.II.3.

42 Cf. ENB Summary of BSWG-4 (n. 33), 5; *Mackenzie* et al., IUCN Guide (n. 4), MN. 217–218.

43 *Ibid.*

involves the handling of nucleic acid *in vitro*, i.e. outside the target organism.[44]

Consequently, '*in vitro* nucleic acid techniques' includes all laboratory procedures where nucleic acid is modified or synthetically produced outside of the organism and subsequently inserted into the target organism. This includes the CRISPR/Cas technique, regardless of how the effector complex is inserted into the target organism. The ODM technique is covered by the definition too, as the oligonucleotides used in this technique also constitute nucleic acid. SDN-2 techniques, which involve the insertion of a DNA snippet as a 'repair template', also fall under the definition.[45]

In contrast, some older genome editing techniques do not involve any *in vitro* handling of nucleic acid. For instance, the TALENs and ZFN-1 techniques rely on engineered nucleases, which are enzymes that cleave DNA at specific target sequences once inserted into the cell.[46] Technically, however, these techniques do not involve any *in vitro* handling of nucleic acid. It could, therefore, be questioned whether they are covered by the definition of 'modern biotechnology'.[47] At the same time, these techniques are still *in vitro* techniques used to modify the target organism's DNA (i.e. nucleic acid). An extensive interpretation would also find support in the Protocol's negotiating history since, as noted above, the parties wanted to ensure that the definition also covered future techniques.[48] But including *any* laboratory technique to modify genetic information would certainly overstretch the notion of '*in vitro* nucleic acid techniques'. An interpretation that excludes techniques involving engineered nucleases from the scope of the Protocol would also not be 'manifestly absurd or unreasonable', which would be necessary to deviate from the grammatical and textual interpretation of the term. Therefore, techniques not involving

44 The literal meaning of *in vitro* is 'in glass', cf. Oxford Dictionary of Biochemistry and Molecular Biology (n. 37), 351.

45 It is undisputed that any technique that involves the insertion of foreign DNA into the organism, including ZFN-3, is covered by the protocol, cf. New Techniques Working Group, Final Report (n. 39), 19–20; *Kahrmann* et al. (n. 39), 177 n. 11; Dutch Commission on Genetic Modification (COGEM) (n. 39), 10; *Sprink* et al. (n. 39), 1497.

46 See chapter 1, sections B.II.1 and B.II.2.

47 See *Jens Kahrmann/Georg Leggewie*, CJEU's Ruling Makes Europe's GMO Legislation Ripe for Reformation, 16 (2018) EurUP 497, 502, although the main argument of these authors is that targeted mutagenesis does not overcome natural physiological and reproductive barriers (see next section).

48 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 217–218.

the *in vitro* use of nucleic acid but of other mutagenic substances, such as engineered nucleases, are arguably not covered by the Protocol's definition of 'modern biotechnology'.[49] However, these methods have largely been replaced by the more efficient CRISPR technique and are unlikely to be used widely in the future.[50]

bb) '… that overcome natural physiological reproductive or recombination barriers…'

The definition further requires that the application of the aforementioned techniques must 'overcome natural physiological reproductive or recombination barriers'. It has been suggested that 'natural barriers' are such that would normally prevent the exchange or recombination of DNA.[51] Hence, the definition would apply when DNA sequences are introduced from species that would not be able to exchange genetic material with the target organism (e.g., through mating) under natural conditions. But in some applications of genome editing techniques, especially when used to create point mutations, there is no exchange or recombination of DNA at all. The wording of this criterion is therefore inconclusive with regard to more recent biotechnological techniques.[52]

According to one possible interpretation, the condition of 'overcoming natural barriers' requires that the resulting genotype could not even theoretically arise in a natural way through recombination or reproduction.[53] Since point mutations can also result from natural processes, their creation through genome editing techniques would not amount to overcoming natural barriers, and the resulting organisms would not constitute LMOs in the sense of the Protocol.[54]

However, it should not be overlooked that the criterion of 'overcoming natural barriers' is used to characterize the *techniques* of genetic modifica-

49 Likewise *Sirinathsinghji* (n. 11), 3–4.
50 *Ibid.*, 4; *Heidi Ledford*, CRISPR, the Disruptor, 522 (2015) Nature 20, 21–22.
51 *Mackenzie* et al., IUCN Guide (n. 4), 50; also see 'recombination', in: Henderson's Dictionary of Biology (n. 20), 501.
52 Cf. *van der Meer* (n. 13), 286.
53 Cf. *Callebaut* (n. 11), 53.
54 Cf. *Kahrmann/Leggewie* (n. 47), 502.

tion rather than the *result* of such modification.[55] As shown above, the Cartagena Protocol's LMO definition refers to both the resulting organism (which has to possess a 'novel combination of genetic material') and the techniques through which this result is obtained ('application of modern biotechnology').[56] The requirement that natural barriers need to be overcome is included in the definition of the latter term, modern biotechnology, and thus refers to the *means* of modification and not to its *result*.[57] Consequently, the decisive question is not whether the resulting organism could also occur naturally, but whether the techniques employed are capable of achieving genetic changes that cannot be achieved by relying on natural reproduction and recombination mechanisms. This includes the creation of targeted point mutations through genome editing techniques: although point mutations do also occur naturally, only genome editing techniques allow to introduce them at specific locations of the genome.

This interpretation is also supported by the negotiating history of the Cartagena Protocol.[58] As noted earlier, it was long proposed during the negotiations to define an LMO by whether its genetic material is unlikely (or unknown) to occur in nature.[59] This element was eventually dropped in favour of the broader requirement that there must be a 'novel combination' of genetic material.[60] Around the same time, it was agreed that the definition should refer to both the techniques of modification and the resulting organism.[61] The 'novel combination' criterion was then used to define the resulting organism, while the reference to 'overcoming natural and reproductive barriers' was included in the definition of modern

55 The context in which a term is used is, besides the term's ordinary meaning, a primary factor for its interpretation. See Article 31(1) VCLT (n. 18); cf. *Dörr*, Article 31 VCLT (n. 18), MN. 43–51.
56 Cf. ENB Summary of BSWG-4 (n. 33), 5; *van der Meer* (n. 13), 285.
57 But see *Callebaut* (n. 11), 53, who argues that 'the phrasing of this provision necessarily also relates to the result, i.e. the new (novel) combination of genetic material obtained through the use of these techniques'. The same seems to be assumed by *Piet van der Meer* et al., The Status Under EU Law of Organisms Developed Through Novel Genomic Techniques (2021) European Journal of Risk Regulation 1, 15.
58 See *supra* n. 28.
59 Cf. BSWG, Consolidated Text from Fourth Meeting (n. 29), 10–11; see ENB Summary of BSWG-4 (n. 33), 5; *Gupta* (n. 29), 23; *van der Meer* (n. 13), 285.
60 Cf. BSWG, Draft Negotiating Text (From the Fifth Meeting), UN Doc. UN Doc. UNEP/CBD/BSWG/6/2 (1998), 6; *Gupta* (n. 29), 23; see *supra* section A.I.1.c).
61 Cf. ENB Summary of BSWG-4 (n. 33), 5; *van der Meer* (n. 13), 285.

biotechnology, reportedly to resolve a dispute about whether and to what extent cell fusion should be included in the Protocol's scope.[62]

Consequently, the decisive criterion is whether a natural process of genetic alteration is being replaced by techniques that can only be applied *in vitro* by overcoming natural barriers. Since genome editing techniques generally involve the insertion of endonucleases or nucleic acids that were specifically modified or synthetically produced *in vitro*, their application generally overcomes natural reproductive or recombination barriers in terms of the Protocol.

cc) '… and that are not techniques used in traditional breeding and selection'

Lastly, the definition of modern biotechnology requires that the techniques applied are not 'techniques used in traditional breeding and selection'. While this phrase seems self-explanatory at first glance, the notion of 'traditional' is ambiguous and leaves much room for interpretation.[63] It would not seem to have been the subject of closer legal analysis so far.[64]

In its ordinary meaning, which is the starting point for interpretation pursuant to Article 31(1) VCLT, the adjective 'traditional' characterizes something as long-established, customary or conventional.[65] In the present context, 'traditional' appears to denote methods of breeding and selection that have been subject to continuous and widespread use for a long period of time. This would include the most conventional forms of breeding plants and animals, which have been practised by humankind for hundreds of years. In essence, all these techniques rely on selecting individuals that exhibit desired traits and mating them with other individuals from the same or closely related species.[66] Deliberate hybridization – i.e., crossing

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62 *Van der Meer* (n. 13), 286; see IISD, Highlights of BSWG-5 #9: Wednesday, 26 August 1998, ENB Vol. 9 No. 106 (1998), 2.

63 *Van der Meer* (n. 13), 286.

64 The only detailed discussion appears to be *Mackenzie* et al., IUCN Guide (n. 4), MN. 221–226; for a scientific perspective, see *Clemens van die Wiel* et al., Traditional Plant Breeding Methods (2010).

65 Cf. 'traditional', in: Oxford English Dictionary (n. 12).

66 *Mackenzie* et al., IUCN Guide (n. 4), MN. 221; see generally *Rolf H. J. Schlegel*, Concise Encyclopedia of Crop Improvement (2007), 5–52; *Noël Kingsbury*, Hybrid: The History and Science of Plant Breeding (2009), 39–54; *George Acquaah*, Conventional Plant Breeding Principles and Techniques, in: Jameel M.

different varieties or species to produce new ones – has been practised since the late seventeenth century and would equally constitute a traditional technique.[67] The same is true for a range of other strategies used to facilitate the selection of desired traits and the exchange of genetic material.[68]

However, the term is generally deemed to include not only century-old practices, but also more sophisticated techniques which were developed since the twentieth century and which operate on the molecular level, such as methods to create interspecific hybrids by overcoming sexual crossing barriers and approaches to increase the amount of genetic variation by exposing an organism to mutagenic agents.[69]

At first sight, this seems to contradict – or at least substantially modify – the aforementioned meaning of 'traditional'. However, the wording does not expressly require the technique *itself* to be traditional, but rather that it is a technique used in *traditional breeding and selection*. The main characteristic of traditional breeding and selection is that it relies on *random* genetic change,[70] as opposed to breeding methods that rely on introducing *specific* changes in the genetic material. In that sense, the term 'traditional' appears to be synonymous with 'conventional' rather than referring to a certain history of application. Referring to 'methods not involving recombinant DNA techniques'[71] would result in circular reasoning and thus be of little use, because 'recombinant DNA' is a separate element used in the LMO definition.[72]

At the same time, whether or not a certain technique used in traditional breeding has a long-standing history of application is not relevant. What counts instead is whether a technique is used in breeding methods that rely on random genetic change rather than targeted interventions in the genome. Consequently, genome editing techniques that allow genetic

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Al-Khayri/Mohan Jain/Dennis V. Johnson (eds.), Advances in Plant Breeding Strategies (2015) 115.

67 See *Schlegel* (n. 66), 42–52; *Kingsbury* (n. 66), 71.

68 See *Schlegel* (n. 66), 85–135; *Mackenzie* et al., IUCN Guide (n. 4), MN. 225.

69 *Mackenzie* et al., IUCN Guide (n. 4), MN. 221–225; see *Acquaah* (n. 66), 150–151; for an extensive overview of 'traditional' yet modern techniques (in the context of European legislation), see *van die Wiel* et al. (n. 64), 6.

70 *Caius M. Rommens*, Intragenic Crop Improvement: Combining the Benefits of Traditional Breeding and Genetic Engineering, 55 (2007) Journal of Agricultural and Food Chemistry 4281, 4281–4282: see *Hermann J. Muller*, Artificial Transmutation of the Gene, 66 (1927) Science 84.

71 Cf. *van die Wiel* et al. (n. 64), 5.

72 See *supra* section A.I.1.d)aa)).

modification at the level of single nucleotides (or 'base pairs') cannot be construed as 'techniques used in traditional breeding and selection'.

e) Coverage of Certain New and Emerging Techniques

aa) Genome Editing

The preceding analysis has shown that the Cartagena Protocol is wide in scope and capable of capturing the recent progress made in biotechnology. Its definition of the term 'living modified organism' has been deliberately drafted in anticipation of scientific developments that would occur after the adoption of the Protocol. The definition refers to both the *resulting organism*, which is expected to contain a novel combination of genetic material (but not necessarily exogenous DNA), and the *technique of modification*, which must be one of modern biotechnology.

Arguably, the requirement that the technique must 'overcome natural physiological barriers' introduces a certain level of ambiguity that might lead to different interpretative results. However, the drafting history of this element clearly shows that it is not the *product*, but the *process* of genetic modification that must overcome natural barriers. The definition does not exclude organisms from its scope that were produced by *in vitro* nucleic acid techniques but could – hypothetically – also arise from natural processes.

Based on the above analysis, it is concluded that modified organisms resulting from any genome editing technique using site-specific nucleases (SDN), including the CRISPR/Cas technique, are covered by the Cartagena Protocol even when they only carry targeted point mutations resulting from the application of these techniques (SDN-1 and SDN-2).[73]

On the other hand, it seems to be undisputed that the Cartagena Protocol is applicable to modified organisms that carry exogenous genetic information, regardless of whether these elements were inserted by conventional means of genetic engineering or by genome editing techniques (SDN-3).[74]

73 *Sirinathsinghji* (n. 11).
74 *Araki* et al. (n. 11), 234–235.

bb) Engineered Gene Drives

The scope of the Cartagena Protocol also includes *engineered gene drives*. As outlined in the first chapter, gene drives are currently developed by integrating genes for the drive mechanism along with any desired payload genes into the genome of the target organism.[75] This necessarily implies that foreign genetic material is permanently introduced into the organism.

Organisms equipped with engineered gene drives therefore possess a novel combination of material obtained through modern biotechnology, namely through in vitro nucleic acid techniques. Since the genes encoding for the drive mechanism could not be inserted into the host organism's genome in a natural way, the modification also overcomes natural physiological reproductive and recombination barriers. Therefore, organisms carrying engineered gene drives based on techniques like CRISPR-Cas constitute LMOs in terms of Article 3(h) of the Cartagena Protocol.[76]

It has been suggested that once an engineered gene drive is released into the environment, the progeny might cease to constitute LMOs and thus fall outside the scope of the Cartagena Protocol.[77] According to this view, engineered gene drives use natural reproduction in order to diffuse traits into their target population and, for this reason, do not overcome *re-*

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75 See chapter 1, section C.II.

76 AHTEG on Synthetic Biology, Report of the Ad Hoc Technical Expert Group on Synthetic Biology: Montreal, Canada, 5–8 December 2017, UN Doc. CBD/SYNBIO/AHTEG/2017/1/3 (2017), para. 28; *Li C. Lim/Li L. Lim*, Gene Drives: Legal and Regulatory Issues (2019), 27; *Keiper/Atanassova* (n. 11), 15; *Greet Smets/Patrick Rüdelsheim*, Study on Risk Assessment: Application of Annex I of Decision CP 9/13 to Living Modified Organisms Containing Engineered Gene Drives, UN Doc. CBD/CP/RA/AHTEG/2020/1/4, Annex (2020), 30; *Delphine Thizy* et al., Providing a Policy Framework for Responsible Gene Drive Research: An Analysis of the Existing Governance Landscape and Priority Areas for Further Research, 5 (2020) Wellcome Open Research 173, 13. For similar reasons, these organisms are also covered by the EU's legislation on GMO as well as laws of EU member states implementing that legislation, cf. *Marion Dolezel* et al., Beyond Limits – The Pitfalls of Global Gene Drives for Environmental Risk Assessment in the European Union, 15 (2020) BioRisk 1, 5–6. For instance, the German Central Committee on Biological Safety deems recombinant gene drive systems based on the CRISPR-Cas technique to be covered by the scope of the German Genetic Engineering Law, cf. ZKBS, Position Statement of the ZKBS on the Classification of Genetic Engineering Operations for the Production and Use of Higher Organisms Using Recombinant Gene Drive Systems, Az. 45310.0111 (2016).

77 *Florian Rabitz*, Gene Drives and the International Biodiversity Regime, 28 (2019) RECIEL 339, 345.

productive barriers in the sense of the definition of 'modern biotechnology' in Article 3(i) CP.[78] It was further suggested that engineered gene drives do not necessarily overcome *recombination barriers*, because 'the trait itself may well be inside the normal evolutionary boundaries'.[79] But these assumptions are rooted in a misconception of the functioning of engineered gene drive systems. As shown earlier, nuclease-based gene drive systems operate by performing a genetic modification in each progeny, thereby guaranteeing their own inheritance to further offspring.[80] Each of these modifications overcomes natural reproductive and recombination barriers, as the DNA encoding for the drive system is copied onto the chromosome inherited from the wild-type parent. Hence, all progeny of an organism carrying an engineered gene drive constitute LMOs.

However, as noted in the first chapter, the efficacy of engineered gene drives is not always 100 %.[81] Due to a number of factors, the drive system may not succeed in every individual, leaving some of the progeny unmodified. Moreover, evolutionary factors might lead to the emergence of resistances, which may cause the drive to (partly) phase out.[82] Against this background, it has been argued that progeny that no longer carries the DNA encoding for the drive system would not constitute LMOs.[83] In principle, this appears to be correct. But it could well be argued that progeny of LMOs are legally presumed to be LMOs too unless it is proven that their genome no longer contains any novel combination of DNA obtained through modern biotechnology. Moreover, it is impossible to predict which of the offspring will not inherit the drive system. In any event, it seems impossible to determine with certainty that a gene drive, once released, has been completely eradicated from the environment. For these reasons, the fact that the drive system may become lost in some (or even all) of the progeny has no bearing on the regulation of the parent organisms to be released into the environment.

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78 *Ibid.*
79 *Ibid.*
80 See chapter 1, section C.II.
81 See chapter 1, section C.IV.1.
82 *Ibid.*
83 *Rabitz* (n. 77), 345.

cc) Genetically Modified Viruses

Genetically modified viruses, regardless of the way they are used,[84] are also covered by the Cartagena Protocol's scope. As shown above, viruses are not themselves capable of replicating genetic material, but are expressly included in the definition of 'living organism'.[85] In most cases, these modifications will involve recombinant DNA, i.e. the insertion of transgenic material from other viruses or organisms. However, as shown above, the Cartagena Protocol also applies to modified organisms (and viruses) which do not carry foreign genetic material.[86] Consequently, the Cartagena Protocol applies to all applications of modified viruses discussed in the first chapter.

dd) Techniques That Harness Natural Mechanisms of Self-Propagation (Wolbachia)

In contrast to synthetic gene drives and genetically modified viruses, techniques that harness naturally occurring mechanisms of self-propagation without genetically modifying the target organism are outside the scope of the Cartagena Protocol. This concerns, in particular, undertakings aimed at releasing mosquitoes infected with the heritable *Wolbachia* bacterium in order to reduce the mosquitoes' potential to transmit human pathogens such as *Zika* and *Dengue*.[87] As long as neither the genetic material of the insect nor that of the bacterium are modified by means of modern biotechnology, they are not covered by the Cartagena Protocol.[88] However, because certain *Wolbachia* strains cause significant physiological changes to

84 See chapter 1, sections D, E.I, and E.II.
85 See *supra* section A.I.1.a).
86 See *supra* section A.I.1.e)aa).
87 See chapter 1, section E.IV.; see World Mosquito Program, FAQ, available at: https://www.worldmosquitoprogram.org/en/learn/faqs (last accessed 28 May 2022), which notes: 'Our method is not genetic modification, as the genetic material of the mosquito has not been altered. Neither the Aedes aegypti mosquitoes nor the Wolbachia have been genetically modified in the lab and the strain of Wolbachia we are using is naturally occurring.'
88 This view is shared by *John M. Marshall*, The Cartagena Protocol and Releases of Transgenic Mosquitoes, in: Brij K. Tyagi (ed.), Training Manual: Biosafety for Human Health and the Environment in the Context of the Potential Use of Genetically Modified Mosquitoes (GMMs) (2015) 163, 168, who warns that: 'It would be unfortunate if a method of modification were chosen first and foremost

the infected mosquitoes, it has been argued that the biosafety implications involved with these approaches are similar to those of genetic modifications.[89]

2. Restriction to Hazardous LMOs?

According to Article 4, the Cartagena Protocol applies to all LMOs

> '*that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health*'.[90]

According to some authors, this phrase has the effect of limiting the Protocol's scope to only those LMOs that 'may have' the said effects, thereby excluding LMOs which are unlikely to have adverse effects.[91]

Such a substantial restriction of the Protocol's scope can, however, not be simply assumed. There is no express provision which imposes such a (potentially far-reaching) restriction on the Protocol's scope of application, and the Protocol contains neither substantive criteria nor a procedure for excluding certain organisms from the scope of the entire Protocol.[92] Instead, Article 7(4) provides a dedicated procedure to exempt LMOs that are 'not likely to have adverse effects' from the Protocol's *Advance Informed Agreement* procedure,[93] albeit not from the Protocol as a whole. Such an exemption requires an express decision by the meeting of the parties to the

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for its immunity to excessive regulatory requirements, rather than on the basis of its safety and efficacy.'

89 Cf. *John M. Marshall*, The Cartagena Protocol and Genetically Modified Mosquitoes, 28 (2010) Nature Biotech. 896, 897; *Guy R. Knudsen*, International Deployment of Microbial Pest Control Agents: Falling Between the Cracks of the Convention on Biological Diversity and the Cartagena Biosafety Protocol, 30 (2012) Pace Envtl. L. Rev. 625.

90 The same wording can be found in Article 1, which lays down the Protocol's objective. On considerations for risks to human health, see *Nathalie Bernasconi-Osterwalder*, The Cartagena Protocol on Biosafety: A Multilateral Approach to Regulate GMOs, in: Edith Brown Weiss/John H. Jackson/Nathalie Bernasconi-Osterwalder (eds.), Reconciling Environment and Trade (2nd ed. 2008) 645, 649.

91 This interpretation seems to be adopted, even though without reasoning, by *Pavoni* (n. 4), 118 at footnote 17; *Ezra Ricci*, Biosafety Regulation: The Cartagena Protocol (2004), 17; *John Komen*, The Emerging International Regulatory Framework for Biotechnology, 3 (2012) GM Crops & Food 78, 80.

92 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 168.

93 See *infra* section A.II.1.

Cartagena Protocol (COP-MOP).[94] To date, the procedure of Article 7(4) has never been used.[95]

Hence, LMOs are not *included* in the Protocol's scope because they are deemed hazardous, but rather can be *excluded* from certain provisions when they are deemed unlikely to have adverse effects.[96] This approach is an implementation of the precautionary principle:[97] LMOs are subject to the Protocol even when there is no scientific certainty about their hazardousness, as long as they have not proven to be safe.[98] This interpretation is also coherent with Articles 10(6) and 11(8) of the Protocol, which allow states to unilaterally restrict the import of LMOs on grounds of the precautionary approach when there is a lack of scientific certainty regarding the extent of their potential adverse effects.[99]

At the same time, it should be noted that the Cartagena Protocol does not consider LMOs as *generally* and *inherently* hazardous or dangerous to the environment.[100] This is an important difference from other interna-

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94 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 279; see *Jutta Brunnée*, COPing with Consent: Law-Making Under Multilateral Environmental Agreements, 15 (2002) Leiden J. Int'l L. 1, 22–23, noting that this mechanism allows the parties to the Cartagena Protocol to modify the substantive terms of the instrument, namely to reduce the scope of the agreement, by simple decision instead of a formalized amendment procedure. *René Lefeber*, Creative Legal Engineering, 13 (2000) Leiden Journal of International Law 1, 6–8, notes that this modification might even be decided by majority vote, and thus against the express will of a minority of parties. On the role of COP decisions, also see chapter 5, section B.

95 Cf. CBD Secretariat, COP-MOP Decisions on AIA (Art. 7–10), available at: https://bch.cbd.int/protocol/decisions/?subject=cpb-art7-10 (last accessed 28 May 2022).

96 *Eggers/Mackenzie* (n. 4), MN. 528; *Aarti Gupta*, Creating a Global Biosafety Regime, 2 (2000) International Journal of Biotechnology 205, 218–219; *Mackenzie* et al., IUCN Guide (n. 4), MN. 168.

97 References to the precautionary approach contained in Principle 15 of the Rio Declaration can be found can be found in several provisions of the Cartagena Protocol, including the Preamble and Article 1. For a detailed assessment of the precautionary principle, see chapter 4, section B.VI.

98 *Mackenzie* et al., IUCN Guide (n. 4), MN. 279.

99 Cf. *Komen* (n. 91), 80; *Mackenzie* et al., IUCN Guide (n. 4), MN. 339–341; see *infra* sections A.II.1.d) and f).

100 *Worku D. Yifru* et al., The Decision-Making Procedures of the Protocol, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 78, 86; *Akiho Shibata*, A New Dimension in International Environmental Liability Regimes: A Prelude to the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 17, 21.

tional agreements such as the 1989 *Basel Convention*[101] and the 1998 *Rotterdam Convention*,[102] in which the parties agree on the hazardousness of certain substances specifically listed in annexes to these Conventions.[103] In contrast, under the Cartagena Protocol, the ultimate decision on whether a certain LMO is deemed to be hazardous is made individually by the country of import, namely after an assessment of the *potential* risks in accordance with the Protocol's provisions.[104] Consequently, the reference to adverse effects in Article 4 is of merely declaratory value and does not restrict the Protocol's scope. The Protocol applies to *any* LMO, while LMOs that have proven to be safe can be exempted from the AIA procedure pursuant to Article 7(4) CP.[105]

3. Activities Covered by the Protocol

Article 4 CP also specifies the activities involving LMOs to which the Cartagena Protocol applies, namely the 'transboundary movement, transit, handling and use' of LMOs.

The term transboundary movement is defined in Article 3(k) CP as the 'movement of a living modified organism from one Party to another Party'.[106] This refers predominantly to intentional transboundary movements, i.e. the import of an LMO into the territory of another state. But transboundary movements may also occur unintentionally, which is specifically

101 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (22 March 1989; effective 05 May 1992), 1673 UNTS 57 (hereinafter 'Basel Convention').

102 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (10 September 1998; effective 24 February 2004), 2244 UNTS 337 (hereinafter 'Rotterdam Convention').

103 *Redgwell* (n. 4), 555.

104 *Ibid.*, 555–556; *Peter-Tobias Stoll*, Controlling the Risks of Genetically Modified Organisms: The Cartagena Protocol on Biosafety and the SPS Agreement, 10 (1999) YB Int'l Env. L. 82, 95.

105 *Mackenzie* et al., IUCN Guide (n. 4), MN. 168; also see *Tomme R. Young*, National Experiences with Legislative Implementation of the Protocol, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 329, 346–348.

106 Article 3(k) further provides that, for the purposes of the Protocol's provisions on unintentional transboundary movements in Article 17 and on transboundary movements to non-parties in Article 24, the term transboundary movement also extends to movements between parties and non-parties.

addressed in Article 17 CP.[107] For the purposes of this provision, the term transboundary movement also extends to movements between parties and non-parties to the Cartagena Protocol; the same applies to Article 24 which specifically addresses the role of non-parties.[108]

Since the notion of 'transboundary movement' is expressly defined as a movement '*from* one Party *to* another Party'[109] and Article 24 only applies to transboundary movements '*between* parties and non-parties',[110] the Cartagena Protocol seems not to apply to transboundary movements from parties into areas beyond national jurisdiction, especially the high seas.[111] Article 2(3) CP expressly provides that the Protocol shall not affect the rights and freedoms of states under international law of the sea. However, Article 196(1) of the *UN Convention on the Law of the Sea* (UNCLOS)[112] obliges states to prevent the introduction of 'new' species, which arguably includes LMOs,[113] into the marine environment.[114]

The other activities listed in Article 4 CP – transit, handling, and use – are not defined in the Protocol. However, some guidance concerning 'transit' is provided by Article 6(1) CP, which refers to the right of each party to regulate the transit of LMOs 'through its territory'. This implies that 'transit' refers to the passage of an LMO through or across the territory of one or several states.[115] With regard to 'use', reference can be made to the definition of 'contained use' in Article 3(b) CP, which suggests that 'use' can mean *any* operation which involves LMOs. Hence, it can be assumed that while the terms 'transboundary movement' and 'transit' refer to specific forms of carriage of LMOs, 'handling and use' cover any activity

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107 See *infra*, section A.II.2.b).
108 See *infra* section A.II.4.
109 Article 3(k) CP (emphasis added).
110 Emphasis added.
111 *Mackenzie* et al., IUCN Guide (n. 4), MN. 234.
112 United Nations Convention on the Law of the Sea (10 December 1982; effective 16 November 1994), 1833 UNTS 3 (hereinafter 'UNCLOS').
113 *Markus Böckenförde*, The Introduction of Alien or New Species into the Marine Environment: A Challenge for Standard Setting and Enforcement, in: Peter Ehlers/Elisabeth Mann-Borgese/Rüdiger Wolfrum (eds.), Marine Issues (2002) 241, 250–251; *Detlef Czybulka*, Article 196 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017), MN. 14.
114 See *infra* section G.
115 This is also consistent with the use of the term 'transit' in other international agreements, cf. UNCLOS (n. 112), Article 124(1)(c); Basel Convention (n. 101), Article 2(12); also see *Marquard* (n. 14), 295–297; *Mackenzie* et al., IUCN Guide (n. 4), MN. 234.

involving LMOs, regardless of whether they remain in containment or are released into the environment.

4. Exemption for Transboundary Movement of LMOs Which Are Pharmaceuticals (Article 5)

According to Article 5, the Cartagena Protocol does not apply to

> '*the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations*'.

Article 5 only encompasses 'living modified organisms which are pharmaceuticals', which implies that the LMO itself must be the pharmaceutical.[116] Moreover, the pharmaceutical must be addressed by other agreements or organizations.[117] This may be the case for *in vivo* uses of genetically modified bacteria or viruses as vaccines[118] or to deliver drugs, therapeutic proteins or gene therapy vectors to the human body with higher specificity than by conventional means.[119] At the same time, appli-

116 See *Marquard* (n. 14), 294–295.

117 Relevant instruments in this context are the Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products (08 October 1970; effective 26 May 1971), 956 UNTS 3, which has been extended by the (informal) Pharmaceutical Inspection Co-operation Scheme (PIC/S), see PIC/S, Introduction, available at: https://www.picscheme.org/en/about (last accessed 28 May 2022), and the World Health Organization's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, cf. *A. Wehrli*, The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, 31 (1997) Drug Information Journal 899.

118 Cf. *Joachim Frey*, Biological Safety Concepts of Genetically Modified Live Bacterial Vaccines, 25 (2007) Vaccine 5598; *Elena Angulo/Juan Bárcena*, Towards a Unique and Transmissible Vaccine Against Myxomatosis and Rabbit Haemorrhagic Disease for Rabbit Populations, 34 (2007) Wildlife Research 567; *Anne I. Myhr/Roy A. Dalmo*, DNA Vaccines: Mechanisms and Aspects of Relevance for Biosafety, in: Terje Traavik/Li C. Lim (eds.), Biosafety First (2009) 253; *Young* (n. 105), 384.

119 Cf. *Manoj Kumar* et al., Bioengineered Probiotics as a New Hope for Health and Diseases: An Overview of Potential and Prospects, 11 (2016) Future Microbiology 585; see *Gupta* (n. 96), 212.

cations in which LMOs are used outside the organism (*in vitro*) to produce non-living drugs or vaccines are not covered by Article 5.[120]

Applications involving the *in vivo* injection of nucleic acids or nucleases for therapeutic purposes, such as mRNA vaccines developed against SARS-CoV-2[121] and the injection of preassembled CRISPR-Cas components to treat sickle-cell anaemia,[122] are not covered by Article 5. While these applications rely on the use of modern biotechnology, especially *in vitro* nucleic acid techniques in the sense of Article 3(i) CP,[123] they do not involve the creation of a living modified organism. For this reason, these applications fall entirely outside the scope of the Cartagena Protocol.

It has been proposed that LMOs used for disease control purposes might constitute pharmaceuticals in the sense of Article 5.[124] According to such an interpretation, insects equipped with transgenes or engineered gene drives could be exempted from large parts of the Protocol when they are used for disease control purposes.[125] The same would apply to genetically modified viruses and transmissible vaccines. However, such an interpretation is not persuasive for three reasons: Firstly, in its ordinary meaning the noun 'pharmaceutical' refers to a 'medicinal drug'.[126] This is confirmed, secondly, by the use of this term in international agreements relating

120 *Mackenzie* et al., IUCN Guide (n. 4), MN. 243. A different view is taken by *Odile J. Lim Tung*, Genetically Modified Organisms and Transboundary Damage, 38 (2013) SAYIL 67, 71, who assumes that LMOs intended as raw materials for the production of pharmaceuticals or nutraceuticals may not be covered by the Cartagena Protocol and the Supplementary Protocol. However, this view is not further substantiated and also ignores the wording of Article 5 CP, which unequivocally refers to LMOs 'which are pharmaceuticals' rather than LMOs which are intended for being processed to pharmaceuticals. Article 7(2) CP demonstrates that the Protocol indeed makes such a distinction between LMOs intended for direct use and LMOs intended for processing.

121 See *Lindsey R. Baden* et al., Efficacy and Safety of the MRNA-1273 SARS-CoV-2 Vaccine, 384 (2021) N. Engl. J. Med. 403.

122 Cf. *Heidi Ledford*, CRISPR Deployed to Combat Sickle-Cell Anaemia, Nature News, 12 October 2016, available at: https://www.nature.com/news/crispr-deployed-to-combat-sickle-cell-anaemia-1.20782 (last accessed 28 May 2022); see Chapter 1, section B.III.2.

123 See *supra* A.I.1.d)aa).

124 *Lim Tung* (n. 120), 71; *Odile J. Lim Tung*, Transboundary Movements of Genetically Modified Organisms and the Cartagena Protocol: Key Issues and Concerns, 17 (2014) Potchefstroom Electronic Law Journal 1739, 1744–1745.

125 On the use of engineered gene drive systems for disease vector control, see chapter 1, section C.III.1.

126 Cf. 'pharmaceutical', in Oxford English Dictionary (n. 12).

to pharmaceutical products,[127] which also refer to medicines and similar products for human or animal use.[128] Thirdly, Article 5 expressly refers to 'pharmaceuticals for humans', which semantically rules out products which are not *applied* to humans but only indirectly improve human health, such as genetically modified insects released to limit the spread of certain diseases. Consequently, LMOs intended for disease control purposes are not excluded from the scope of the Protocol.[129]

Article 5 is subject to two important caveats. Firstly, the exemption expressly retains the right of parties to subject LMOs excluded under Article 5 to a risk assessment before making a decision on their import.[130] Secondly, Article 5 stipulates that it only applies to the transboundary movement of said LMOs. This means that the Protocol's general provisions not relating to transboundary movement, in particular those on risk management,[131] remain applicable.[132]

5. Conclusions

The above analysis has shown that the Cartagena Protocol is wide in scope and capable of covering techniques developed after its adoption. The definition of the term 'living modified organism' consists of two elements that refer to both the technique employed ('use of modern biotechnology') and the characteristics of the resulting organism ('novel combination of genetic material').

127 Pursuant to Article 31(3)(c) VCLT, any relevant rules of international law applicable in the relations between the parties shall be taken into account together with the context of a treaty's terms.

128 See references in *supra* n. 117.

129 Cf. *Marshall* (n. 88), 167, assuming that 'the interpretation of [genetically modified mosquitoes] as pharmaceuticals is not widespread'.

130 Cf. *Pavoni* (n. 4), 124; *Mackenzie* et al., IUCN Guide (n. 4), MN. 245.

131 See *infra* section A.II.2.

132 *Mackenzie* et al., IUCN Guide (n. 4), MN. 242; but see *Eggers/Mackenzie* (n. 4), 529; *Falkner* (n. 4), 307, assuming that pharmaceuticals are entirely excluded from the scope of the Protocol. However, see *Tewolde Berhan Gebre Egziabher*, The Cartagena Protocol on Biosafety: History, Content and Implementation from a Developing Country Perspective, in: Terje Traavik/Li C. Lim (eds.), Biosafety First (2009) 389–405, 399, indicating that excluding the pharmaceuticals from the scope of the AIA mechanism, but not from the Protocol as a whole, was a compromise reached during the negotiations.

The criterion of a 'novel combination' is broad; it neither requires that the resulting organism contains foreign genetic material nor that the combination could not have arisen naturally. Hence, the more decisive criterion is whether the organism was obtained through modern biotechnology, particularly through *in vitro* nucleic acid techniques that overcome natural physiological reproductive or recombination barriers. In this regard, it is important to note that the technique employed, and not the resulting organism, must overcome natural barriers. This requires that the natural process of genetic alteration – which relies, in one form or another, on random genetic change – is replaced by techniques that allow generating targeted genetic changes.

As a result, it is submitted that the Cartagena Protocol applies to all modified organisms resulting from the application of site-specific nucleases, including the CRISPR/Cas technique, regardless of whether it involves the introduction of foreign genetic material into the target organism. While this may be controversial concerning organisms modified through genome editing, there appears to be no doubt that organisms carrying engineered gene drives are covered by the Cartagena Protocol.

The Cartagena Protocol applies to all activities involving LMOs, both in contained use and when released into the environment. Contrary to what the wording of Article 4 might imply, it is not limited to LMOs identified as involving a particular risk for biodiversity. LMOs that are pharmaceuticals for humans can be excluded from the Protocol's provisions on transboundary movement, provided they are addressed by other relevant international agreements or organisations.

II. Substantive Provisions

The substantive provisions of the Cartagena Protocol can be divided into provisions on international trade in LMOs on the one hand and general provisions on risk management in relation to LMOs on the other. International trade is regulated by the establishment of an *Advance Informed Agreement* mechanism, which establishes a harmonized procedure for obtaining the advance consent of the importing party prior to the first importation of a particular LMO (1.).

The Protocol's general rules primarily address the prevention of both unintentional and illegal transboundary movements (2.). Furthermore, there are provisions concerning the exchange of information (3.), the application of the Protocol in relation to third states (4.), and the right of parties to adopt more rigid standards than those laid down in the Cartagena Protocol (5.). Finally, the Protocol contained a mandate for elaborating an additional instrument on liability, which later resulted in the *Nagoya–Kuala Lumpur Supplementary Protocol* (6.).

1. Advance Informed Agreement Procedure for Transboundary Movements of LMOs

The *Advance Informed Agreement* (AIA) procedure, which is laid down in Articles 7 to 10 and 12, is the Cartagena Protocol's central mechanism for regulating the transboundary movement of LMOs.[133] The underlying principle of the AIA mechanism is that LMOs shall not be imported into the territory of any contracting party without that party's prior and express consent.[134] Thus, the party of export is required to ensure that the party of import is notified of any intended transboundary movement of an LMO.[135] The competent authority of the party of import shall ensure that a risk assessment is carried out for the LMO in question,[136] and subsequently render a decision on whether the transboundary movement may proceed.[137] The AIA mechanism under the Cartagena Protocol was modelled after the *Prior Informed Consent* procedures previously adopted in two other multilateral agreements on hazardous substances, namely the *Basel Convention* on transboundary movements of hazardous wastes of 1989,[138] and the *Rotterdam Convention* of 1998,[139] which established a Prior Informed Consent procedure for international trade in certain hazardous chemicals.[140]

133 *Yifru* et al. (n. 100), 78; *Tobias Sdunzig*, Die UN-Konvention über Biodiversität und ihre Zusatzprotokolle (2017), 243.
134 *Mackenzie* et al., IUCN Guide (n. 4), MN. 264; see *Thomas O. McGarity*, International Regulation of Deliberate Release Biotechnologies, in: Francesco Francioni/Tullio Scovazzi (eds.), International Responsibility for Environmental Harm (1991) 319, 336–338.
135 Article 8(1) CP.
136 Articles 10(1) and 15(2) CP.
137 Article 10(2) CP; cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 264.
138 Basel Convention (n. 101).
139 Rotterdam Convention (n. 102).
140 Cf. *Stoll* (n. 104), 91; *Eggers/Mackenzie* (n. 4), 529; *Redgwell* (n. 4), 555; *Yifru* et al. (n. 100), 83–86; *Shibata* (n. 100), 21.

a) Scope of the AIA Provisions

The scope of the AIA mechanism is defined in Article 7(1). According to this provision, the Advance Informed Agreement of the party of import shall be obtained

> *'prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import'.*

The term 'transboundary movement' is defined by Article 3(k) CP as the 'movement of a living modified organism from one Party to another Party'. The *Court of Justice of the European Union* found this definition to be 'particularly wide', as it encompassed not only movements of LMOs of an agricultural nature, but also movements for charitable or scientific purposes and movements serving the public interest.[141]

However, the AIA mechanism only applies to LMOs 'for intentional introduction into the environment of the Party of import'. Thus, a number of scenarios are excluded from the scope of the AIA procedure: Firstly, the AIA procedure does not apply to the transit of LMOs through a party's territory.[142] Secondly, no AIA is required for LMOs 'destined for contained use', which refers to LMOs for which no environmental release is intended.[143] Thirdly, LMOs intended for direct use as food or feed or for processing are not subject to the AIA procedure but to a simplified approval mechanism under Article 11 CP.[144] Finally, as mentioned above, the AIA mechanism does not apply to LMOs identified in a decision by the meeting of parties as 'being not likely to have adverse effects on the conservation and sustainable use of biological diversity'.[145]

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141 CJEU, Cartagena Protocol, Opinion 2/00, 06 December 2001, 2000 ECR I-09713, para. 38.

142 Article 6(1) CP; cf. *Marquard* (n. 14), 295–296; *Eric Schoonejans*, Advance Informed Agreement Procedures, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 299–320, 317–318.

143 Article 6(2) CP; cf. *Marquard* (n. 14), 291–293.

144 Article 7(2) and (3) CP; see *infra* section A.II.1.f).

145 Article 7(4) CP; see *supra* section A.I.2.

b) Procedure of Obtaining an Advance Informed Agreement From the Party of Import

The procedure of obtaining an AIA for an intended transboundary movement is comprised of several steps and commences with a notification submitted to the competent authority of the party of import. The exporting state party shall either submit the notification itself or require the exporter to ensure that the importing party is notified.[146] The notification shall contain detailed information about the LMO, including its origin, the means of modification, the resulting characteristics and its intended use.[147] The party of import has to acknowledge receipt of the notification.[148] Within 270 days, it shall then render a decision whether it allows, conditionally allows, or prohibits the import.[149] Unless the party of import unconditionally approves the import, it is required to set out the reasons on which it based its decision.[150] When new scientific information about potential adverse effects of an LMO becomes available, the part of import is entitled to review and change an earlier decision.[151] Similarly, the exporter may request the importing party to review an earlier decision when circumstances have changed or when additional information has become available that may influence the outcome of the decision.[152]

c) Risk Assessment

According to Article 10(1) of the Cartagena Protocol, each decision under the AIA mechanism shall be based on a risk assessment carried out in a scientifically sound manner. Article 15(1) stipulates that the objective of such risk assessments is to identify and evaluate the possible adverse effects of LMOs on biodiversity.[153] To that end, risk assessments shall be carried

146 Article 8 CP. On the decision to impose a notification duty on the exporting party, see *Schoonejans* (n. 142), 307–308.
147 See Annex I to the Cartagena Protocol.
148 Article 9 CP.
149 Article 10(3) CP; see *Pavoni* (n. 4), 121.
150 Article 10(4) CP.
151 Article 12(1) CP.
152 Article 12(2) CP.
153 See *Ryan Hill*, Risk Assessment and Risk Management, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 63.

out in a scientifically sound manner, taking into account recognized risk assessment techniques, and shall at least be based on the information submitted by the notifier as well as 'other available scientific evidence'.[154] The party of import may require the exporter to either carry out the risk assessment itself or to bear the costs for it.[155]

Annex III stipulates extensive requirements that a risk assessment carried out under the Cartagena Protocol must fulfil.[156] As a general principle, the Annex provides that 'lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk'.[157] Moreover, it stipulates that the risks should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.[158]

With regard to methodology, the Annex provides for a number of steps a risk assessment should include: First of all, any novel characteristics of the LMO that may have adverse effects in the likely potential receiving environment should be identified.[159] Then, both the likelihood of these adverse effects[160] and the consequences if they materialize shall be evaluated.[161] These factors shall be combined into an estimation of the overall risk posed by the LMO.[162] The risk assessment procedure shall culminate in a recommendation as to whether the risks are manageable, as well as identify appropriate strategies to manage these risks.[163] Any remaining uncertainty about the level of risk shall be addressed by requesting further information or by implementing appropriate risk management strategies and/or monitoring the LMO in the receiving environment.[164] This multi-step process is common to many international and domestic risk assessment frameworks relating to genetically modified organisms.[165]

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154 *Ibid*.
155 Article 15(2) and (3) CP.
156 See *Bernasconi-Osterwalder* (n. 90), 652–653.
157 Annex III to the Cartagena Protocol, para. 4.
158 *Ibid.*, para. 5.
159 *Ibid.*, para. 8(a).
160 *Ibid.*, para. 8(b).
161 *Ibid.*, para. 8(c).
162 *Ibid.*, para. 8(d).
163 *Ibid.*, para. 8(e).
164 *Ibid.*, para. 8(f).
165 Cf. Codex Alimentarius Commission, Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (2011), CAC/GL 44–2003; OIE, Guidelines for Assessing the Risk of Non-Native Animals Becoming Invasive (Novem-

The Annex also provides a list of issues that should be considered in a risk assessment, including the biological characteristics of the recipient organism or the parental organism, the donor organism, and the vector.[166] The genetic characteristics of the inserted nucleic acid and the function it specifies, and/or the characteristics of the modification introduced, should also be considered in the risk assessment.[167] Moreover, the identity of the LMO and its differences from the recipient or parental organism should be considered as well as suggested detection and identification methods.[168] Finally, the risk assessment should also take into account information relating to the intended use of LMO and the characteristics of the likely potential receiving environment.[169]

d) Role of the Precautionary Principle in Decision-Making (Article 10(6))

Article 10(6) CP provides that lack of scientific certainty regarding the extent of potential adverse effects of the LMO shall not prevent the party of import 'from taking a decision, as appropriate, with regard to the import of the living modified organism in question […], in order to avoid or minimize such potential adverse effects'.[170] Although it cannot easily be derived from a literal reading, the provision is generally regarded as imple-

ber 2011); International Plant Protection Convention/FAO, International Standard for Phytosanitary Measures No. 11: Pest Risk Analysis for Quarantine Pests, last amended in April 2013 (hereinafter 'ISPM 11'); Australian Government, Office of the Gene Technology Regulator, Risk Analysis Framework (4th ed. 2013); Commission Directive (EU) 2018/350 of 8 March 2018 Amending Directive 2001/18/EC of the European Parliament and of the Council as Regards the Environmental Risk Assessment of Genetically Modified Organisms (2018), OJ L 67, p. 30 (hereinafter 'Commission Directive (EU) 2018/350'); see *Hill* (n. 153), 67–69; CBD Secretariat, Risk Assessment and Risk Management (Articles 15 and 16): Note by the Executive Secretary, UN Doc. UNEP/CBD/BS/COP-MOP/2/9 (2005).

166 Annex III to the Cartagena Protocol, paras. 9(a)–(c).

167 *Ibid.*, para. 8(d).

168 *Ibid.*, paras. 8(e)–(f).

169 *Ibid.*, paras. 8(g)–(h).

170 On the implementation of the precautionary principle in the Cartagena Protocol generally, see *Ruth Mackenzie/Philippe Sands*, Prospects for International Environmental Law, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 457, 461–463.

menting the precautionary approach.[171] When the conditions of Article 10(6) are met, a party of import may invoke the precautionary approach[172] to deny its approval in order to avoid or minimize such potential effects.[173]

According to its wording, the provision only applies when there is scientific uncertainty about the *extent* of potential adverse effects, but not about the *level* of risk or regarding the *nature* or *likelihood* of potential adverse effects.[174] In most cases concerning LMOs, scientific uncertainty will concern the *existence* and *nature* of a risk rather than its *extent.*[175] Against this background, it appears justifiable to construe the term 'extent' broadly as comprising any scientific uncertainty about the potential adverse effects of an LMO on the conservation and sustainable use of biological diversity.[176]

e) Role of Socio-Economic Considerations in Decision-Making (Article 26)

Article 26 CP allows parties to take into account socio-economic considerations arising from the impact of LMOs on biodiversity, provided that they are consistent with their international obligations.[177] An agreed definition of the term 'socio-economic considerations' can neither be found in the text of the Protocol nor in the relevant scholarly literature.[178]

171 *Mackenzie* et al., IUCN Guide (n. 4), MN. 339; *Stoll* (n. 104), 98; *Böckenförde* (n. 8), MN. 13; *Laurence Graff*, The Precautionary Principle, in: Christoph Bail/ Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 410, 418–419.

172 On the precautionary principle or approach generally, see *Alan E. Boyle/Catherine Redgwell*, Birnie, Boyle, and Redgwell's International Law and the Environment (4th ed. 2021), 170–183; also see chapter 4, section B.VI.

173 *Graff* (n. 171), 418; *Pavoni* (n. 4), 128–134; *Mackenzie* et al., IUCN Guide (n. 4), MN. 341.

174 Cf. *Stoll* (n. 104), 98–99; *Böckenförde* (n. 8), MN. 13.

175 Cf. *Stoll* (n. 104), 116.

176 Cf. *ibid.*, 99; *Graff* (n. 171), 418–419. National implementation in many states appears to be based on this interpretation, see *Young* (n. 105), 348–350.

177 *Gregory Jaffe*, Implementing the Cartagena Biosafety Protocol Through National Biosafety Regulatory Systems: An Analysis of Key Unresolved Issues, 5 (2005) Journal of Public Affairs 299, 305–306.

178 *Graff* (n. 171), 419; *Karinne Ludlow* et al., Introduction to Socio-Economic Considerations in the Regulation of Genetically Modified Organisms, in: Karinne Ludlow/Stuart J. Smyth/José B. Falck-Zepeda (eds.), Socio-Economic Considerations in Biotechnology Regulation (2014) 3, 8–9.

Generally, the term 'socioeconomics' denotes a (scientific) approach that observes the interdependencies between the economy and other spheres of social life, such as culture, politics, technology and social relations.[179] In the present context, 'socio-economic considerations' can thus be construed as referring to the economic, environmental, social, cultural, and impacts an LMO might have.[180] The notion also correlates with that of 'sustainable development', which refers to the interplay between economic, social and cultural development.[181] Consequently, the term covers 'a broad spectrum of concerns about the actual and potential consequences of biotechnology'.[182] The five most common issues considered by those countries that integrate socio-economic considerations in their domestic biosafety regimes are food security, health-related impacts, the coexistence of LMOs and non-GM agriculture, impact on market access, and compliance with biosafety measures.[183] However, the meaning and scope of Article 26 CP remain subject to controversy.[184]

The need to further clarify the meaning of Article 26 CP was also recognized by the meeting of the parties to the Cartagena Protocol (COP-MOP), which set up a working group in 2016 to develop 'conceptual clarity' on

179 Cf. *Simon N. Hellmich*, What Is Socioeconomics? An Overview of Theories, Methods, and Themes in the Field, 46 (2017) Forum for Social Economics 3, 3.
180 *Kathryn Garforth*, Socio-Economic Considerations in Biosafety Decision-Making: An International Sustainable Development Law Perspective, CISDL Working Paper (2004), 19–22; also see *Fransen* et al. (n. 180), 2–3.
181 *Frederic Perron-Welch*, Socioeconomics, Biosafety, and Sustainable Development, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 147, 149.
182 *Antonio La Vina/Lindsey Fransen*, Integrating Socio-Economic Considerations into Biosafety Decisions: The Challenge for Asia (2004), 3.
183 CBD Secretariat, Summary Report on the Survey on the Application of and Experience in the Use of Socio-Economic Considerations in Decision-Making on Living Modified Organisms: Note by the Executive Secretary, UN Doc. UNEP/CBD/BS/COP-MOP/5/INF/10 (2010), 5; cf. *Perron-Welch* (n. 181), 154–156; *Ludlow* et al. (n. 178), 8–10 with references to further lists of socio-economic issues related to biotechnology drawn up by various institutions; for the EU, also see European Commission, Report on Socio-Economic Implications of GMO Cultivation on the Basis of Member States Contributions, as Requested by the Conclusions of the Environment Council of December 2008, SANCO/10715/2011 Rev. 5 (2011).
184 *José B. Falck-Zepeda*, Socio-Economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What Are the Issues and What Is at Stake?, 12 (2009) AgBioForum 90, 95–96.

this provision.[185] Among other issues, the working group developed an operational definition of the term 'socio-economic considerations', which reads:

> *'Socio-economic considerations in the context of Article 26 of the Cartagena Protocol may, depending on national or regional circumstances and on national measures to implement the Protocol, cover economic, social, cultural/traditional/religious/ethical aspects, as well as ecological and health-related aspects, if they are not already covered by risk assessment procedures under Article 15 of the Protocol'.*[186]

In 2017, the working group elaborated 'Guidance' outlining principles and a procedural framework for assessing socio-economic considerations when preparing a decision on the import of LMOs.[187] The working group noted that taking socio-economic considerations into account in the decision-making on the import of LMOs must be consistent with international obligations arising from trade, environmental and human rights agreements.[188] It also concluded that the assessment of socio-economic considerations 'should be science-based and evidence-based and lead to defendable results'.[189] Subsequently, the Guidance outlines a multi-stage process that resembles the guidelines for risk assessment contained in Annex III to the Cartagena Protocol[190]. It suggests identifying possible socio-economic effects based on a 'problem statement' and that a 'wide array of methodological approaches is available to assess socio-economic effects, including both quantitative and qualitative methods, as well as participatory approaches'.[191]

Notably, the meetings of the parties to the Cartagena Protocol refused to 'welcome' the Guidance, as was proposed by the working group,[192]

185 CP COP-MOP, Decision BS-VI/13. Socio-Economic Considerations, UN Doc. UNEP/CBD/BS/COP-MOP/6/18, p. 93 (2016), para. 4.
186 AHTEG on Socio-Economics, Revised Framework for Conceptual Clarity on Socio-Economic Considerations, UN Doc. UNEP/CBD/BS/COP-MOP/8/13, Annex (2016).
187 AHTEG on Socio-Economics, Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety, UN Doc. CBD/CP/MOP/9/10, Annex (2018).
188 *Ibid.*, 5.
189 *Ibid.*
190 See *supra* section A.II.1.c).
191 AHTEG on Socio-Economics (n. 187), 7.
192 Cf. *ibid.*, para. 10(1).

but instead only 'took note' of it.[193] Consequently, the Guidance is neither legally binding nor can it be said to constitute quasi-normative 'soft law'.[194]

Moreover, the working group appears to have overlooked that, according to its wording, Article 26 is limited to socio-economic considerations that arise 'from the impact of LMOs on biological diversity'.[195] This means that the provision only applies when the release of an LMO affects biological diversity in a way that raises socioeconomic concerns.[196] Only in such cases may a party rely on Article 26 to justify the denial of its advance agreement or other restrictions on the import and use of an LMO.[197] It may be argued that measures to accommodate socio-economic concerns not covered by Article 26 may nevertheless be imposed because the Protocol only provides for a minimum standard and parties are free to adopt more protective measures.[198] In any event, the boundaries for such measures are less likely to arise from the Cartagena Protocol than from international trade law, which sets high thresholds for justified trade restrictions.[199] This is also recognized in Article 26, which provides that any decision based on socio-economic considerations must be in accordance with the parties' other international obligations.[200]

f) Rules for LMOs Intended for Direct Use as Food or Feed, or for Processing (Article 11)

Article 11 CP establishes a separate process for LMOs that are not designated for intentional introduction into the environment but for direct use as food or feed, or for processing (LMO-FFPs).[201] Although each party

193 Cf. CP COP-MOP, Decision 9/14. Socio-Economic Considerations (Article 26), UN Doc. CBD/CP/MOP/DEC/9/14 (2018), para. 1.
194 See *Brunnée* (n. 94); for a detailed discussion of the normative quality of COP/MOP decisions, see chapter 5, section B.
195 *Mackenzie* et al., IUCN Guide (n. 4), MN. 628; *Perron-Welch* (n. 181), 153.
196 *Mackenzie* et al., IUCN Guide (n. 4), MN. 628–629; *Falck-Zepeda* (n. 184), 95; *Perron-Welch* (n. 181), 153.
197 Cf. *Falck-Zepeda* (n. 184), 95.
198 Article 2(4) CP; cf. *La Vina/Fransen* (n. 182), 3; *Garforth* (n. 180), 23–29; *Ludlow* et al. (n. 178), 8–9; *Falck-Zepeda* (n. 184), 95.
199 See *infra* section C.
200 *Eggers/Mackenzie* (n. 4), 532; *Mackenzie* et al., IUCN Guide (n. 4), MN. 633; *Stoll* (n. 104), 97.
201 See *Yifru* et al. (n. 100), 80–83.

remains free to decide on the import, domestic use and placing on the market of these organisms, the Protocol does not impose an obligation of prior notification or prior consent on the exporter.[202] Instead, each party is required to inform the other parties through the Biosafety Clearing-House of any final decision taken on the domestic use or marketing of LMO-FFPs that may be subject to transboundary movement.[203] Hence, the parties of import need to proactively regulate the import and use of LMO-FFPs if they wish to do so.[204] Notably, developing countries that do not yet have a domestic framework to regulate the import of LMO-FFPs may invoke Article 11(6), which means that imports must nonetheless be notified and are subject to approval by the receiving state.[205] However, this exception has only been used by two states.[206] Many other states have instead extended their regular AIA procedures to LMO-FFPs, which is deemed to constitute a lawful upward derogation under Article 2(4) CP.[207]

g) Exemption of Contained Use and LMO-FFP: The 'Intended Use' Problem

As noted above, the AIA procedure does not apply to LMOs which are 'destined' for contained use or 'intended' for direct use as food or feed, or for processing.[208] Hence, whether the AIA procedure applies does not depend on objectively identifiable characteristics of the LMO, but on the intended use of the LMO in the party of import.

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202 Cf. *Pavoni* (n. 4), 122; *Gupta* (n. 96), 213–214.
203 *Yifru* et al. (n. 100), 81–82.
204 *Young* (n. 105), 344–346; *Böckenförde* (n. 8), MN. 14; *François Pythoud*, Commodities, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 321, 325–328.
205 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 365–369; *Böckenförde* (n. 8), MN. 15.
206 Namely Barbados and Saint Lucia, see Biosafety Clearing-House, available at: http://bch.cbd.int/ (last accessed 28 May 2022).
207 *Young* (n. 105), 344–346.
208 See Articles 6(2) and 7(2) CP; see *supra* section A.II.1.a).

aa) Genuine and Disguised Changes to the Intended Use

Since the 'intended use' is not an objective characteristic that is inherent in the LMO itself, the applicability of the AIA procedure ultimately relies on the stated intentions of the actors involved in the transboundary movement. However, there is no procedure for verifying these statements. Even more, neither the exporter nor the importer is required to make a formal declaration about how the LMO will be used after being imported. There is also no provision expressly barring subsequent changes of the 'intended use' after the transboundary movement has taken place.

This problem is illustrated by a case concerning the transboundary movement of genetically modified mosquitoes. As noted in the first chapter,[209] the international research consortium *Target Malaria*[210] imported a genetically modified strain of the *Anopheles gambiae* mosquito from Italy to Burkina Faso in November 2016.[211] Reportedly arguing that the mosquitoes were imported 'for an initial period of contained use' and thus were not subject to the AIA procedure,[212] the exporters did not notify the transboundary movement in accordance with Regulation (EC) No 1946/2003,[213] which implements the Cartagena Protocol into European Union law.[214] After being brought to Burkina Faso, the mosquitoes were

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209 See chapter 1, section C.III.1.c).

210 Target Malaria is an international research consortium that aims to develop gene drives to reduce the transmission of malaria, see Target Malaria, Who We Are, available at: https://targetmalaria.org/who-we-are/ (last accessed 28 May 2022).

211 The modified strain does not contain a gene drive, but was modified to yield males that are sterile (i.e. incapable of sexual reproduction) and carry fluorescent markers, which allows to identify modified individuals, see *Keith R. Hayes* et al., Risk Assessment for Controlling Mosquito Vectors with Engineered Nucleases: Controlled Field Release for Sterile Male Construct: Risk Assessment Final Report (2018), 14; *Nikolai Windbichler* et al., Targeting the X Chromosome During Spermatogenesis Induces Y Chromosome Transmission Ratio Distortion and Early Dominant Embryo Lethality in Anopheles Gambiae, 4 (2008) PLOS Genetics e1000291, 2.

212 It appears that Target Malaria have not made this statement publicly, but only in communication towards the British NGO *Genewatch UK*, cf. African Centre for Biodiversity et al., GM Mosquitoes in Burkina Faso: A Briefing for the Parties to the Cartagena Protocol on Biosafety (2018), 6; *Hayes* et al. (n. 211).

213 Cf. *ibid.*; see Regulation (EC) No 1946/2003 on Transboundary Movements of Genetically Modified Organisms (15 July 2003), OJ L 287, p. 1 (hereinafter 'Regulation 1946/2003').

214 On the pertinent EU legislation, see *infra* section A.IV.

mated with local strains of *Anopheles coluzzii* and subsequently released into the environment.[215] This raises the question whether a period of contained use or subsequent changes to the LMO (such as back-crossing with local strains) can indeed waive the requirement to notify the transboundary movement and to seek the AIA of the receiving state.

The Cartagena Protocol does not specifically address subsequent changes to the use of an LMO once it has been imported. In particular, it does not expressly require the exporter to ensure that an LMO destined for contained use is only used in containment and that the containment standards are adequate.[216] Furthermore, once the import has been completed, subsequent changes to the intended use have no retroactive effect on the import procedure. Consequently, only the *first* intended use of the LMO in the importing state is decisive for whether the AIA procedure applies, regardless of any subsequent uses already envisaged at the time of import. Therefore, a phase of initial containment after the import might effectively sidestep the AIA procedure prescribed by the Cartagena Protocol, including the requirement to carry out a risk assessment.[217]

Set aside situations of a genuine subsequent change to the intended use, importers may exploit the 'contained use' exception to circumvent the AIA procedure. While this would not affect any domestic regulations applicable to a later release in the receiving state, a plausible motive could be to avoid more stringent requirements that apply in the state of origin. For example, EU legislation requires that if an LMOs intended for deliberate release is moved into a non-member state, a risk assessment must be conducted according to the same standards that apply for environmental releases in EU member states,[218] which are more far-reaching than the re-

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215 See chapter 1, section C.III.1.c); also see African Centre for Biodiversity et al. (n. 212), 6.

216 *Mackenzie* et al., IUCN Guide (n. 4), MN. 259. On containment standards, see chapter 5, section C.III.

217 *John M. Marshall*, Commentary: The Cartagena Protocol in the Context of Recent Releases of Transgenic and Wolbachia-Infected Mosquitoes, 19 (2011) Asia-Pacific Journal of Molecular Biology and Biotechnology 91, 95; *Marshall* (n. 88), 169; also see *Yifru* et al. (n. 100), 87; *Marshall* (n. 89), 897.

218 Pursuant to Annex I of Regulation 1946/2003 (n. 213), lit. k, a notification prior to the first intentional transboundary movement of an LMO must contain a previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms (12 March 2001), OJ L 106, p. 1 (hereinafter 'Directive 2001/18/EC').

quirements laid down in Annex III to the Cartagena Protocol.[219] Another motivation for attempting to evade the AIA mechanism could be to avoid the early disclosure of the transboundary movement through the Biosafety Clearing-House.[220]

bb) Responsibilities of Exporting Parties

The responsibility to prevent such behaviour is shared by exporting and importing parties to the Cartagena Protocol alike. If an exporting state is a party to the Cartagena Protocol, it is obliged to implement the Protocol in good faith.[221] Under Article 8(1), it must ensure that the receiving state is notified about any intended transboundary movement that is subject to the AIA mechanism and originates from its jurisdiction.[222] The notification must include information about the intended use of the LMO.[223] Article 8(2) requires the party of export to 'ensure that there is a legal requirement for the accuracy of information provided by the exporter'.[224] In the context of information, the term 'accurate' means 'conforming exactly with the truth'.[225]

Hence, any party to the Cartagena Protocol is obliged to ensure that transboundary movements originating from its jurisdiction and subject to the AIA mechanism are duly notified to the receiving state and that the intended use of the LMO is truthfully stated. It must also ensure that private actors under its jurisdiction comply with these requirements, if necessary, by penalizing exports carried out in contravention of the pertinent implementing measures.[226] At the same time, the exporting state has no means to prevent *genuine* subsequent changes to the use of an LMO.

219 See Principles for Environmental Risk Assessment, contained in Annex II to Directive 2001/18/EC, as revised by Commission Directive (EU) 2018/350 (n. 165).
220 See *infra* section A.II.3.
221 Cf. Article 2(1) CP and Article 26 VCLT (n. 18).
222 *Schoonejans* (n. 142), 307; see *Young* (n. 105), 332–336.
223 Annex I to the Cartagena Protocol, paras. (i).
224 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 283.
225 Cf. 'accurate, adj.' in: Oxford English Dictionary (n. 12).
226 Article 25(1). On the question whether this provision directly applies to exporting parties, see *infra* section A.II.2.c)aa).

cc) Responsibilities of Importing Parties

Parties of import should insist on the application of the AIA procedure – as implemented in their domestic law – whenever it appears *possible* or *likely* that an LMO initially imported for contained use will subsequently be released into the environment. Such possibility or likelihood must be assessed by objective standards rather than the stated intentions of the exporter.[227] Furthermore, LMOs imported for contained use should be subject to a general prohibition of release into the environment, which would only be lifted once an AIA has been sought and granted *post hoc*. Such domestic requirements are consistent with the requirement to (effectively[228]) implement the Cartagena Protocol into domestic law laid down in Article 2(1) CP. In any event, they would constitute an upward derogation permitted by Article 2(4) CP.[229]

One reason why the AIA procedure does not apply to LMOs intended for contained use is that it requires an evaluation of the effects that an LMO may have on the 'likely potential receiving environment'.[230] However, LMOs imported for contained use have no destined 'receiving environment', and even where a subsequent release is planned, the release site may not yet be determined.[231] Yet, this could be resolved by not waiving the AIA requirement entirely, but only the requirement of assessing the receiving environment for LMOs destined for contained use, or by limiting this assessment to a generic evaluation of the conditions in the receiving state.[232]

Admittedly, these approaches require a robust administrative apparatus in the receiving state, which may not always be given, particularly in developing countries. For this reason, it is important to stress the aforementioned responsibilities of exporting states, which often will be industrialized states with sufficient scientific and regulatory capacities.

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227 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 259.
228 Cf. *Dörr*, Article 31 VCLT (n. 18), MN. 56.
229 See *infra* section A.II.5.
230 Cf. Annex III to the Cartagena Protocol, paras. 8 and 9(h).
231 *Marshall* (n. 217), 95.
232 *Ibid.*

h) Conclusions

The AIA procedure for transboundary movements of LMOs is one of the key features of the Cartagena Protocol. However, as the procedure only applies to LMOs intended for deliberate release into the environment, the percentage of internationally traded biotechnology products that are subject to an AIA is rather small.[233] In practice, the main subjects of the AIA mechanism are genetically modified seeds and live fish.[234] In addition, imports of LMOs wrongly declared to be intended for contained use only, or subsequent changes in the intended use of an LMO after import, threaten to undermine the effectiveness of the AIA mechanism. However, exporting and importing parties bear a joint responsibility to prevent the mechanism from being circumvented. Most importantly, the requirements for obtaining a release permit in the receiving state should not be more lenient than those for obtaining the AIA at the time of import.

Where the AIA mechanism applies, the Cartagena Protocol merely governs the procedure of obtaining an AIA from the receiving state. However, it does not provide any substantive criteria to guide the actual decision-making about whether to allow or deny the import of a specific LMO.[235] The Protocol does not contain any material agreement between the parties on the grounds on which a state may legitimately refuse to import a certain LMO.[236] In principle, states are therefore free in their decision-making and may admit or refuse LMOs as they deem fit. This is also confirmed by Article 2(4) CP, which provides that states may take measures that are *more protective of biodiversity* than those stipulated in the Protocol.[237] However, this freedom is significantly restricted by the rules of international trade law, as shown below.[238]

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233 *Gupta* (n. 96), 214; *Schoonejans* (n. 142), 306; *Stewart/Johanson* (n. 4), 7.
234 *Stewart/Johanson* (n. 4), 7; *Bernasconi-Osterwalder* (n. 90), 646; see US Department of State, Fact Sheet: Cartagena Protocol on Biosafety (2000).
235 *Hill* (n. 153), 70.
236 Cf. *Stoll* (n. 104), 95; *Pavoni* (n. 4), 115–116; *Jaffe* (n. 177), 303–305; *Redgwell* (n. 4), 556.
237 See *infra* section A.II.5.
238 See *infra* section C.

2. Risk Management and Preparedness

Articles 16–18 and 25 of the Cartagena Protocol contain general provisions on risk management. These provisions operate outside the AIA framework and therefore, subject to the limitations discussed below, apply regardless of whether an LMO is or is not subject to an (intentional) transboundary movement.[239]

a) Risk Management (Article 16)

Article 16 is the Cartagena Protocol's core provision on risk management. The first paragraph stipulates a general obligation to establish and maintain appropriate measures to manage the risks associated with LMOs (aa)). The second paragraph specifically addresses the prevention of adverse effects that imported LMOs may have on the biological diversity in the territory of the importing state (bb)). The third paragraph stipulates an obligation to prevent unintentional transboundary movements of LMOs (cc)). The fourth paragraph requires that any LMO, even when it is developed and used locally, is subjected to an appropriate observation period before it is put to its intended use (dd)). Finally, the fifth paragraph provides an obligation to cooperate in the identification and management of risks of LMOs (ee)).

aa) Obligation to Establish Appropriate Risk Management Measures (para. 1)

Under Article 16(1) CP, parties are required to establish and maintain appropriate mechanisms, measures, and strategies to regulate, manage and control the risks associated with the use, handling, and transboundary movement of LMOs. The provision refers to the general provision contained in Article 8(g) of the CBD, which requires parties to establish or maintain means to regulate, manage, or control the risks associated with the use and release of LMOs.[240]

239 Cf. *Sandrine Maljean-Dubois*, Biodiversité, biotechnologies, biosécurité: Le droit international désarticulé (2000) Journal du Droit International 947, 981–982.

240 See *infra* section B.III.

Article 16(1) CP applies to 'risks identified in the risk assessment provisions of this Protocol'. In its ordinary meaning, the phrase 'risks *identified* in the risk assessment provisions' suggests that the risk assessment provisions specify the risks to be addressed.[241] However, the Protocol's provisions on risk assessment – namely, Article 15 and Annex III – do not name any specific risks but rather provide a framework for determining these risks on a case-by-case basis.[242] Hence, the reference to 'risks identified *in the risk assessment provisions*' makes little sense and seems best explained by a drafting error.[243]

A possible solution would be to understand the reference to 'risks' to mean the risks identified during a risk assessment carried out in accordance with the risk assessment provisions of the Protocol. This would resolve the discrepancy while keeping the interpretation as close as possible to the ordinary meaning of the provision. But at the same time, such an interpretation would limit the scope of Article 16(1) CP to only those LMOs for which an AIA has been sought, because, as shown above, the Protocol's provisions on risk assessment operate within the AIA mechanism.[244] This may be inconsistent with the wording of the provision, which applies to the 'use, handling *and* transboundary movement' of LMOs, while risk assessments are only required for the latter. Moreover, confining the first paragraph of Article 16 CP to transboundary situations would also strip the relevance of the second paragraph, which specifically provides for risk management measures based on risk assessment following the transboundary movement of an LMO.[245] Finally, the provision's reference to Article 8(g) CBD also contradicts this interpretation because the latter generally refers to managing the risks associated with the use and release of LMOs, not to transboundary movements.

Consequently, it appears more appropriate to construe the notion of risks in Article 16(1) CP as generally referring to the risks that LMOs may pose to the conservation and sustainable use of biological diversity, taking

241 Cf. 'identify', in Oxford English Dictionary (n. 12).

242 Annex III to the Cartagena Protocol, para. 5; cf. *Jaffe* (n. 177), 303; see *supra* section A.II.1.c).

243 Other language versions seem to be coherent in this regard, as the French version refers to 'les risques définis par les dispositions du Protocole relatives à l'évaluation des risques' and the Spanish version uses 'los riesgos determinados con arreglo a las disposiciones sobre evaluación del riesgo del presente Protocolo'.

244 Cf. *Pavoni* (n. 4), 119.

245 See *infra* section bb).

also into account human health (i.e. all risks covered by the scope of the Cartagena Protocol).[246] This not only accommodates the concerns raised by the interpretation discussed before, but also better suits the substance of the provision, which broadly refers to 'mechanisms, measures and strategies to regulate, manage and control risks […] associated with the use, handling and transboundary movement' of LMOs. Thus, the scope is not limited to the transboundary movement of LMOs, but also extends to their use and handling in a domestic context. Finally, this approach brings the provision in line with the subsequent paragraphs of Article 16, which separately address deliberate and indeliberate transboundary movements as well as purely domestic uses of LMOs.

In any case, the substantive content of Article 16(1) CP remains broad and unspecific. The Protocol offers no distinction between the terms 'mechanisms', 'measures', and 'strategies'. The same applies to notions of regulation, management, and control of risks, which the Protocol also does not further specify.[247] The only criterion is that the measures adopted by the parties must be 'appropriate'. This term indicates that the present obligation is one of *due diligence*, which means that the parties shall take all reasonable steps to effectively address the risks in question.[248] However, the occurrence of harm does not automatically indicate that a state has not taken all appropriate steps to prevent harm.[249] It is doubtful whether it is at all possible to review the compliance of parties with this obligation.

bb) Imposition of Preventive Measures Based on Risk Assessment (para. 2)

Article 16(2) CP provides that measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects on the biological diversity within the territory of the party of import. Since it expressly addresses the protection of biodiversity in the territory of importing parties, the provision only applies to LMOs that were subject to a transboundary movement. Hence, the risk assessment on which measures shall be based will usually be that already carried out during the AIA procedure. But

246 This seems to be implied by *Mackenzie* et al., IUCN Guide (n. 4), MN. 444.
247 For an overview of risk management measures commonly applied, see *ibid.*, MN. 447–448.
248 Cf. *Joanna Kulesza*, Due Diligence in International Law (2016), 187; see chapter 4, section C.
249 See chapter 4, section E.I.

the provision also applies to LMOs for which no AIA was obtained, for instance because they were declared to be intended for contained use at the time of import.[250]

Article 16(2) CP provides that measures shall be imposed 'to the extent necessary' to prevent adverse effects. This implies a double threshold: on the one hand, the measures must be actually capable of handling the risks that have been identified, but on the other hand, they shall not go beyond what is required for achieving an adequate level of protection. In this understanding, the requirement of 'necessary' measures reminds of the necessity requirement under international trade law.[251] Interestingly, the provision does not specify the bearer of the obligation it stipulates. While the importing party usually will be in the best position to impose the required measures, the exporting party may also be required to take measures to prevent adverse effects in the importing party's territory. This may especially be the case when the importing party lacks adequate regulatory capacities capable of imposing and enforcing the required measures.[252]

cc) Prevention of Unintentional Transboundary Movements (para. 3)

Article 16(3) CP requires each party to take appropriate measures to prevent unintentional transboundary movements of LMOs.

(1) The Notion of 'Unintentional Transboundary Movement'

The provision applies to any LMO which may be subject to an *unintentional* transboundary movement, regardless of whether it is also subject to *intentional* transboundary movements. Article 16(3) CP complements the AIA mechanism by ensuring that no transboundary movements occur without the express approval of the receiving state. It relates to Article 25, which addresses *illegal transboundary movements*, i.e., movements carried

250 Cf. *Young* (n. 105), 372–374; see *supra* section A.II.1.g).

251 Cf. General Agreement on Tariffs and Trade 1994 (15 April 1994; effective 01 January 1995), 1867 UNTS 187, Annex 1A (hereinafter 'GATT 1994'), Article XX; see *Pavoni* (n. 4), 133 and *infra* section C.

252 See *Young* (n. 105), 340.

out intentionally but in contravention of the state's domestic measures implementing the Cartagena Protocol, including the AIA mechanism.[253]

The term 'transboundary movement' is defined by Article 3(k) CP as the 'movement of a living modified organism from one Party to another Party'.[254] Since the term *movement* is not further specified, it presumably covers all possibilities of how an LMO may travel from one state's territory into another, regardless of whether it migrates naturally, is carried by another organism or parts of it (such as animals, crop or pollen), or is unintentionally transported by humans.

In a decision adopted by COP-MOP 8, the term 'unintentional transboundary movement' was defined as 'a transboundary movement of a living modified organism that has inadvertently crossed the national borders of a Party where the living modified organism was released'.[255] This definition adds little clarity, as it essentially replaces 'unintentional' with the term 'inadvertently', which is largely synonymous.[256] Yet, with regard to the ordinary meaning of these terms, a transboundary movement can be deemed 'unintentional' in terms of the present provision when it is not carried out by at least one human person acting in a wilful manner.[257] Unintentional transboundary movements can result from both intentional and accidental releases, such as when an LMO escapes a contained use

253 See *infra* section A.II.2.c).

254 It can be assumed that the present provision also provides for the prevention of unintentional movements into the territory of non-parties. Article 3(k) provides that, for the purposes of Articles 17 and 24, the term transboundary movement extends to movement between parties and non-parties. Article 17 provides for the notification of affected states in case unintentional transboundary movements occur (see *infra* section A.II.2.b). Since it would be incoherent to assume that the Protocol covered response measures to unintentional movements to non-parties but not their prevention in the first place, Article 16(3) should be interpreted extensively in this regard.

255 CP COP-MOP, Decision VIII/16. Unintentional Transboundary Movements and Emergency Measures (Article 17), UN Doc. CBD/CP/MOP/DEC/VIII/16 (2016), Annex. The definition goes on to restrict the scope of the duty to notify in cases of unintentional transboundary movements pursuant to Article 17 to LMOs which are likely to have significant adverse effects, see *infra* section A.II.2.b).

256 Cf. 'inadvertence, n.', in: *Bryan A. Garner* (ed.), Black's Law Dictionary (11th ed. 2019), 908; 'inadvertently, adv.', in: Oxford English Dictionary (n. 12).

257 Cf. 'unintentional act', in: Black's Law Dictionary (n. 256), 32; 'unintentional, adj.', in: Oxford English Dictionary (n. 12).

facility.[258] Hence, the present provision also covers negligent conduct that leads to an unintentional transboundary movement.[259]

(2) Obligation to Take 'Appropriate Measures'

According to Article 16(3) CP, each party is required to take 'appropriate measures to prevent unintentional transboundary movements'. The Protocol does not define what is required by 'appropriate measures'. However, Article 16(3) resembles the obligation to prevent significant transboundary under general international law, which, according to the seminal codification by the *International Law Commission* (ILC), requires all states to 'take all appropriate measures to prevent significant transboundary harm'.[260] In this context, the duty to take 'appropriate measures' denotes an obligation to act with *due diligence*.[261] Since Article 16(3) CP also seeks to avoid undue transboundary environmental interference, its reference to 'appropriate measures' arguably incorporates this general due diligence standard.[262]

The obligation to exercise due diligence requires the responsible state to exercise a reasonable degree of care commensurate to the risk at stake. Practically, it must adopt appropriate legislative rules and measures and

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258 *Mackenzie* et al., IUCN Guide (n. 4), MN. 467.

259 If not inherent in the term 'unintentional', the term 'inadvertently' used in the COP-MOP decision clearly points to negligent conduct, see the references in n. 256.

260 ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148 (hereinafter 'ILC, Articles on Prevention'), Art. 3. Similar provisions can be found in numerous international soft-law documents and treaties, e.g., UNCLOS (n. 112), Article 192; CBD (n. 5), Article 3; Rio Declaration on Environment and Development (14 June 1992), UN Doc. A/CONF.151/26/Rev.1 (Vol. I) (hereinafter 'Rio Declaration 1992'), Principle 2. For a detailed account, see chapter 4, section A.

261 ILC, Report of the International Law Commission on the Work of Its Fifty-Second Session, YBILC 2000, vol. II(2) (2000), para. 718; see *Leslie-Anne Duvic-Paoli*, The Prevention Principle in International Environmental Law (2018), 200–207.

262 *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 77; *Felix Beck*, The International Regime on Liability for Damage Arising from the Use of Genome Editing and Gene Drives in Agriculture: Current Shortcomings and Pathways for Future Improvement, in: Christian Dürnberger/Sebastian Pfeilmeier/Stephan Schleissing (eds.), Genome Editing in Agriculture (2019) 135, 142.

ensure their effective implementation, including by exercising administrative control over both public and private operators.[263] However, obligations of due diligence are not obligations of result,[264] which means that even full compliance does not guarantee that the undesired event will not occur in any case.[265] Hence, while the state is required to take all reasonable steps to prevent unintentional transboundary movements, the occurrence of such a movement does not automatically indicate that the state violated its obligation.[266] To invoke another state's responsibility for a breach of Article 16(3), a claimant state would have to prove that the responsible state has not taken 'all appropriate measures' – in the sense of all measures a 'reasonable government' would have taken under normal conditions[267] – and that this was causal for the unintended transboundary movement.[268]

(3) Requirement of a Risk Assessment

Article 16(3) further provides that the appropriate measures to be taken shall include 'such measures as *requiring a risk assessment* to be carried out prior to the first release'[269] of an LMO. It is questionable whether this phrase introduces a general obligation to carry out risk assessments for *all* LMOs before their first release, regardless of whether they have been subject to intentional transboundary movements. Such an obligation would be in line with a recent development in customary international

263 ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment of 20 April 2010, ICJ Rep. 14, 197; ITLOS, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, Advisory Opinion of 01 November 2011, Case No. 17, ITLOS Rep. 10, paras. 110–120, see *Lefeber* (n. 262), 77; *Duvic-Paoli* (n. 261), 207–210.

264 ILC, Draft Articles on the Law of the Non-Navigational Uses of International Watercourses and Commentaries Thereto, YBILC 1994, vol. II(2), p. 89 (1994), Art. 7 para. 4.

265 Cf. *ibid.;* ILC, Articles on Prevention (n. 260), Commentary to Article 3, para. 7; ITLOS, Responsibilities and Obligations of States (n. 263), para. 110; *Lefeber* (n. 262), 77; see chapter 4, section E.I.

266 *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 61–62; also see ITLOS, Responsibilities and Obligations of States (n. 263), MN. 189.

267 ILC, Articles on Prevention (n. 260), Commentary to Article 3, para. 17.

268 *Beck* (n. 262), 143.

269 Emphasis added.

law, which increasingly requires environmental impact or risk assessments to be carried out for projects that may potentially have negative transboundary effects.[270] However, the term 'such […] as' could imply that risk assessments are merely given as an example of what appropriate measures could comprise, without stipulating a specific obligation in this regard. Furthermore, since a general obligation to require risk assessments would be a very far-reaching obligation, it could be argued that such an obligation would need to be expressly provided for by the Protocol rather than merely be mentioned in the apodosis of a single provision.[271]

Another argument against the assumption that Article 16(3) CP introduces a general obligation to require risk assessments can be drawn from the fourth paragraph of the same Article, which stipulates that states shall 'endeavour to ensure' appropriate observation periods for LMOs before they are put to their intended use. This provision, which is weaker but expressly applies to 'any LMO', would run empty if Article 16(3) CP was interpreted to require a risk assessment for all LMOs in all cases.

dd) Appropriate Observation Period for Any LMO (para. 4)

Pursuant to Article 16(4) CP, parties shall 'endeavour to ensure' that any LMO, whether imported or locally developed, be subjected to an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use. As shown above, the Cartagena Protocol's provisions on risk assessment, which are contained in Article 15 and Annex III, only apply to LMOs that are subject to transboundary movements of LMOs.[272] Therefore, Article 16(4) CP defines a minimum standard of care for those organisms that are not subject to any transboundary movement but are developed and used domestically. In any case, the scope of the provision also includes imported LMOs, although these

270 Cf. ICJ, Pulp Mills (n. 263), para. 204; ITLOS, Responsibilities and Obligations of States (n. 263), para. 145; ICJ, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) and Construction of a Road in Costa Rica along the San Juan River (Nicaragua v. Costa Rica), Merits Judgment of 16 December 2015, ICJ Rep. 665, para. 104; see chapter 4, section D.II.

271 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 270), para. 164, which held that the similar provision in Article 14(1)(a) CBD did 'not create an obligation to carry out an environmental impact assessment'. For a discussion, see *infra* section B.VI.

272 See *supra* section A.II.1.a).

LMOs are already addressed by the more stringent requirements contained in Article 16(2) CP, which stipulates the obligation of the importing party to adopt preventive measures based on the risk assessment carried out during the AIA procedure.

In principle, Article 16(4) CP establishes a legal obligation like most other of the Protocol's provisions. However, the wording of this provision is particularly lenient, since it merely requires states to 'endeavour to ensure' that LMOs have undergone appropriate observation periods before they are put to their intended use. Thus, it is doubtful whether this provision establishes any specific procedural duties whose implementation by parties can be reviewed and enforced.[273]

ee) Obligation to Cooperate (para. 5)

Finally, Article 16(5) CP requires parties to cooperate in two specific ways. First, states shall cooperate in identifying LMOs or specific traits that may have adverse effects on biodiversity. This primarily concerns the exchange of information about hazardous LMOs or traits as well as cooperation in the identification of new hazards. The second element relates to the appropriate treatment of LMOs or traits that have been identified as hazardous. It has been suggested that this may include the development and implementation of joint strategies to address these risks or, once they have materialized, mitigate adverse effects.[274]

b) Notification in Case of Unintentional Transboundary Movements (Article 17)

Article 17 provides for an obligation of parties to notify other states in the event of an unintentional transboundary movement. It applies when a party knows of an 'occurrence' under its jurisdiction resulting in a release that leads (or may lead) to an unintentional transboundary movement. An 'occurrence' may constitute an accidental release, a failure in risk management measures, or an unexpected spread of an LMO within the party of origin. Whether a release 'leads or may lead' to an unintentional transboundary movement depends on the factual circumstances, including

273 *Pavoni* (n. 4), 119.
274 *Mackenzie* et al., IUCN Guide (n. 4), MN. 460.

the capacity of the LMO to spread and the proximity to the border of other states.[275]

Moreover, the LMO in question must be 'likely to have significant adverse effects' on biodiversity. A decision adopted by COP-MOP 8 clarified that the requirements of Article 17 only apply when the LMO involved is likely to have significant adverse effects on biodiversity in the affected or potentially affected states.[276] Whether this is the case will largely depend on the individual characteristics of the LMO and the likely receiving environment. However, the purpose of the obligation, which is to allow other states to take necessary response action, implies that notifications should rather err on the side of caution.[277]

Article 17(3) CP specifies the minimum information that any notification to affected or potentially affected states should contain.[278] This includes any available information on the estimated quantities and relevant characteristics or traits of the LMO, the possible adverse effects the LMO may have, and possible risk management measures. According to Article 17(2) CP, each state shall communicate its point of contact to receive these notifications. Moreover, Article 17(4) CP requires the responsible party to immediately consult the affected or potentially affected states 'to enable them to determine appropriate responses and initiate necessary action, including emergency measures'.

Apart from notifying and consulting with the affected state, the Cartagena Protocol does not oblige the responsible state to offer any other response to an unintentional transboundary movement. This falls short of the provision on *illegal* transboundary movements in Article 25(2), which requires the responsible state to dispose of the LMO at its own expense by repatriation or destruction.[279] The Cartagena Protocol contains no comparable obligation to contain and dispose of an LMO in cases of unintentional transboundary movements. Since the scope of Article 25 is expressly limited to intentional transboundary movements,[280] there is

275 *Ibid.*, MN. 483.
276 CP COP-MOP Decision VIII/16 (2016) (n. 255), Annex; see *Lim/Lim* (n. 76), 32–33.
277 *Mackenzie* et al., IUCN Guide (n. 4), MN. 484–485.
278 See *Young* (n. 105), 337–338.
279 See *infra* section A.II.2.c)bb).
280 *Susanne Förster*, Internationale Haftungsregeln für schädliche Folgewirkungen gentechnisch veränderter Organismen (2007), 55, discusses whether unintentional transboundary movements could also constitute illegal transboundary movements. However, the phrase '*carried out* in contravention' in Article 25(1)

also no room for an extensive interpretation of that provision. Hence, the Cartagena Protocol does not provide any substantive obligations (besides notification and consultation) in cases of unintentional transboundary movements.

c) Illegal Transboundary Movements (Article 25)

Article 25 CP concerns intentional[281] but illegal transboundary movements, which are defined as movements carried out in contravention of the party's domestic measures to implement the Cartagena Protocol.

aa) Prevention of Illegal Transboundary Movements (para. 1)

Article 25(1) CP provides that states shall adopt appropriate measures[282] to prevent illegal transboundary movements. In principle, the provision applies to both exports and imports of LMOs.[283] *Importing parties* are required to enforce their domestic implementation of the AIA mechanism. This means that states shall not admit the import of LMOs into their territory unless their competent authority has approved the import in accordance with the domestic laws implementing the AIA mechanism. Moreover, as the scope of Article 25(1) CP is not limited to LMOs that are subject to the AIA procedure, the provision also applies to any other domestic measures to implement the Protocol.[284]

The obligations of *exporting parties* under Article 25(1) CP are more difficult to identify. As noted earlier, Article 8 requires exporting parties to ensure that the competent authority of the importing party is duly notified prior to the intended transboundary movement.[285] However, the Cartagena Protocol does not contain an express provision obliging the exporting party to prevent and penalize exports of LMOs without the AIA of the importing party. This sharply contrasts with comparable instruments,

clearly indicates that the provision only concerns intentional transboundary movements.

281 See previous footnote.

282 See *supra* section A.II.2.a)cc)(2).

283 *Mackenzie* et al., IUCN Guide (n. 4), MN. 616.

284 *Ibid.*, MN. 618.

285 See *supra* sections A.II.1.b) and A.II.1.g)bb).

such as the Basel Convention[286] and the Amsterdam Convention[287], which expressly require their respective parties to prohibit exports when the consent of the importing state is pending or has been denied.[288] Nevertheless, the practical differences appear to be negligible: in the European Union, Article 5 of Regulation 1946/2003[289] provides that transboundary movements to states outside the customs territory of the EU shall not be made without the 'prior written express consent' of the importing state.[290] According to Article 18 of Regulation 1946/2003, the EU member states shall implement 'effective, proportionate and dissuasive penalties' for infringements of the Regulation.[291] In Germany, for instance, any intentional transboundary movement made in violation of Article 5 of Regulation 1946/2003 shall be punishable by up to three years imprisonment.[292]

Notably, under Article 25(1) CP, the illegal nature of a transboundary movement is judged exclusively against a party's domestic implementing measures, not the provisions of the Protocol itself.[293] Hence, the obligation presumes that the parties concerned have adopted appropriate domestic measures to implement the Cartagena Protocol, as required by Article 2(1) CP. However, parties enjoy much leeway how they implement the

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286 Pursuant to Article 4(1) of the Basel Convention (n. 101), parties shall prohibit or shall not permit the export of hazardous wastes if the state of import has prohibited the import of such wastes, or does not consent in writing to the specific import.

287 Pursuant to Article 11 of the Rotterdam Convention (n. 102), each party shall take appropriate legislative or administrative measures to ensure that exporters within its jurisdiction comply with decisions of the importing party about the import of chemicals governed by the Convention, and shall ensure that chemicals are not exported when the importing party has failed to communicate a decision.

288 *Stoll* (n. 104), 91.

289 Regulation 1946/2003 (n. 213); see *infra* section A.IV.1.

290 Note that Regulation 1946/2003 not only applies to transboundary movements to third states which are parties to the Cartagena Protocol, but expressly includes transboundary movements to non-parties.

291 For examples from other jurisdictions, see *Young* (n. 105), 367–370.

292 See Gesetz zur Durchführung der Verordnungen der Europäischen Gemeinschaft oder der Europäischen Union auf dem Gebiet der Gentechnik und über die Kennzeichnung ohne Anwendung gentechnischer Verfahren hergestellter Lebensmittel (Act Implementing the Regulations of the European Community or of the European Union in the Field of Genetic Engineering and on Labelling of Food Manufactured without using Genetic Engineering Procedures) (22 June 2004), as last amended by ordinance of 4 July 2021 (Bundesgesetzblatt Pt. I, p. 3274), Section 6(2).

293 *Mackenzie* et al., IUCN Guide (n. 4), MN. 619.

Cartagena Protocol's provisions into their domestic law.[294] Consequently, the Protocol does not necessarily provide a universal standard of what is considered an illegal transboundary movement.[295]

Therefore, a particular transboundary movement may be illegal under the laws of the receiving state even if it was lawful under the measures of the party of export.[296] Moreover, the Protocol does not expressly address situations in which a party has failed to enact appropriate domestic implementation measures.[297] In such a case, Article 25(1) might be inapplicable. The legal consequences of such a situation, which would constitute a breach of the Cartagena Protocol, are governed by the general international law on state responsibility.[298]

bb) Obligation to Dispose of the LMO in Case of an Illegal Transboundary Movement (para. 2)

Article 25(2) CP provides that when an illegal transboundary movement occurs, the affected party may request the party of origin to dispose of the LMO in question by repatriation or destruction at its own expense. Although a literal reading might suggest otherwise,[299] it is not at the discretion of the party of origin whether it complies with such a request. Instead, the phrase 'may request' implies the right of the affected party to choose whether it wants the LMO to be disposed of, with the party of origin being legally required to comply with such a request. The responsible

294 *Ibid.*, MN. 178; see *Kirsten Schmalenbach*, Article 26, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 47, who points out that 'numerous treaties explicitly address the duty to take measures of domestic implementation […] without constraining the party's freedom of choice with respect to the manner of domestic implementation'.

295 *Mackenzie* et al., IUCN Guide (n. 4), MN. 619.

296 *Ibid.*

297 *Ibid.*

298 Note that Article 11 of the Nagoya/Kuala Lumpur Supplementary Protocol expressly states that the international law of state responsibility shall remain unaffected by said protocol. See *Lefeber* (n. 262), 76–78 and chapter 6, section E.III. On the law of state responsibility, see chapter 9.

299 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 622, who suggest that it could be at the discretion of the responsible party whether it complies with a request under Article 25(2) CP, contrasting the present provision with Article 9 of the Basel Convention (n. 101) which provides that the responsible party 'shall ensure' that the wastes are appropriately disposed of.

party does not necessarily have to take the necessary measures itself. It may also require the person or entity responsible for the illegal transboundary movement to implement these measures, or commission a third party to take the required action.[300] However, the responsible party remains fully responsible for the fulfilment of its obligation. Article 25(2) does not stipulate a mere procedural obligation but provides for a particular result, namely the complete removal of the LMO from the territory of the affected party.

The consequences of this provision are potentially far-reaching, as they could amount to a form of *de facto* 'strict state liability' for illegal transboundary movements, which would apply independently from whether the state of origin has itself breached its obligation to prevent such movements.[301] A similar obligation can be found in the *Basel Convention on Hazardous Wastes*: if a transboundary movement of hazardous wastes is illegal due to the conduct of the generator or exporter, the state of export shall ensure that the wastes in question are taken back into its territory or otherwise disposed of lawfully.[302] Thus, whereas an illegal transboundary movement does not by itself give rise to the international responsibility of the state of export, non-compliance with the obligations to take back such wastes may entail state responsibility.[303]

Nevertheless, the precise content of the obligation in Article 25(2) is ambiguous. The LMO in question shall be disposed of by 'repatriation or destruction'. 'Repatriation' means the re-import of the LMO to its state of origin.[304] As 'destruction' is mentioned as an alternative to its 'repatriation', it can be assumed that destruction could also be carried out within the territory of the affected party. However, the Protocol does not further indicate how the repatriation or destruction of the LMO shall be achieved. While this may be rather easy to accomplish as long as the LMO is held in containment, it is not clear how an LMO shall be repatriated or destroyed once it has been released into the environment of the affected party. This is especially true in the context of self-spreading LMOs such as engineered gene drives or viruses.

300 *Mackenzie* et al., IUCN Guide (n. 4), MN. 621.
301 See chapter 10.
302 Basel Convention (n. 101), Article 8(2).
303 See *Katharina Kummer Peiry*, Transboundary Movement of Hazardous Waste and Chemicals, in: André Nollkaemper/Ilias Plakokefalos et al. (eds.), The Practice of Shared Responsibility in International Law (2017) 936, 947–949.
304 *Mackenzie* et al., IUCN Guide (n. 4), MN. 620; cf. 'repatriation, n.', in Oxford English Dictionary (n. 12).

Moreover, the Protocol does not address cases in which both repatriation and destruction are materially impossible or would involve a burden out of all proportion. Hence, the obligation is breached whenever the state of origin neither repatriates nor disposes of the LMO, regardless of the reasons. However, in some cases, the international responsibility of the state of origin may nevertheless be precluded if its failure to dispose of the LMO is owed to *force majeure*.[305] It has also been suggested that if the situation requires urgent action, the affected party might take the required measures and subsequently claim reimbursement of the necessary expenses from the responsible party.[306]

Finally, Article 25(2) CP insufficiently addresses situations in which an LMO that was subject to an illegal transboundary movement has already caused damage in the territory of the affected party.[307] In these cases, the affected party needs to resort to the provisions on liability and redress contained in the Supplementary Protocol (insofar as they are applicable)[308] or to the principles of state responsibility (insofar as a failure of the exporting party to adequately regulate and oversee the conduct of the relevant private actors can be established).[309]

d) Handling, Transport, Packaging, and Identification (Article 18(1))

In order to avert adverse effects on biodiversity, Article 18(1) requires that LMOs subject to intentional transboundary movement are 'handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards'.[310] Such rules and standards are

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305 Cf. ILC, Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries (2001), YBILC 2001, vol. II(2), p. 31, Article 23; see chapter 9, section A.IV.4.

306 *Gurdial S. Nijar* et al., Developing a Liability and Redress Regime Under the Cartagena Protocol on Biosafety: For Damage Resulting from the Transboundary Movements of Genetically Modified Organisms (2005), 60.

307 *Förster* (n. 280), 202, referring to *Nijar* et al. (n. 306), 61, who suggest that when the presence has created an irreversible situation that cannot be restored by the destruction of the LMO, Article 25(2) could also give rise to other forms of reparation.

308 See chapter 6.

309 See chapter 9.

310 For an account of relevant international instruments, see *Stoll* (n. 104), 92. For a review of national laws dealing with handling, transport, packaging, and identification of LMOs, see *Thomas P. Redick*, Handling, Transport, Packaging, and In-

promulgated, for example, in the measures adopted under the frameworks of the International Plant Protection Convention,[311] the World Organisation for Animal Health,[312] and the *Codex Alimentarius*.[313] Moreover, specific international rules exist on the transport of hazardous goods, which may also apply to certain LMOs.[314] Article 18(2) CP requires that LMOs are accompanied by documentation that identifies them as LMOs, specifies any requirements for their safe handling and use, and declares a point of contact for obtaining further information.[315] With regard to LMO-FFPs, COP-MOP 3 adopted additional requirements for documentation.[316]

e) Conclusions

In principle, the risk management provisions in Articles 16–18 and 25 of the Protocol are independent of the Protocol's AIA mechanism. Yet, most of these provisions still focus on the transboundary movement of LMOs. Articles 16(2) and 18 CP only apply to LMOs that are subject to intentional transboundary movement, while Articles 16(3), 17 and 25 CP provide for the prevention of unintentional and illegal transboundary movements, as well as for response measures where such movements occur nevertheless. Only Article 16(1), (4) and (5) CP apply to all LMOs regardless of whether they are subject to transboundary movement. But these provisions are particularly vague and merely require states to cooperate and to 'endeavour' to subject all LMOs to adequate observation periods.

This shows that the present provisions are not so much aimed at protecting biodiversity as a global common, but rather at protecting the national sovereignty of receiving states and their environment.[317] Within certain limits, each state is free to determine its own standard of care[318] as long as

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formation, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 89, 95–107.

311 See *infra* section D.

312 See *infra* section E.

313 See *infra* section F.

314 See *infra* section H.

315 Cf. *Eggers/Mackenzie* (n. 4), 532–533; *Bernasconi-Osterwalder* (n. 90), 653–654.

316 Cf. CP COP-MOP, Decision BS-III/10. Handling, Transport, Packaging and Identification of Living Modified Organisms: Paragraph 2 (A) Of Article 18, UN Doc. UNEP/CBD/BS/COP-MOP/3/15, p. 60 (2006).

317 Cf. *Pavoni* (n. 4), 118–120.

318 Cf. *ibid.*, 116; *Falkner* (n. 4), 311; *Jaffe* (n. 177), 304.

it ensures that LMOs are not unintentionally or illegally moved into the territory of other states.

3. Information-Sharing Through the Biosafety Clearing-House (Article 20)

Article 20 of the Protocol establishes the so-called *Biosafety Clearing-House* (BCH), an internet platform facilitating the exchange of scientific, technical, environmental and legal information relating to the use of and trade in LMOs.[319] The Cartagena Protocol specifies categories of information that parties are required to submit to the BCH.[320] Most importantly, parties shall notify their final decisions regarding the importation or release of LMOs.[321] Moreover, parties must make available summaries of their risk assessments or environmental reviews generated by their regulatory processes in accordance with Article 15 CP.[322]

In the aforementioned case concerning the transboundary movement of modified mosquitoes to Burkina Faso, the government reportedly authorized experimental releases of genetically modified mosquitoes.[323] As of May 2022, no information has been made available on the BCH.[324] However, there is no deadline for submitting risk assessment summaries

319 Biosafety Clearing-House (n. 206); see CP COP-MOP, Decision BS-I/3. Information-Sharing and the Biosafety Clearing-House (Article 20): Modalities of Operation of the Biosafety Clearing-House, UN Doc. UNEP/CBD/BS/COP-MOP/1/15, p. 35 (2004); also see *Tomme R. Young*, Use of the Biosafety Clearing-House in Practice, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 137.

320 For a full list of the categories of information that parties are required to submit to the BCH, see CP COP-MOP Decision BS-I/3 (2004) (n. 319), Annex, Part A; *Mackenzie* et al., IUCN Guide (n. 4), MN. 542.

321 Article 20(3)(d) CP.

322 Article 20(3)(c) CP. Note that this provision could also be interpreted as only requiring the submission of assessments carried out pursuant to Article 15, which means within an AIA procedure. However, the provision expressly refers to assessments and reviews ‘generated by [the party’s] regulatory process’ besides those carried out in accordance with Article 15.

323 See *supra* section A.II.1.g).

324 Cf. Biosafety Clearing-House, Burkina Faso: Country's Decision or Any Other Communication, available at: https://bch.cbd.int/en/countries/BF/DEC (last accessed 28 May 2022).

and release permits to the BCH.[325] Burkina Faso previously notified its authorizations with significant delays of one year and longer.[326]

Besides the aforementioned information, parties shall share relevant information on their domestic regulatory framework implementing the Cartagena Protocol and any relevant international arrangements.[327] Parties must also notify unintentional transboundary movements and illegal transboundary movements.[328] In addition, the BCH is meant to assist parties in implementing the Protocol and to facilitate information-sharing between governments and researchers.[329] Most information shared with the BCH is publicly available,[330] and non-parties to the Cartagena Protocol are expressly encouraged to contribute appropriate information to the BCH.[331]

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325 Such a deadline has been set neither in Article 20 CP nor in COP decision BS-I/3 of 2004 establishing the modalities of operation for the Biosafety Clearing-House. Also see UNEP-GEF BCH Project, An Introduction to the Biosafety Clearing House (2011), 21, which indicates that no timeframe is specified for reporting information pursuant to Article 20(3) CP. In contrast, within the AIA procedure, state parties must to communicate their decision whether or not to allow the import of an LMO to the Biosafety Clearing-House and the notifier within 270 days of the date of receiving the notification.

326 See Biosafety Clearing-House (n. 324).

327 Article 20(3)(a) CP.

328 Articles 17(1) CP and 25(3) CP.

329 Cf. *Kirsty G. McLean*, Bridging the Gap Between Researchers and Policy-Makers: International Collaboration Through the Biosafety Clearing-House, 4 (2005) Environmental Biosafety Research 123.

330 On this issue, see *Aarti Gupta*, Transparency to What End? Governing by Disclosure Through the Biosafety Clearing House, 28 (2010) Environment and Planning C: Government and Policy 128.

331 Cf. Article 24(2) Cartagena Protocol.

4. Application in Relation to Non-Parties (Article 24)

In principle, international treaties only create rights and obligations between their parties.[332] Hence, a non-party[333] is neither bound by the provisions of the Cartagena Protocol nor can it derive any rights from it. This raises the question of how transboundary movements between parties and non-parties to the Cartagena Protocol should be governed.

Some multilateral environmental agreements on trade in potentially harmful substances prohibit transactions with non-parties unless the non-party fulfils certain minimum standards of protection.[334] The Cartagena Protocol does not contain such a provision but merely stipulates in Article 24 CP that transboundary movements between parties and non-parties shall be 'consistent with the objective of this Protocol'.[335]

According to Article 1 CP, the general objective of the Protocol is to ensure an adequate level of protection in the field of the safe transfer, handling and use of LMOs. This is mainly implemented through the Protocol's AIA mechanism, under which transboundary movements of LMOs shall be subject to the prior consent of the importing party.[336] It appears safe to conclude that this also forms part of the Protocol's objective. Consequently, it follows from Article 24 CP that transboundary movements

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332 See Article 34 VCLT (n. 18), which reads: 'A treaty does not create either obligations or rights for a third State without its consent', while 'third State' is defined in Article 2(1)(h) VCLT as a state not party to the treaty. Also see PCIJ, Certain German Interests in Polish Upper Silesia, Merits Judgment of 25 May 1926, PCIJ Rep. Ser. A, No. 7, 29, which observed: 'A treaty only creates law as between the States which are parties to it; in case of doubt, no rights can be deduced from it in favour of third States.'

333 The term 'non-Party' is not defined in the CBD or the Cartagena Protocol, but appears to be synonymous to that of a 'third State' as defined in Article 2(1)(h) VCLT (n. 18) (see preceding footnote).

334 Cf. Convention on International Trade in Endangered Species of Wild Fauna and Flora (03 March 1973; effective 01 July 1975), 993 UNTS 244, Article X; Montreal Protocol on Substances that Deplete the Ozone Layer (16 September 1987; effective 01 January 1989), 1522 UNTS 3, as last amended by the Meeting of Parties in 2018, Article 4; Basel Convention (n. 101), Articles 4(5) and 11; see *Mackenzie* et al., IUCN Guide (n. 4), Box 42 on p. 154; *Bernasconi-Osterwalder* (n. 90), 654–655.

335 See generally *Kate Cook*, Non-Parties, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 351.

336 See *supra* section A.II.1.h).

of LMOs shall not be conducted without obtaining the consent of the importing party.[337]

The consequences of this principle differ according to whether the party to the Protocol is importing an LMO *from* a non-party or exporting an LMO *to* a non-party. When the party is the importing state, Article 24 CP requires it not to allow imports of LMOs intended for release into the environment without prior authorization by its national authorities based on a risk assessment.[338] However, the exporting non-party is not bound by the Cartagena Protocol and therefore not obliged to ensure prior notification of the receiving state under Article 8 CP. The importing party should attempt to compensate this by requiring a prior notification from the importer under its domestic legislation and by prohibiting and penalizing imports of LMOs carried out without authorization by its competent national authority.[339] In practice, this will often result in extending the domestic laws implementing the AIA mechanism to imports from non-parties.[340] However, the party must ensure that its requirements are compatible with its obligations under international trade law, because it cannot rely on the Cartagena Protocol to justify trade restrictions vis-à-vis the non-party.[341]

When the party is the exporting state, Article 24 CP requires it to ensure that a non-party is notified prior to any intended transboundary movement, either according to Article 8 CP or in another appropriate way that allows the importing party to deny or approve the movement.[342] Moreover, parties shall ensure that a risk assessment is carried out in line with the standards of the Cartagena Protocol.[343] An exporting party, however, is not required to wait for the receiving state to agree to the

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337 See *Bernasconi-Osterwalder* (n. 90), 655, who assumes that trading with non-parties is not necessarily subject to the specific provisions on AIA or risk assessment, but that parties are required to apply a precautionary approach in the sense of Principle 15 of the Rio Declaration 1992 (n. 260).

338 *Cook* (n. 335), 360; *Mackenzie* et al., IUCN Guide (n. 4), MN. 612.

339 Cf. CP COP-MOP, Guidance on the Transboundary Movement of Living Modified Organisms Between Parties and Non-Parties, Annex to Decision BS-I/11, UN Doc. UNEP/CBD/BS/COP-MOP/1/15, p. 139 (2004), para. 1d.

340 Cf. *ibid.*

341 See *infra* section C.

342 Cf. *Mackenzie* et al., IUCN Guide (n. 4), MN. 612; CP COP-MOP, Guidance on Transboundary Movements between Parties and Non-Parties (2004) (n. 339), paras. 1a and 1b.

343 CP COP-MOP, Guidance on Transboundary Movements between Parties and Non-Parties (2004) (n. 339), para. 1c.

transboundary movement because the latter, as a non-party, cannot derive any rights from the Protocol.[344] If the receiving state does not react to a notification, it could, therefore, be assumed that it has acquiesced to the transboundary movement.[345] However, when the receiving state has no appropriate regulatory framework to regulate the use and environmental release of LMOs,[346] it may be problematic to assume consent by acquiescence. In these situations, it may be questioned whether an export is at all consistent with the objective of the Protocol, as required by Article 24.[347] This is particularly relevant for LMOs that are capable of self-propagation and, therefore, may have a lasting impact on the environment of the receiving state.

5. Upward Derogation (Articles 2(4) and 14)

The Cartagena Protocol contains several provisions that expressly allow for 'upward derogation',[348] which means that parties are free to adopt stricter rules than those foreseen in the Protocol. The most important of these clauses is Article 2(4), which generally allows parties to take action that is 'more protective' of biodiversity than provided for in the

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344 But see *Cook* (n. 335), 353. On the question of treaties conferring rights on third parties, see *Alexander Proelß*, Article 34, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 27–28.

345 On acquiescence in international law generally, see *Nuno S. M. Antunes*, Acquiescence, in: Wolfrum/Peters (ed.), MPEPIL; *Christian J. Tams*, Waiver, Acquiescence and Extinctive Prescription, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 1035, 1042–1045. In the European Union, Article 5(1) of Regulation 1946/2003 (n. 213) governing transboundary movements to and from third states provides: 'A failure by the Party of import to acknowledge receipt of a notification or to communicate its decision shall not imply its consent to an intentional transboundary movement. No first intentional transboundary movement may be made without prior written express consent of the Party or, where appropriate, non-Party of import.' It can clearly be inferred from this provision that the failure of a non-party to reply shall not be regarded as an implied consent either.

346 A number of developing states are not members to the Cartagena Protocol, including Equatorial Guinea, Haiti, Nepal, and Sierra Leone (see UN OLA (n. 6)), and it is questionable whether these states have adopted domestic regulatory frameworks on biotechnology and biosafety without participating in the relevant international forum.

347 *Mackenzie* et al., IUCN Guide (n. 4), MN. 612.

348 Cf. *Redgwell* (n. 4), fn. 52 on p. 556; see *Pavoni* (n. 4), 114–115.

Protocol, provided that such action is consistent with both the Protocol and with that party's international obligations under international (e.g. trade) law.[349] Similarly, Article 14 allows parties to conclude bilateral, regional or multilateral agreements on the transboundary movement of LMOs, provided that such agreements do not result in a lower level of protection than provided for by the Protocol.

6. Liability and Redress (Article 27)

The Cartagena Protocol does not contain substantive provisions relating to liability for damage resulting from transboundary movements of LMOs. Instead, Article 27 committed the parties to enter into negotiations on liability after the Protocol entered into force.[350] Deferring the issue of liability to a separate instrument was a compromise reached during the negotiations of the Cartagena Protocol, where it was highly controversial whether the Protocol should include rules on liability at all.[351] Many developing countries insisted on the inclusion of substantive provisions on liability, arguing that they were not prepared to bear the risks associated with the transboundary movement of LMOs into their territories, particularly in light of their often very limited capacities to carry out adequate risk assessments.[352] Many developed countries opposed the inclusion of provisions on liability altogether, arguing that this issue could be dealt with by domestic legislation, private international law,[353] and the international law of state responsibility.[354] Eventually, it was agreed to detach and postpone the deliberations of liability and to adopt an 'enabling clause' in

349 Cf. *Redgwell* (n. 4), 555; *Bernasconi-Osterwalder* (n. 90), 648.

350 Article 27 of the Cartagena Protocol reads: 'The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.'

351 See generally *Kate Cook*, Liability: 'No Liability, No Protocol', in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 371.

352 *Ibid.*, 373–374.

353 *Mackenzie* et al., IUCN Guide (n. 4), MN. 643.

354 *Cook* (n. 351), 374.

Article 27.[355] Negotiations based on this mandate led to the adoption of the *Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress* in 2010, which is assessed in chapter 6 below.

III. Conclusions

The preceding analysis has shown that the Cartagena Protocol is primarily concerned with ensuring that products of modern biotechnology that are permitted under the jurisdiction of one state and are, in principle, freely available in international markets do not cause harm to the environment of other states.[356] To this end, the Cartagena Protocol contains detailed rules on the procedure of seeking an AIA and the associated risk assessment. At the same time, the Cartagena Protocol contains no material provision outlining under what circumstances an import should be allowed, subjected to conditions, or denied entirely. Instead, the standardized procedure and the harmonized risk assessment are only in place to enable the receiving state to take a sovereign decision in line with its risk management demands and the level of environmental protection chosen for its national territory.[357] The regulatory pathway chosen for the AIA mechanisms reflects the Protocol's overall spirit: The Protocol is not meant not to establish a comprehensive regime on trade in LMOs but rather follows a 'minimal harmonization' approach.[358] On the procedural side, the Protocol establishes guardrails for coordinating transboundary situations

355 Cf. IISD, Report of the Sixth Session of the Open-Ended Ad Hoc Working Group on Biosafety and the First Extraordinary Session of the CBD Conference of the Parties: 14–23 February 1999, ENB Vol. 9 No. 117 (1999), 8.

356 *Pavoni* (n. 4), 118.

357 *Ibid.*, 127. In this respect there is a striking similarity to environmental human rights law, where international judicial bodies often confer strong procedural and participatory rights to the affected individuals while leaving states a wide margin of discretion with regard to the material questions, i.e. the outcome of decision-making processes, see *Silja Vöneky/Felix Beck*, Umweltschutz und Menschenrechte, in: Alexander Proelß (ed.), Internationales Umweltrecht (2nd ed. 2022) 191, MN. 158.

358 *Pavoni* (n. 4), 114. But see *Sdunzig* (n. 133), 398–401, who concludes that the preciseness and specificity of the obligations laid down in the Cartagena Protocol are quite high, in particular when compared to the CBD.

while, in substantive terms, it retains the sovereign right of parties to set the level of biosafety protection they deem appropriate.[359]

In any case, while the Cartagena Protocol broadly retains the right of each state to take sovereign decisions about whether or not to allow the import and use of certain LMOs, it appears likely that international trade law will largely restrict this broad margin of discretion.[360]

The Cartagena Protocol also contains a range of provisions that apply regardless of whether an LMO is subject to a (deliberate) transboundary movement and thus regulated by the AIA mechanism. However, many of these provisions remain rather vague and it is questionable how compliance with them can be reasonably monitored. In this regard, the subsequent work done by the COP-MOP and a number of subsidiary bodies is of special relevance.[361]

IV. Excursus: The Relationship Between the Cartagena Protocol and EU Biotechnology Law

It is widely assumed that the European Union's (EU) regulatory framework on *genetically modified organisms* (GMOs) is in line with the Cartagena Protocol's provisions on *living modified organisms* (LMOs).[362] It is questionable, however, whether the scopes of both regimes are indeed fully congruent. The present section firstly provides an overview of the European legal framework for GMOs, including the regulation implementing the Cartagena Protocol (1.), before discussing the scope of the European regime in light of the judgment on *targeted mutagenesis* rendered by the

359 Cf. *Pavoni* (n. 4), 114–116; *Gregory Jaffe*, Crafting National Biosafety Systems, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 48, 56.

360 See *infra* section C.

361 For an analysis on the ongoing discussion about the international regulation of engineered gene drives, see chapter 5.

362 See, e.g., *Christoph Bail* et al., European Union, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 166; Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council on the Transboundary Movement of Genetically Modified Organisms, Explanatory Memorandum (25 June 2002), COM(2002) 85 final – 2002/0046(COD) (hereinafter 'Commission Proposal on Directive 1946/2003'); *Callebaut* (n. 11), 47; *Kahrmann/Leggewie* (n. 47), 501–502.

Court of Justice of the European Union in 2018 (2.). A comparison of the European regime with the Cartagena Protocol shows that the scope of the latter is significantly wider, which must be taken into account when discussing a reform of the EU's GMO legislation (3.).

1. The European Union's Legal Framework for GMOs

The EU's biotechnology legislation consists of a complex web of Regulations and Directives.[363] The most important of these instruments is *Directive 2001/18/EC*, which addresses the deliberate release of GMOs into the environment.[364] Under this Directive, authorization must be obtained before a GMO is released into the environment or placed on the market for the first time.[365] The Directive provides for a case-by-case assessment of the potential adverse effects a particular GMO may have on human health and the environment, which is conducted under the auspices of the *European Food Safety Authority* (EFSA). Authorizations shall be recognized throughout the EU, although member states are allowed to unilaterally restrict or prohibit the release of a GMO even if it has been authorized at the European level.[366] For genetically modified food and feed, a similar authorization procedure has been introduced by Regulation (EC) No 1829/2003.[367]

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363 For an overview of the pertinent legal acts, see European Commission, GMO Legislation, available at: https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-legislation_en (last accessed 28 May 2022). For general introductions to the regulation of GMOs in the EU, see *Maria Lee*, EU Regulation of GMOs (2008); *Hans-Georg Dederer*, Options for the Regulation of Genome Edited Plants – Framing the Issues, in: Christian Dürnberger/Sebastian Pfeilmeier/Stephan Schleissing (eds.), Genome Editing in Agriculture (2019) 77.

364 Directive 2001/18/EC (n. 218).

365 See Articles 4, 6 and 13 of Directive 2001/18/EC. For an overview of the Directive's key mechanisms, see *Paula Rey García*, Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs: An Overview and the Main Provisions for Placing on the Market, 3 (2006) JEEPL 3.

366 See Article 26b of Directive 2001/18/EC, which was introduced by Directive (EU) 2015/412 Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of Genetically Modified Organisms (GMOs) In Their Territory (11 March 2015), OJ L 68, p. 1.

367 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed (22 September 2003), OJ L 268, p. 1.

Directive 2001/18/EC can be described as the 'centrepiece' of the European Union's GMO legislation because it contains the decisive definition of what constitutes a 'genetically modified organism' and sets the substantive requirements for the risk assessment. All other European legislative instruments on GMOs either refer to this definition[368] or use nearly identical language to determine their own scope.[369]

Both the European Union and all of its member states have signed and ratified the Cartagena Protocol on Biosafety.[370] To implement the Protocol's provisions in internal law, the European Union has adopted Regulation (EC) No 1946/2003,[371] which aims to 'ensure coherent implementation of the provisions of the Protocol on behalf of the Community'.[372] The Regulation applies to the transboundary movement of LMOs between the EU and third states, but not to intentional transboundary movements among EU member states.[373] This is in accordance with Article 14(3) of the Cartagena Protocol, which allows other agreements to take precedence over the Protocol, provided that these agreements are consistent with the objective of the Protocol and do not result in a lower level of protection.[374] The EU regime on GMOs, which provides for a Union-wide authorization procedure for the placing on the market and deliberate environmental release of such organisms,[375] is deemed to constitute such a separate agreement that is consistent with the requirements of Article

368 Cf. *ibid.*, Article 2(5); Regulation (EC) No 1830/2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms (22 September 2003), OJ L 268, p. 24, Article 3(1); Regulation 1946/2003 (n. 213), Article 2(5). All these provisions apply to 'genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC'.

369 Cf. Directive 2009/41/EC on the Contained Use of Genetically Modified Micro-Organisms (06 May 2009), OJ L 125, p. 75, Article 2 lit. b, which provides that '"genetically modified micro-organism" (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.

370 Cf. UN OLA (n. 6); see Council of the European Communities, Council Decision Concerning the Conclusion of the Convention on Biological Diversity (93/626/EEC) (25 October 1993), OJ L 309, p. 1.

371 Regulation 1946/2003 (n. 213).

372 *Ibid.*, Article 1.

373 *Ibid.*, Article 3(14).

374 Cf. Commission Proposal on Directive 1946/2003 (n. 362).

375 Cf. Directive 2001/18/EC (n. 218).

14(1) of the Cartagena Protocol.[376] The EU legislation also covers imports of GMOs from third states into the European Union. This is in line with Article 14(4) of the Cartagena Protocol,[377] which allows parties to use their domestic regulations instead of the Cartagena Protocol's AIA procedure for regulating specific imports into its territory.[378]

2. Scope of the GMO Regime in the European Union

Unlike the Cartagena Protocol, the European Union's biosafety legislation does not apply to *LMOs*, but to *GMOs*. The term 'genetically modified organism' is defined in Article 2(2) of Directive 2001/18/EC as

> *'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.*

The definition is complemented by three lists in an Annex to the Directive. The first list specifies certain techniques that are deemed to result in GMOs in terms of the Directive.[379] The second list specifies techniques that are deemed *not* to result in GMOs.[380] The third list contains techniques that, despite being deemed to result in a genetic modification, are exempted from regulation under certain conditions.[381] This third list includes the term 'mutagenesis' but does not further define this term.[382]

There has been fierce controversy over whether the current regulatory regime for GMOs in the EU applies to organisms (in particular, plants[383]) in which the genetic material has been altered with *targeted mutagenesis techniques*. This denotes applications of genome editing where only point mutations are created without (permanently) inserting foreign DNA into

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376 Commission Proposal on Directive 1946/2003 (n. 362).

377 *Mackenzie* et al., IUCN Guide (n. 4), 411–413; Commission Proposal on Directive 1946/2003 (n. 362).

378 Regulation 1946/2003 (n. 213), Recitals 13–14 and Article 3(2).

379 Cf. Directive 2001/18/EC (n. 218), Annex I A Part 1.

380 Cf. *ibid.*, Annex I A Part 2.

381 Cf. *ibid.*, Annex I B; also see Directive 2001/18/EC (n. 218), Article 3(1).

382 Cf. *ibid.*, Annex I B, para. 1.

383 In the controversy over the regulation of genome-edited crops in the European Union, frequent use is made of the term 'New Plant Breeding Techniques' which includes not only genome editing techniques but also a number of other modern breeding methods such as *agro-infiltration*, *grafting* and *reverse breeding*, cf. New Techniques Working Group, Final Report (n. 39).

the genome of the target organism.[384] According to proponents of these techniques, targeted mutagenesis leads to genetic modifications which cannot be distinguished from mutations that (could) have occurred naturally and that the resulting organisms should therefore not be regulated as GMOs.[385]

In July 2018, the *Court of Justice of the European Union* held that organisms whose genetic material has been modified by targeted mutagenesis techniques fall within the scope of the Directive 2001/18/EC and thus are subject to regulation as GMOs in the EU.[386] In particular, the Court held that organisms bred with these techniques were not covered by the aforementioned exemption of 'mutagenesis' techniques, because this exemption did not apply to techniques that have emerged since the Directive was adopted in 2001.[387] Consequently, more recent mutagenesis techniques do not benefit from the exemption and are thus fully covered by the regulatory regime set out in Directive 2001/18/EC and most other of the EU's GMO regulations.[388] Notably, it seems undisputed that this also ap-

384 Cf. *Hans-Georg Dederer*, The Challenge of Regulating Genetically Modified Organisms in the European Union: Trends and Issues, in: Yumiko Nakanishi (ed.), Contemporary Issues in Environmental Law (2016) 139; *Sprink* et al. (n. 39).

385 *Lusser/Davies* (n. 10), 440–441; *Frank Hartung/Joachim Schiemann*, Precise Plant Breeding Using New Genome Editing Techniques: Opportunities, Safety and Regulation in the EU, 78 (2014) The Plant Journal 742, 749; *Callebaut* (n. 11), 75; *Sprink* et al. (n. 39), 1499–1450; *Kahrmann* et al. (n. 39), 180; *Dennis Eriksson*, Recovering the Original Intentions of Risk Assessment and Management of Genetically Modified Organisms in the European Union, 6 (2018) Front. Bioeng. & Biotechnol. 845, 1–2.

386 CJEU, Confédération paysanne et al. v. Premier ministre et al., Judgment of 25 July 2018, C-528/16. For a detailed assessment of the judgment, see *Felix Beck*, All About that Risk? A (Re-)Assessment of the CJEU's Reasoning in the "Genome Editing" Case, 17 (2019) EurUP 246.

387 CJEU, Confédération paysanne et al. v. Premier ministre et al. (n. 386), para. 51. For comparisons with other jurisdictions, see *supra* n. 10.

388 *Ibid.*, para. 54. For a discussion on consequences of this judgment, see *Martin Wasmer*, Roads Forward for European GMO Policy, 7 (2019) Front. Bioeng. & Biotechnol. 367. But see *van der Meer* et al. (n. 57), 6–12, who contend that the decisive criterion remained whether the resulting organism is 'altered in a way that does not occur naturally by mating and/or natural recombination' (as required by the GMO definition in Article 2(2) of Directive 2001/18/EC) and that, as long as an organism could have occurred naturally, the scope of the 'mutagenesis' exemption (in Annex I A, part 2) and its interpretation by the CJEU was irrelevant (*ibid*., p. 10). But this rests on an overspecific interpretation of the judgment. The Court clearly recognized that it was 'called upon to rule, in particular, on the techniques/methods of *directed mutagenesis* involving the

plies to self-spreading techniques such as engineered gene drives, as they commonly involve the use of recombinant DNA in the target organism.[389]

3. Compatibility of the European GMO Regime With the Cartagena Protocol

When ratifying the Cartagena Protocol, the European Commission assumed that the Protocol's definition of the term *living modified organism* was 'largely consistent' with the definition of a *genetically modified organism* under the European Directive 2001/18/EC, and that the existing differences were 'not likely to impinge on operational aspects of the legislation'.[390] The Commission did not provide a reasoning for this conclusion. In fact, it is questionable whether both definitions are indeed fully congruent in scope. In contrast to the definition under EU law, the Cartagena Protocol does not focus on whether the genetic material 'has been modified in a way that does not occur naturally'.[391] Instead, it contains two separate elements that clearly distinguish between the process of modification (i.e. 'application of modern biotechnology') and its result (i.e. 'a novel combination of genetic material').[392]

In specifying the meaning of 'modern biotechnology', the Cartagena Protocol uses the generic term '*in vitro* nucleic acid techniques', whereas the EU Directive refers to '*recombinant* nucleic acid techniques'.[393] This

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use of genetic engineering which have appeared or have been mostly developed since Directive 2001/18 was adopted' (CJEU, Confédération paysanne et al. v. Premier ministre et al. (n. 386), para. 47, emphasis added). The Court also expressly held that *all* mutagenesis techniques – both conventional and those relying on 'genetic engineering' – altered the genetic material of an organism in a way that does not occur naturally in the sense of Article 2(2) (*ibid.*, para. 29). While the accuracy of this statement may be challengable from a scientific standpoint, the Court's conclusions in this regard are unequivocal, since it held that the mutagenesis exemption 'cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted' (*ibid.*, para. 51; see *Beck* (n. 386), 248–253).

389 Cf. *Dolezel* et al. (n. 76), 5–6; see *supra* sections A.I.1.e)bb) and cc).

390 Commission Proposal on Directive 1946/2003 (n. 362); on the European Union's position during the negotiations of the Cartagena Protocol, see *Bail* et al. (n. 362).

391 See *supra* section A.IV.2.

392 *Callebaut* (n. 11), 49–50; *van der Meer* et al. (n. 57), 15. See *supra* section A.I.1.

393 Cf. Directive 2001/18/EC (n. 218), Annex I A, Part 1 (emphasis added).

constitutes a decisive difference between both definitions: The term 'recombinant DNA' was coined in the 1970s when DNA molecules of different origins were joined together (i.e. *recombined*) for the first time.[394] Today, the term is commonly used to denote DNA produced *in vitro* by merging genes from different sources.[395] For this reason, some authors have suggested that this could exclude genome editing techniques as long as they do not involve the (permanent) insertion of foreign DNA into the target organism.[396] In contrast, the Cartagena Protocol refers to '*in vitro* nucleic acid techniques'. As shown above, this notion is substantially wider; it does not only cover recombinant DNA techniques (and direct injection of heritable material), but rather all methods where any kind of nucleic acid is prepared *in vitro* and then inserted into the organism to modify that organism's DNA.[397]

The differences between both regimes can also be explained historically. When the European Commission proposed the first Directive on deliberate release in 1988[398] and its revision that was adopted in 2001,[399] it noted the need to periodically update the Directive in order to 'keep pace with scientific and technological progress'.[400] Hence, no need was seen

394 See *D. A. Jackson* et al., Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40, 69 (1972) PNAS 2904; *Stanley N. Cohen* et al., Construction of Biologically Functional Bacterial Plasmids in Vitro, 70 (1973) PNAS 3240.

395 Cf. 'recombinant DNA', in: Henderson's Dictionary of Biology (n. 20), 500–501.

396 New Techniques Working Group, Final Report (n. 39), 6; EFSA, EFSA Response to Mandate M-2015–0183: Request for EFSA to Provide Technical Assistance with Regard to Issues Related to the Legal Analysis of New Plant Breeding Techniques (2015), 1–2; *Callebaut* (n. 11), 62–64; *Kahrmann* et al. (n. 39), 181.

397 See *supra* section A.I.1.d)aa).

398 Commission of the European Communities, Proposal for a Council Directive on the Deliberate Release to the Environment of Genetically Modified Organisms, Explanatory Memorandum (04 May 1988), COM(88) 160 final – SYN 131, 7–10; which states: '[Annex I] is intended to provide, through a periodical update, as [sic] a clarification of what techniques can make an organism 'genetically modified' within the meaning of this Directive'; also see Arts. 18–20 of the proposal, which were eventually not adopted in the Directive.

399 Commission of the European Communities, Report of the Review of Directive 90/220/EC in the Context of the Commission's Communication on Biotechnology and the White Paper (10 December 1996), COM(96) 630 final.

400 *Ibid.*, 10. See *Eriksson* (n. 385).

to further specify the actual definition of the term ‘genetically modified organism’ contained in Article 2(2) of Directive 2001/18/EC.[401]

Like the European legislator, the drafters of the Cartagena Protocol also envisaged that there would be scientific and technological progress after the adoption of the Protocol. They agreed that its scope should be defined in a manner so as to include future techniques that were still unknown at the time.[402] However, including lists of techniques that were to be updated periodically – like originally envisaged in the EU – was not an option for the Cartagena Protocol, as the process of amending multilateral treaties is time-consuming and succeeds only rarely.[403] For this reason, the definition of the terms ‘living modified organism’ (in Article 3(g) CP) and ‘modern biotechnology’ (in Article 3(i) CP) were of special relevance for the scope of the entire Protocol and had to be crafted in a manner that would include potential future techniques. This can also be seen from the intense negotiations that were conducted on the wording of these definitions.[404]

As a result, the scope of the EU’s regulatory framework for GMOs might ‘largely correspond’[405] to that of the Cartagena Protocol, but the scope of both regimes is not identical. Instead, the definition of the term ‘living modified organism’ in the Cartagena Protocol is significantly wider than the respective definition of the term ‘genetically modified organism’ under European law. A future reform of the EU’s legal framework for GMOs, for

401 In fact, however, neither the annexes nor the GMO definition itself have ever been amended, apart from editorial changes. The Directive has been amended five times since its adoption, but none of these amendments addressed the GMO definition or other provisions pertaining the scope of the regime: Regulation (EC) 1829/2003 concerned GM food and feed; Regulation (EC) 1830/2003 concerned rules on traceability; Directive 2008/27/EC changed rules on implementing powers conferred on the Commission; Directive (EU) 2015/412 introduced the ‘opt-out’ mechanism (see fn. 366 and accompanying text); and Commission Directive (EU) 2018/350 amended the rules on environmental risk assessment of GMOs. Also see *Callebaut* (n. 11), 18–19.

402 Cf. ENB Summary of BSWG-4 (n. 33), 5; see *supra* section A.I.1.d)aa).

403 See Article 39 VCLT (n. 18), which lays down rules on the amendment of multilateral treaties; also see *Jan Klabbers*, Treaties, Amendment and Revision, in: Wolfrum/Peters (ed.), MPEPIL, MN. 19–21.

404 Cf. *Gupta* (n. 29), 23; *van der Meer* (n. 13); see *supra* section A.I.1.c).

405 *Callebaut* (n. 11), 47.

which there have been calls[406] and proposals[407], should ensure compatibility with the obligations assumed by the EU and its member states under the Cartagena Protocol.

B. Convention on Biological Diversity

The *Convention on Biological Diversity* of 1992 (CBD) aims to ensure the conservation and sustainable use of biological diversity as well as the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.[408] The CBD contains a number of provisions which are relevant to the regulation of biotechnology and living modified organisms. Although the Cartagena Protocol, which was negotiated within the framework of Article 19(3) CBD, addresses LMOs in much greater detail, the CBD's provisions have not become irrelevant. This is mainly because a number of states that are major stakeholders in the area of modern biotechnology have not ratified the Cartagena Protocol.[409] In contrast, the CBD has been ratified by virtually all states except the United States,[410]

406 Cf. *Agnes E. Ricroch* et al., Editing EU Legislation to Fit Plant Genome Editing, 17 (2016) EMBO Reports 1365; *Sanwen Huang* et al., A Proposed Regulatory Framework for Genome-Edited Crops, 48 (2016) Nature Genetics 109; *Eriksson* (n. 385); *Wasmer* (n. 388); *Petra Jorasch*, Will the EU Stay Out of Step with Science and the Rest of the World on Plant Breeding Innovation?, 39 (2020) Plant Cell Reports 163.

407 Cf. *Dennis Eriksson* et al., Options to Reform the European Union Legislation on GMOs: Scope and Definitions, 38 (2020) Trends in Biotechnology 231; *Juan A. Vives-Vallés/Cécile Collonnier*, The Judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and Interim Legislative Proposal, 10 (2019) Frontiers in Plant Science 1813, 8–9.

408 Article 1 CBD. On the CBD generally, see *Lyle Glowka* et al., A Guide to the Convention on Biological Diversity (1994); *Fiona McConnell*, The Biodiversity Convention (1996); *Désirée M. McGraw*, The CBD – Key Characteristics and Implications for Implementation, 11 (2002) RECIEL 17; *Nele Matz-Lück*, Biological Diversity, International Protection, in: Wolfrum/Peters (ed.), MPEPIL, MN. 25–48; *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 388–397.

409 See *supra* n. 7 and accompanying text.

410 The United States has signed the CBD in 1993 but has not ratified it since. Besides the United States, only the Holy See is not a party to the CBD, see UN OLA, Status of the Convention on Biological Diversity, United Nations Treaty Collection, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8&chapter=27&clang=_en (last accessed 28 May 2022).

thus establishing rules which are – apart from this one exception – universally applicable.[411]

I. Jurisdictional Scope (Article 4)

Article 4 CBD governs the jurisdictional scope of the Biodiversity Convention. With respect to the *components of biological diversity*,[412] the CBD applies to areas within the limits of national jurisdiction. At the same time, the scope is considerably broader for *processes and activities*: the CBD applies to all processes and activities, regardless of whether their effects occur, that are carried out under the party's jurisdiction or control. This expressly includes activities that are conducted in areas beyond the limits of national jurisdiction, such as vessels flying the flag of a party when they are on the high seas.[413] At the same time, the phrase 'regardless of whether their effects occur' signifies that the CBD's scope also includes effects that occur in areas beyond national jurisdiction.[414] Consequently, the CBD applies to both activities conducted and effects occurring in areas beyond national jurisdiction, provided that the activity in question was carried out under the jurisdiction or control of a party to the Convention.[415]

II. Prevention of Transboundary Harm (Article 3)

Article 3 CBD provides that states have the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction. The CBD has been the first legally binding instrument to en-

411 Cf. *Redgwell* (n. 4), 551.

412 The term 'components of biological diversity' is defined nowhere in the CBD. Depending on the context in which it is used, it refers either to the three conceptual levels of biodiversity (ecosystem/species/genetic diversity), or to specific tangible entities such as specific ecosystems; cf. *Glowka* et al., IUCN Guide to the CBD (n. 408), 16. For the purpose of delimiting the scope of the CBD, it suffices to conclude that the term refers to those parts of the variability among living organisms from all sources (cf. Art. 2 CBD) that are permanently or temporarily present in areas within the limits of a party's national jurisdiction; cf. *Glowka* et al., IUCN Guide to the CBD (n. 408), 28.

413 *A. Charlotte de Fontaubert* et al., Biodiversity in the Seas (1996), 3.

414 *Redgwell* (n. 4), 552–553.

415 *Glowka* et al., IUCN Guide to the CBD (n. 408), 28.

shrine this principle, which originated from the Stockholm Declaration of 1972.[416] Interestingly, Article 3 refers not to the CBD's contracting parties as the bearers of the obligation, but to 'States'. Moreover, the provision stipulates that the obligation shall be performed 'in accordance with the Charter of the United Nations and the principles of international law'. This indicates that the drafters of the CBD felt that Article 3 reiterated a principle that was already binding upon states as customary international law. An expert group on liability established by the Conference of Parties to the CBD (CBD COP) assumed that the ILC's *Articles on Prevention*[417] could provide 'useful guidance' for states with respect to Article 3 CBD.[418] The substantive content of Article 3 CBD thus appears to reflect the general 'no harm' doctrine.[419]

III. Regulation and Control of Risks Associated With the Use and Release of Living Modified Organisms (Article 8(g))

Article 8(g) CBD provides that contracting parties shall establish or maintain

> *'means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health'.*

Unlike the Cartagena Protocol, the present provision applies not only to LMOs resulting from 'modern biotechnology' but from 'biotechnology' generally, which is defined in Article 2 CBD as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'.[420] As shown above, the Cartagena Protocol contains a distinct definition of 'modern

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416 *Ibid.*, 26.
417 ILC, Articles on Prevention (n. 260).
418 CBD COP, Report of the Group of Legal and Technical Experts on Liability and Redress in the Context of Paragraph 2 of Article 14 of the Convention on Biological Diversity, UN Doc. UNEP/CBD/COP/8/27/ADD3 (2005), para. 33.
419 See chapter 4.
420 Notably, the term 'biotechnology' already emerged in the 1920s, see 'biotechnology', in: Oxford English Dictionary (n. 12); Henderson's Dictionary of Biology (n. 20), 68.

biotechnology', which specifically refers to *in vitro* nucleic acid techniques and cell fusion.[421] Therefore, the meaning of 'biotechnology' under the CBD is broader than that of 'modern biotechnology' under the Cartagena Protocol.[422] Consequently, the term 'living modified organism' also has a broader meaning under the CBD than it has under the Cartagena Protocol.[423] If certain applications of genome editing fell outside the scope of the Cartagena Protocol, they would thus still be covered by Article 8(g) CBD.[424]

Article 8(g) CBD applies to LMOs 'which are likely to have adverse environmental impacts'. Whether this is the case is usually not known *ab initio*, but needs to be determined in a risk assessment. Hence, the provision has been interpreted as requiring states to approach the potential risks of LMOs 'in a rational, precautionary manner based on the assessment and subsequent regulation, management or control of the risks'.[425] This is supported by Article 7(c) CBD, which provides that parties shall identify processes and activities which have or are likely to have significant adverse impacts on biodiversity.[426] The degree of control applied should be premised on the likelihood that an organism will have adverse impacts.[427]

The CBD COP has only rarely addressed Article 8(g). Instead, its focus was mostly on the need for, and modalities of, a protocol on biosafety as envisioned in Article 19(3) CBD.[428] After the adoption of the Cartagena Protocol, most of the work on LMOs was conducted in the framework of the meeting of the parties to the latter. At first sight, this may seem like a mere formality, as the CBD COP also serves as the meeting of parties to the Cartagena Protocol (COP-MOP).[429] However, since fewer states have ratified the Cartagena Protocol than the CBD, any decisions adopted

421 See Article 3(i) CP and *supra* section A.I.1.d).
422 Report of the AHTEG on Synthetic Biology 2019 (n. 11), para. 21.
423 See chapter 2, n. 5 and accompanying text.
424 Report of the AHTEG on Synthetic Biology 2019 (n. 11), para. 20.
425 *Glowka* et al., IUCN Guide to the CBD (n. 408), 45.
426 Cf. *Lim/Lim* (n. 76), 10.
427 *Glowka* et al., IUCN Guide to the CBD (n. 408), 46.
428 See CBD Secretariat, Handbook of the Convention on Biological Diversity (3rd ed. 2005), 131–132 with further references.
429 Cf. Article 29(1) CP. According to Article 29(2) CP, parties to the CBD which are not parties to the Cartagena Protocol may participate as observes in the proceedings of the meeting of parties to the latter, but decisions under the Cartagena Protocol shall be taken only by those that are parties to it.

under the CBD have a significantly larger international reach than those adopted under the Cartagena Protocol.[430]

IV. Provision of Information to Parties Receiving LMOs (Article 19(4))

Article 19(4) is the only provision of the CBD that directly addresses the transboundary movement of LMOs.[431] It provides that when LMOs are to be introduced from one party into another party, the party of origin shall share two types of information with the receiving party. Firstly, it shall provide 'any available information about the use and safety regulation it requires in handling such organisms'[432] This overlaps with Article 20(3)(a) CP, which requires parties to the Cartagena Protocol to provide information about their national biosafety regimes to the Biosafety Clearing-House. Secondly, it shall provide 'any available information on the potential adverse impact of the specific organisms concerned' that are to be introduced into the territory of the other party.[433] The party of origin shall provide this information either directly, or require any natural or legal person under its jurisdiction 'providing the organisms', i.e. the developer, producer or exporter. Although this obligation has been superseded by the more specific information-sharing obligations under the Cartagena Protocol, especially as part of the AIA mechanism[434] and through the Biosafety Clearing-House,[435] Article 19(4) CBD nevertheless remains relevant in respect to those states which are not parties to the Cartagena Protocol.

V. Control of Invasive Alien Species (Article 8(h))

Pursuant to Article 8(h) CBD, each contracting party to the CBD is required to 'prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species'. The provision refers to what is more commonly known as *invasive* alien species, which is

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430 Cf. *Lim/Lim* (n. 76), 23; see chapter 5, section B.
431 See *Redgwell* (n. 4), 553.
432 *Glowka* et al., IUCN Guide to the CBD (n. 408), 98–99.
433 *Ibid.*, 99.
434 Cf. Article 8(1); see *supra* section A.II.1.b).
435 Cf. Article 20(3)(c) CP; see *supra* section A.II.3.

defined as any species which is introduced into the environment outside its natural habitat, is an agent of change, and threatens native biological diversity.[436]

The CBD COP has addressed the topic of invasive species under Article 8(h) CBD in a number of decisions.[437] At COP 6 in 2002, the parties adopted a set of Guiding Principles on invasive species, which call on states to recognize the risk that activities within their jurisdiction or control may pose to other states as a potential source of invasive alien species and to take appropriate measures to minimize that risk.[438] Examples of such potentially hazardous activities include the intentional transfer of invasive species to another state (even if it is harmless in the state of origin), and the intentional introduction of alien species into the environment of their own state if there is a risk of that species subsequently spreading into another state (with or without a human vector) and becoming invasive there.[439]

It has been argued that Article 8(h) CBD 'theoretically covers any self-dispersive GMO that threatens to become invasive'.[440] In scholarship, LMOs and invasive species are usually treated separately, which is probably because they are subject to different regulatory regimes.[441] In fact, however, it is recognized that LMOs and synthetic organisms can become just as invasive as 'traditional' invasive species.[442] At the same time, it has also

436 See the definition of '*alien invasive species*', in: IUCN, Guidelines for the Prevention of Biodiversity Loss Caused by Alien Invasive Species (2002), 4; the terms 'alien invasive species' and 'invasive alien species' are used interchangeably, cf. CBD COP, Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threaten Ecosystems, Habitats or Species, Annex to Decision VI/23, UN Doc. UNEP/CBD/COP/6/20, p. 256 (2002), fn. 57.

437 See CBD Secretariat, Handbook to the CBD (n. 428), 133–138.

438 CBD COP (n. 436), Guiding Principle 4, para. 1.

439 *Ibid.*, Guiding Principle 4, para. 2(a) and (b).

440 *Elena Angulo/Ben Gilna*, When Biotech Crosses Borders, 26 (2008) Nature Biotech. 277, 280.

441 See, e.g., IUCN (n. 436), 3, arguing that many of the issues and principles laid out in the principles could also apply to genetically modified organisms; *Clare Shine*, Invasive Species in an International Context: IPPC, CBD, European Strategy on Invasive Alien Species and Other Legal Instruments, 37 (2007) EPPO Bulletin 103, assuming that GMOs fall outside the scope of the aforementioned Guiding Principles adopted by the CBD-COP (see *supra* fn. 438). Also see *Young* (n. 105), 379–380, noting that many national laws on 'alien species' technically include LMOs unless specifically exempt.

442 *Jonathan M. Jeschke* et al., Novel Organisms: Comparing Invasive Species, GMOs, and Emerging Pathogens, 42 (2013) Ambio 541, 542–543. Also see

been pointed out that organisms with engineered gene drives intended to genetically modify *native* species in their natural habitat could not be regarded as 'alien', and thus could not be regarded as invasive alien species in the sense of Article 8(h) CBD.[443] Yet, where a gene drive system or other genetically modified organism spreads beyond the species' geographic range and caused damage to biodiversity there, it would constitute an invasive alien species in the sense of Article 8(h) CBD and states would be obliged to prevent their introduction into the environment.

In 2006, COP 8 expressly addressed the potential risks of biocontrol[444] agents as invasive alien species.[445] It also urged the parties to the CBD to evaluate and take appropriate measures (e.g., develop guidance or codes of practice regarding the trade and use of biocontrol agents) at national, regional and global levels to address these potential risks.[446] Moreover, the decision also encouraged parties, other governments and relevant international bodies to ensure that relevant laws and provisions (such as those related to conservation) do not inadvertently constrain the use of appropriate measures to address invasive alien species.[447] Hence, it is recognized by the parties to the CBD that biocontrol agents might themselves become invasive. This not only applies to conventional means of biocontrol but also to more recent approaches, including the use of engineered gene drive systems to suppress or eradicate agricultural pests, weeds, or disease vectors.

On the other hand, when self-spreading LMOs (namely, engineered gene drives) are applied to control invasive non-GM species, the (intended) effect on the targeted species would not be regarded as adverse but beneficial since the invasive species already negatively affected other species in

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IUCN (n. 436), 4, noting that the Guidelines 'do not address the issue of genetically modified organisms, although many of the issues and principles stated here could apply'.

443 *Rabitz* (n. 77), 343.

444 The term 'biocontrol' refers to the control of pests and weeds by other living organisms, usually other insects, bacteria or viruses, or by biological products such as hormones, see 'biological control', in: Henderson's Dictionary of Biology (n. 20), 67. Besides, it may also encompass the control of disease vectors such as mosquitoes.

445 CBD COP, Decision VIII/27. Alien Species that Threaten Ecosystems, Habitats or Species (Article 8 (H)): Further Consideration of Gaps and Inconsistencies in the International Regulatory Framework, UN Doc. UNEP/CBD/COP/DEC/VIII/27 (2006), para. 55.

446 *Ibid.*

447 *Ibid.*, para. 64.

the receiving environment.[448] In this case, the call to 'not inadvertently constrain the use of appropriate measures' could even be invoked to justify the use of gene drives.

VI. Impact Assessment and Minimization of Adverse Impacts (Article 14(1))

Article 14 CBD contains a range of general provisions relating to the prevention of adverse impacts on biodiversity.

1. Environmental Impact Assessments (lit. a)

Article 14(1)(a) provides that parties shall, as far as possible and appropriate, 'introduce appropriate procedures requiring environmental impact assessment of proposed projects that are likely to have significant adverse effects on biological diversity'.[449]

In its merits judgment in the *Certain Activities* case of 2016, the International Court of Justice (ICJ) held that this provision

> *'does not create an obligation to carry out an environmental impact assessment before undertaking an activity that may have significant adverse effects on biological diversity'.*[450]

The Court thereby followed an argument made by Costa Rica that the provision only concerned the 'introduction of appropriate procedures', which Costa Rica claimed it had in place.[451] But this interpretation is overly formalistic. It also disregards the object and purpose of Article 14(1)(a) CBD, which is to ensure that an EIA is carried out for hazardous activities that threaten biodiversity. While this needs to be implemented into domestic environmental and planning laws, such laws cannot be deemed

448 *Axel Hochkirch* et al., License to Kill?, 11 (2018) Conservation Letters e12370, 3; *Heidi J. Mitchell/Detlef Bartsch*, Regulation of GM Organisms for Invasive Species Control, 7 (2020) Front. Bioeng. & Biotechnol. 927, 8.

449 See *Lim/Lim* (n. 76), 10–11, who assume that the release of a gene drive-bearing organism would 'clearly fall under these broad obligations' contained in Article 14(1)(a) CBD.

450 ICJ, Certain Activities/Construction of a Road (Merits) (n. 270), para. 164.

451 Cf. *ibid.*, para. 163; see *Sands* et al. (n. 408), 393.

'appropriate' in the sense of Article 14(1)(a) if they do not actually require an EIA for projects that pose said threats.[452]

Notably, while the Court denied a violation of Article 14(1)(a) CBD, it found that Costa Rica had breached its obligation to carry out an EIA under 'general international law'.[453] Hence, it seems that the Court deemed the obligation under customary international law to be stronger and more far-reaching than that stipulated in the CBD. Again, this is questionable given that Article 14(1)(a) CBD has arguably played a significant role in the emergence of the respective customary obligation.[454]

2. Procedural Obligations (lit. c and d)

Pursuant to Article 14(1)(c) CBD, parties shall promote, on the basis of reciprocity, notification, information exchange and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other states or areas beyond the limits of national jurisdiction.

Article 14(1)(d) CBD provides that, 'in the case of imminent or grave danger or damage' to biodiversity in the territory of other states or in areas beyond national jurisdiction originating under their jurisdiction or control, parties are required to immediately notify the potentially affected states and to initiate action to prevent or minimize such danger or damage. This refers not to situations of a general risk or threat, but to emergencies where transboundary damage is about to occur.[455] Notification duties in case of imminent damage are also laid down in the Cartagena Protocol.[456]

VII. Examination of the Issue of Liability and Redress (Article 14(2))

Pursuant to Article 14(2), the Conference of Parties to the CBD shall 'examine, on the basis of studies to be carried out, the issue of liability

452 Cf. *Glowka* et al., IUCN Guide to the CBD (n. 408), 72.
453 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 270), para. 104; see ICJ, Pulp Mills (n. 263), para. 204; also see chapter 4, section D.II.
454 Cf. ILC, Articles on Prevention (n. 260), Commentary to Article 7, fn. 900, which notes Article 14(1)(a) and (b) of the CBD as one of the international treaties incorporating a requirement to assess the adverse effects of activities.
455 *Glowka* et al., IUCN Guide to the CBD (n. 408), 74.
456 See especially Article 17(1); see *supra* section A.II.2.b).

and redress […] for damage to biodiversity, except where such liability is a purely internal matter'. At COP 6 in 2002, the parties to the CBD requested the Executive Secretary to convene a *Group of Legal and Technical Experts on Liability and Redress*, which was mandated to clarify basic concepts and to develop definitions for the elements of Article 14(2) CBD, including the concept of 'damage to biological diversity'.[457] The group met once in 2005, at a time when the negotiations of a liability instrument specifically addressing damage resulting from LMOs had already commenced in a separate *Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety.*[458] In contrast, the mandate of the CBD working group was to deliberate on liability for biodiversity damage in general, and not just for damage resulting from LMOs. Nevertheless, it must be seen in this context that the working group stated in its report that 'it may be premature at this time to draw a conclusion that an international regime focused on damage to biodiversity should either be developed or not developed'.[459]

At COP 9 in 2008, the Executive Secretary tabled a *Synthesis Report* on technical information relating to biodiversity damage and approaches to valuation and restoration.[460] At COP 10 in 2010, at the same meeting where the parties to the Cartagena Protocol adopted the Supplementary Protocol, the parties to the CBD welcomed the Executive Secretary's synthesis report but deferred the issue to COP 12. At COP 12 in 2014, the parties commended the adoption of the Supplementary Protocol as well as the 2010 UNEP Guidelines on Environmental Liability[461] and decided

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457 CBD COP, Decision VI/11. Liability and Redress (Article 14, Paragraph 2), UN Doc. UNEP/CBD/COP/6/20, p. 178 (2002), para. 1.

458 The CBD working group even received a report on the developments within the framework of Art. 27 CP, see Report of the Expert Group on Liability under Article 14(2) CBD (n. 418), 4.

459 *Ibid.*, Annex, para. 1.

460 CBD COP, Synthesis Report on Technical Information Relating to Damage to Biological Diversity and Approaches to Valuation and Restoration of Damage to Biological Diversity, as Well as Information on National/Domestic Measures and Experiences: Note by the Executive Secretary, UN Doc. UNEP/CBD/COP/9/20/Add.1 (2008).

461 Cf. UNEP, Guidelines for the Development of Domestic Legislation on Liability, Response Action and Compensation for Damage Caused by Activities Dangerous to the Environment: Annex to Governing Council Decision SS.XI/5 B, UN Doc. A/26/25, p. 16 (2010).

to further defer the matter to COP 14.[462] At COP 14 in 2018, the parties welcomed the entry into force of the Supplementary Protocol and again deferred the issue of liability and redress under the CBD to COP 16,[463] which was postponed due to the COVID-19 pandemic and might take place in 2024. Also considering the decreasing length of the aforementioned COP decisions, it appears safe to conclude that there is currently no interest among the parties to the CBD to address the issue of liability for biodiversity damage in addition to – and separately from – what is already addressed by the Supplementary Protocol, namely liability for biodiversity damage caused by LMOs.

VIII. Are Eradication Programmes Prohibited Under the CBD?

As noted in the first chapter, one possible application of engineered gene drives could be to suppress or even eradicate species that are vectors of human pathogens, agricultural pests, or invasive species that cause damage to local ecosystems.[464] However, it has been argued that the deliberate eradication of an entire species may not be in line with the CBD.[465] While the CBD does not contain an express prohibition to eradicate an entire species, this could be contrary to the Convention's objective to conserve biological diversity.[466] Moreover, the CBD's definition of biological diversity encompasses 'the variability among living organisms from all sources'.[467] It thus ascribes an intrinsic value to all species, regardless of their value for humankind.[468]

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462 CBD COP, Decision XII/14. Liability and Redress in the Context of Paragraph 2 of Article 14 of the Convention, UN Doc. UNEP/CBD/COP/DEC/XII/14 (2014).

463 CBD COP, Decision 14/21. Liability and Redress (Article 14, Paragraph 2), UN Doc. CBD/COP/DEC/14/21 (2018).

464 See chapter 1, section C.III.

465 *Hochkirch* et al. (n. 448), 2.

466 *Ibid.*

467 Article 2 CBD.

468 *Hochkirch* et al. (n. 448), 2, referring to UNGA, World Charter for Nature, UN Doc. A/RES/37/7, Annex (1982), which states that 'every form of life is unique, warranting respect regardless of its worth for man'. The same objection is raised by the Swiss Federal Ethics Committee on Non-Human Biotechnology, Gene Drives: Ethical Considerations on the Use of Gene Drives in the Environment (2019), 5. But see *Tina Rulli*, CRISPR and the Ethics of Gene Drive in Mosquitoes, in: David Boonin (ed.), The Palgrave Handbook of Philosophy

Under Article 8(h) CBD, eradications are justified for conservation purposes when an invasive alien species threatens local ecosystems, habitats or species.[469] If, however, an eradication program targeted a species in its native range and was successful, the species would become threatened with extinction and, in turn, become eligible for protection under the CBD.[470]

As far as known, all suppression drives currently considered for potential environmental release are not aimed at eradicating entire species, but only at suppressing them locally.[471] It is also assumed that many drive systems require repeated subsequent releases because mutations conferring resistance to the drive would occur over multiple generations.[472] If, however, a programme in fact aimed at eradicating a species as a whole, it would most likely be incompatible with the CBD's object and purpose and, therefore, be unlawful.[473]

IX. Conclusions

The foregoing analysis has shown that the CBD contains a number of provisions relevant to the international regulation of biotechnology.[474] These rules might become relevant in situations concerning organisms which are not covered by the scope of the Cartagena Protocol or involving states which are no party to the Cartagena Protocol. At the same time, many of the obligations stipulated by the CBD are broad and unspecific, or subject to softening criteria like 'as appropriate'.[475] Ultimately, the standard of conduct required by the CBD is *due diligence*, which means that whether a state has complied with a particular obligation largely depends on the individual circumstances of each case.[476] However, programmes aimed at

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and Public Policy (2018) 509, 514–517, arguing against the assumption that mosquito species have an intrinsic value.

469 See *supra* section B.V.

470 *Hochkirch* et al. (n. 448), 3.

471 See chapter 1, section C.III.1.b).

472 See chapter 1, section C.IV.1.

473 *Hochkirch* et al. (n. 448), 3.

474 Cf. *Redgwell* (n. 4), 552–553; *Förster* (n. 280), 35–37; *Sands* et al. (n. 408), 396–397.

475 See *McGraw* (n. 408), 19, who characterizes the CBD as a framework convention establishing 'general, flexible obligations that parties may apply through national laws and policies'. Also see *Glowka* et al., IUCN Guide to the CBD (n. 408), 1.

476 See chapter 4, section C.

completely eradicating a species within its native habitat range may be in breach of the CBD and thus be prohibited by international law altogether.

C. *International Trade Law*

International trade law aims at reducing barriers to international trade in order to enhance economic development (I.). Thus, while the AIA mechanism under the Cartagena Protocol enables states to restrict the import of LMOs into their territory, international trade law restrains the liberty of states to impose such restrictions, causing a source of tension between both regimes (II.). How these potential conflicts can be resolved is still subject to controversy (III.).

I. Key Provisions of International Trade Law

The main rules of international trade law are contained in the *General Agreement on Tariffs and Trade* (GATT)[477] and a number of subsidiary agreements. In 1994, the *World Trade Organization* (WTO) was established to facilitate the implementation of these agreements, provide a forum for negotiations between member states, and establish a system for the settlement of trade disputes.[478] The WTO has currently 164 member states, including all countries which are key actors in the area of molecular biotechnology.[479]

The main objectives of the WTO agreements are to substantially reduce tariffs and other barriers to international trade and to eliminate discriminatory treatment in international commerce.[480] According to the *most-favoured-nation rule* stipulated in Article I GATT, parties to the Agreement shall apply uniform trade conditions to all other parties and must not accord more favourable conditions to any single party than to all others. Moreover, the *principle of domestic treatment* enshrined in Article III(4)

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477 General Agreement on Tariffs and Trade (30 October 1947; effective 01 January 1948), 64 UNTS 187, revised in GATT 1994 (n. 251).

478 Agreement Establishing the World Trade Organization (15 April 1994; effective 01 January 1995), 1867 UNTS 154.

479 Cf. WTO, Members and Observers, available at: https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last accessed 28 May 2022); see *Abbate* et al. (n. 7).

480 GATT 1994 (n. 251), Preamble, Recital 2.

GATT provides that parties shall not treat imported goods less favourable than like[481] domestic products. The most relevant rule in the present context, which is laid down in Article XI(1) GATT, provides that parties must not establish any prohibitions or restrictions on the trade, import or export of any product other than duties, taxes, or other charges. This runs fundamentally against the idea of the Cartagena Protocol that states are free to decide whether to allow or deny the import of a particular LMO into their territory.[482]

However, the prohibition of trade restrictions in WTO law is not without exception: pursuant to Article XX GATT, member states may impose restrictions on a number of grounds, including measures that are 'necessary to protect human, animal or plant life or health' (lit. b) and 'relating to the conservation of exhaustible natural resources' (lit. g). Further conditions under which parties may lawfully impose restrictions on international trade are set out in a number of subsidiary agreements.

II. Agreement on Sanitary and Phytosanitary Measures: Potential Source of Conflict With the Cartagena Protocol

In the context of international trade in LMOs and products thereof, the most relevant subsidiary agreement to the GATT is the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement).[483] The SPS Agreement governs the imposition of 'sanitary and phytosanitary measures which may, directly or indirectly, affect international trade'.[484] A *sanitary or phytosanitary measure* (SPS measure) is defined as any measure

481 Note that it is also disputed whether GMO and non-GMO products are sufficiently 'like' to fall under this provisions, cf. *Simonetta Zarrilli*, International Trade in GMOs and GM Products (2015), 33–34.

482 Cf. *Stoll* (n. 104), 111. See *supra* section A.II.1.h).

483 Agreement on the Application of Sanitary and Phytosanitary Measures (15 April 1994), 1867 UNTS 493 (hereinafter 'SPS Agreement'). Besides, the Agreement on Technical Barriers to Trade (15 April 1994), 1868 UNTS 120, might be relevant for international trade in LMOs. However, when a trade restriction qualifies as a *sanitary or phytosanitary measure*, the SPS Agreement prevails over the TBT agreement pursuant to Article 1.5 of the latter. Moreover, the Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994), 1869 UNTS 299, might be important for the availability of patents on inventions in the field of biotechnology, see *Debra M. Strauss*, The Application of TRIPS to GMOs, 45 (2009) Stan. J. Int'l L. 287.

484 SPS Agreement (n. 483), Article 1(1).

to protect humans, animals and plants from the risks arising from diseases, pests and disease-carrying organisms as well as from toxins and contaminants in food, beverages and feedstuff.[485] In the *EC-Biotech* case, the panel appointed by the WTO's *Dispute Settlement Body* (DSB)[486] held that the *European Communities'* regulatory framework on the release of GMOs into the environment constituted SPS measures within the meaning of the SPS Agreement.[487]

According to the SPS Agreement, member states have the right to impose trade restrictions when they are necessary for the protection of human, animal or plant life or health.[488] However, such measures are only justified where they are applied only to the extent necessary to protect human, animal or plant life or health, and when they are based on scientific principles, and supported by scientific evidence.[489] Consequently, any SPS measure must be based on a scientific assessment of the pertinent risks.[490] According to WTO case law, such a risk assessment must (1) identify the sanitary or phytosanitary risks in question, (2) evaluate the likelihood of their realization, and (3) evaluate how the measure would mitigate the risk.[491] While the evaluation of likelihood does not need to establish a certain magnitude or threshold level of risk,[492] the assessment must be

485 *Ibid.*, Annex A, para. 1.

486 On the WTO's dispute settlement mechanism generally, see *Peter-Tobias Stoll*, World Trade Organization, Dispute Settlement, in: Wolfrum/Peters (ed.), MPEPIL. The legal framework for dispute settlement within the WHO is the Understanding on the Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the Agreement Establishing the World Trade Organization (15 April 1994), 1869 UNTS 401.

487 WTO DSB, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Report of the Panel of 29 September 2006, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 8.4, see *Jacqueline Peel*, A GMO by Any Other Name … Might Be an SPS Risk!, 17 (2006) EJIL 1009.

488 SPS Agreement (n. 483), Article 2.1.

489 *Ibid.*, Article 2(2)d.

490 Article 5(1) SPS Agreement; see *Joanne Scott*, The WTO Agreement on Sanitary and Phytosanitary Measures (2007), 104–110.

491 WTO DSB, Australia – Measures Affecting Importation of Salmon, Report of the Appellate Body of 20 October 1998, WT/DS18/AB/R, para. 135; see *Scott* (n. 490), 92; *Lee A. Jackson*, Risk Assessment Frameworks in the Multilateral Setting, in: Stuart Smyth/Peter Phillips/David Castle (eds.), Handbook on Agriculture, Biotechnology and Development (2014) 203, 206.

492 WTO DSB, Australia – Salmon, Appellate Body report (n. 491), para. 124.

sufficiently specific to the issue at hand[493] and also consider alternative policy options.[494] Risks that are merely theoretical or uncertain cannot justify measures under the SPS Agreement.[495] Furthermore, measures shall not be more trade-restrictive than required to achieve an appropriate level of sanitary or phytosanitary protection.[496] Where available, SPS measures shall be based on international standards, guidelines or recommendations, including those elaborated under the *International Plant Protection Convention*,[497] the *World Organisation for Animal Health*,[498] and in the *Codex Alimentarius Commission*.[499] SPS measures that are based on such international standards are presumed to be consistent with the SPS Agreement and the GATT.[500]

In cases where the relevant scientific information is 'insufficient', member states may adopt *provisional* sanitary or phytosanitary measures on the basis of the available pertinent information.[501] At first sight, this resembles the precautionary principle embodied in the Cartagena Protocol, which provides that states may refuse the import of an LMO when there is a lack of scientific certainty regarding the extent of potential adverse effects of the LMO in question.[502] However, the WTO Appellate Body has held that 'scientific uncertainty' and 'insufficient scientific information' represent two distinct concepts that are not interchangeable.[503]

Hence, under the SPS Agreement provisional measures may only be adopted in cases of scientific *insufficiency*, but not in cases of scientific *uncertainty*. According to the WTO Appellate Body, scientific evidence is 'insufficient' in terms of the SPS Agreement when the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate risk assessment as required by the Agreement.[504] This is an important difference from the Cartagena Protocol, which does not require that insufficiency of scientific information renders

493 WTO DSB, Japan – Measures Affecting the Importation of Apples, Report of the Appellate Body of 26 November 2003, WT/DS245/AB/R, para. 202.
494 Cf. *Scott* (n. 490), 96, with further references.
495 *Stoll* (n. 104), 107.
496 SPS Agreement (n. 483), Article 5(6).
497 See *infra* section D.
498 See *infra* section E.
499 See *infra* section F.
500 SPS Agreement (n. 483), Article 3(2).
501 *Ibid.*, Article 5(7).
502 See *supra* section A.II.1.d).
503 WTO DSB, Japan-Apples, Appellate Body report (n. 493), para. 184.
504 *Ibid.*, para. 179.

an adequate risk assessment as such impossible, but only that insufficiency of information leads to a lack of scientific certainty as to the risks in question.[505]

In sum, the margin of appreciation awarded to states to deny the import of LMOs into their territory on grounds of their environmental risks under the SPS Agreement is much smaller than under the Cartagena Protocol, which strongly endorses the sovereign decision-making of each state party over the import of LMOs.[506] This may lead to situations in which measures permitted – or even required – by the Cartagena Protocol are not in accordance with the requirements under the SPS Agreement (or, in some instances, *vice versa*).[507] This is further complicated by the fact that the membership to both instruments is only partially overlapping since some parties to the Cartagena Protocol are not WTO members and *vice versa*.[508]

505 Cf. *Robyn Neff*, The Cartagena Protocol and the WTO: Will the EU Biotech Products Case Leave Room for the Protocol?, 16 (2005) Fordham Environmental Law Review 261, 274. Interestingly, the panel in EC-Biotech noted that the European Communities had performed a risk assessment on the products in question and held that this created a 'presumption' that the relevant scientific information was not insufficient, cf. WTO DSB, EC-Biotech (n. 487), 7.3260.

506 Cf. *Balakrishna Pisupati*, Biotechnology, Cartagena Protocol and the WTO Rules, 7 (2005) Asian Biotechnology and Development Review 75, 80.

507 Cf. *Stoll* (n. 104), 117; *Gabrielle Z. Marceau*, Conflicts of Norms and Conflicts of Jurisdictions, 35 (2001) Journal of World Trade 1081, 1097, who distinguishes between situations in which the disputed measure is required by an environmental treaty and situations in which the measure is (only) permitted by that treaty or taken in furtherance of its goals.

508 Out of the 164 members of the WTO, the following are currently no parties to the Cartagena Protocol: Argentina, Australia, Brunei, Canada, Chile, Haiti, Iceland, Israel, Liechtenstein, Nepal, Russia, Sierra Leone, Singapore, United States and Vanuatu. Conversely, of the 171 parties to the Cartagena Protocol, the following are no WTO members: Algeria, Azerbaijan, Bahamas, Belarus, Bhutan, Bosnia and Herzegovina, Comoros, Democratic People's Republic of Korea, Eritrea, Ethiopia, Iran, Iraq, Kiribati, Lebanon, Libya, Marshall Islands, Nauru, Palau, Palestine, Serbia, Somalia, Sudan, Syria, and Turkmenistan. Consequently, 149 states are both members of the WTO and parties to the Cartagena Protocol. The Cartagena Protocol's 'parent' convention, the Convention on Biological Diversity, has 196 parties, including all WTO members except the United States.

III. Resolving Potential Conflicts Between International Trade Law and the Cartagena Protocol

According to general international law on the law of treaties, potential conflicts between norms from different sources shall be avoided primarily by way of interpretation.[509] Pursuant to Article 31(3)(c) VCLT, any relevant rules of international law applicable in the relations between the parties shall be taken into account when interpreting a treaty. Only when a conflict of obligations cannot be avoided, general rules of international law help to determine which obligation takes precedence: First, where available, specific provisions of a treaty governing its relation to other treaties shall be considered.[510] Recital 10 of the preamble to the Cartagena Protocol provides that the Protocol 'shall not be interpreted as implying a change in the rights or obligations of a party under any existing international agreements'. This would mean that the SPS Agreement, which was concluded before the Cartagena Protocol, prevailed. But at the same time, Recital 11 states that the earlier recital was 'not intended to subordinate this Protocol to other international agreements'. Hence, the Cartagena Protocol remains inconclusive as to its relationship to other rules of international law.[511] At the same time, neither the GATT nor the SPS Agreement contains expressions regarding their relation to other rules of international law.

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509 *Manfred Zuleeg*, Vertragskonkurrenz im Völkerrecht, 20 (1977) German YBIL 246, 256; *Seyed-Ali Sadat-Akhavi*, Methods of Resolving Conflicts Between Treaties (2003), chapter 2; in the present context, see *Marceau* (n. 507), 1086–1090 with further references. Positivist scholars even deny the possibility of conflicts of norms, cf. *Hans Kelsen*, Principles of International Law (1952), 426–427, who argues that the 'specific function of juristic interpretation is to eliminate these contradictions by showing that they are merely sham contradictions'.

510 Article 30(2) VCLT; see generally *Sadat-Akhavi* (n. 509), 61–63.

511 But see *Sabrina Safrin*, The Relationship with Other Agreements: Much Ado About a Savings Clause, in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 438, 446–447, who argues that understanding Recital 11 as undoing Recital 12 would ignore the 'clear ordinary and unambiguous meaning' of the former and would violate the duty to interpret a treaty in good with. In her view, Recital 12 was introduced to indicate that 'environmental agreements are not of lower status, class, significance or importance than trade agreements and that the inclusion of a savings clause in the protocol should not be understood to lower or lessen it'. Yet, the author does not elucidate why Recital 11 should be construed as a legally relevant *savings clause* whereas the relevance of Recital 12 would only be declaratory or sentimental.

In the absence of special provisions, the principles of *lex posterior* and *lex specialis* apply. The *lex posterior* rule provides that the treaty which was concluded later in time shall prevail over the earlier treaty on the same subject matter.[512] According to the *lex specialis* rule, provisions which are more specific in content prevail over more general ones.[513] Against this background, some authors have argued that a conflict between WTO law and the Cartagena Protocol would most likely be resolved in favour of the latter, as it was both the more specific and the more recent agreement.[514] This conclusion, however, is questionable: the scope of WTO law has become so broad that it cuts across almost all other areas of international law; yet, it specifically relates to matters of free trade.[515] Furthermore, as shown above, the SPS Agreement stipulates highly specific conditions under which WTO members may restrict trade for sanitary and phytosanitary measures,[516] whereas the Cartagena Protocol contains no substantive rules on the circumstances under which the import of an LMO may be denied.[517] Hence, it cannot generally be assumed that the Cartagena Protocol is more specific than the SPS Agreement.[518]

The relationship between WTO law and other rules of international law was also a major issue in the aforementioned *EC-Biotech* case before the WTO's DSB. The European Communities had argued that the SPS Agreement had to be interpreted consistently with other rules of international law, namely the CBD and the Cartagena Protocol.[519] This could be required by Article 30(3)(c) VCLT, which provides that when interpreting a treaty, account shall be taken of 'any relevant rules applicable in the relations between the parties'. But in the view of the panel, the phrase 'applicable in relations between the parties' implies that Article 30(3)(c) VCLT only applies to rules 'which are applicable in the relations between all parties to the treaty which is being interpreted'.[520] Consequently, the

512 Article 30(3) and (4) VCLT.
513 The *lex specialis* rule is not explicitly mentioned in the VCLT, but is nevertheless recognized as a general rule of international law, see *Dorota M. Banaszewska*, Lex Specialis, in: Wolfrum/Peters (ed.), MPEPIL, MN. 11–20; *Marceau* (n. 507), 1090.
514 *Stoll* (n. 104), 117; *Zarrilli* (n. 481), 38.
515 *A. Lindroos*, Dispelling the Chimera of 'Self-Contained Regimes' International Law and the WTO, 16 (2005) EJIL 857, 864.
516 See *supra* section C.I.
517 See *supra* section A.II.1.h).
518 Cf. *Lindroos* (n. 515), 864.
519 Cf. WTO DSB, EC-Biotech (n. 487), paras. 7.52 – 7.55.
520 *Ibid.*, para. 7.70.

panel held that only rules of international law that bind *all* WTO members would have to be taken into account under Article 30(3)(c) VCLT.[521] Since neither the CBD nor the Cartagena Protocol has been ratified by all WTO members, the panel refused to take into account either of the instruments when interpreting the pertinent provisions of the SPS Agreement.[522]

The panel's narrow understanding of Article 31(3)(c) VCLT was heavily criticized in scholarship,[523] *inter alia* for increasing the fragmentation of international law.[524] It has also been questioned whether the decision would have been upheld by the WTO's *Appellate Body*, which had noted in earlier decisions that WTO law was not 'not to be read in clinical isolation from public international law'.[525] Notably, rules of international environmental law, including the CBD, have already been considered by the Appellate Body in earlier cases.[526] However, since neither of the parties appealed against the panel decision in *EC-Biotech*, it was not reviewed by the Appellate Body.

After all, the relationship between international trade law and international environmental law, particularly the Cartagena Protocol, is still unsettled. The WTO agreements are likely to significantly limit the liberty of states to restrict the import of LMOs into their territory. Under the WTO agreements, especially the SPS Agreement, trade restrictions are only permissible when they are justified by strictly scientific evidence.[527] Unlike international environmental law, a lack of knowledge can only be invoked

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521 *Ibid.*, para. 7.68.

522 *Ibid.*, paras. 7.73 – 7.75.

523 See *Robert Howse/Henrik Horn*, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, 8 (2009) World Trade Review 49, 53–62; *Denise Prévost*, Opening Pandora's Box: The Panel's Findings in the EC-Biotech Products Dispute, 34 (2007) Legal Issues of Economic Integration 67, 92; *Caroline Henckels*, GMOs in the WTO: A Critique of the Panel's Legal Reasoning in EC-Biotech, 7 (2006) Melb. J. Int'l L. 278, 297–301.

524 *Martti Koskenniemi*, Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law: Report of the Study Group of the International Law Commission, UN Doc. A/CN.4/L.682 (2006), para. 471.

525 WTO DSB, United States – Standards for Reformulated and Conventional Gasoline, Appellate Body Report of 29 April 1996, WT/DS2/AB/R, 17; see *Howse/Horn* (n. 523), 61; *Lindroos* (n. 515).

526 WTO DSB, United States – Import Prohibition of Certain Shrimp and Shrimp Products, Report of the Appellate Body of 12 October 1998, WT/DS58/AB/R, paras. 130, 168, see *Howse/Horn* (n. 523), 60–61.

527 Article 5(1) SPS Agreement; cf. WTO DSB, Australia – Salmon, Appellate Body report (n. 491), paras. 112–135; see *supra* section C.II.

to justify preliminary measures when it results from a lack of available data, but not from a general uncertainty about the potential or perceived risks of LMOs.

In addition, the WTO has established a comprehensive dispute settlement mechanism with compulsory jurisdiction.[528] By comparison, the system for dispute settlement under the Convention on Biological Diversity is rather weak, as it only requires states to participate in a non-binding 'conciliation' procedure which merely renders a non-binding proposal for resolving the dispute.[529] Hence, any dispute related to the international trade in LMOs or products thereof will most likely be brought before the WTO DSB rather than a CBD arbitral tribunal or the International Court of Justice.[530] It remains to be seen whether the Dispute Settlement Body will find ways to integrate its jurisprudence into the wider body of international law, and thus avoid further fragmentation and the creation of conflicting obligations.

D. International Plant Protection Convention

The *International Plant Protection Convention* of 1951[531] aims at securing common and effective action to prevent and control the introduction and spread of pests in plants and plant products.[532] Although the IPPC's main focus is on international trade in plants and plant products, its scope also extends to the protection of the natural flora.[533] The Convention, which was substantially revised in 1997, currently has 183 parties, including all major biotechnology nations.[534] In 2004, the FAO (which administers the IPPC) and the CBD Secretariat signed a Memorandum of Cooperation

528 See generally *Stoll* (n. 486).

529 Cf. Article 27(4) and Annex II, Part 2, of the CBD; see chapter 9, section C.III.2.

530 *Stoll* (n. 104), 117; *Zarrilli* (n. 481), 39.

531 International Plant Protection Convention (New Revised Text) (17 November 1997; effective 02 October 2005), 2367 UNTS 223 (hereinafter 'IPPC 1997').

532 *Ibid.*, Article I(1).

533 Cf. *ibid.*, Article 4(c)(b).

534 Cf. UN OLA, Status of the International Plant Protection Convention (New Revised Text), United Nations Treaty Collection, available at: https://treaties.un.org/Pages/showDetails.aspx?objid=0800000280066b19&clang=_en (last accessed 28 May 2022).

recognizing the 'overlapping objectives' of the IPPC and the CBD in the international regulation of biotechnology.[535]

The IPPC has established a *Commission on Phytosanitary Measures*,[536] which adopts *International Standards for Phytosanitary Measures* (ISPMs).[537] Although the ISPMs are not legally binding under the IPPC, they have gained legal relevance as reference standards under the *SPS Agreement*, as phytosanitary measures that conform to the ISPMs are presumed to also comply with the SPS Agreement.[538]

A number of ISPMs apply to Living Modified Organisms.[539] For instance, ISPM 11 on *Pest Risk Assessment for Quarantine Pests* sets out standards to identify plant pests and to evaluate their risk, identify endangered areas and, if appropriate, identify risk management options.[540] The standard expressly acknowledges that some LMOs may present phytosanitary risks.[541] In order to be categorized as a plant pest, an LMO has to be injurious or potentially injurious to plants or plant products under conditions in the relevant area.[542] The types of LMOs that may pose such risks include plants used for agricultural or industrial purposes modified to improve their performance, as well as organisms whose pathogenic characteristics have been modified to make them useful for biological

535 Memorandum of Cooperation Between the Food and Agriculture Organization of the United Nations and the Secretariat of the Convention on Biological Diversity on Cooperation Between the Secretariat of the Convention on Biological Diversity and the Secretariat of the International Plant Protection Convention (25 February 2004); see *Ayse-Martina Böhringer*, Die Kooperationsvereinbarungen der Sekretariate multilateraler Umweltschutzübereinkommen (2014), 170–172.

536 The term 'phytosanitary' (from the ancient Greek term φυτόν) refers to the health of plants, cf. 'phytosanitary, adj.', in: Oxford English Dictionary (n. 12).

537 See Articles X and XI of IPPC 1997 (n. 531).

538 Cf. SPS Agreement (n. 483), Annex A, para. 3(c); see *Jackson* (n. 491), 209–210; on the SPS Agreement, see *supra* section C.II.

539 See International Plant Protection Convention, Overview on International Standards for Phytosanitary Measures (ISPMs) And Their Application to Living Modified Organisms (LMOs) (2016); cf. *Jackson* (n. 491), 209; CBD Secretariat, Standards for Shipments of Living Modified Organisms: Outcomes of an Online Forum, CBD Biosafety Technical Series 01 (2011), 34–39.

540 ISPM 11 (n. 165), 7. For a detailed analysis, see *Meredith T. Mariani*, The Intersection of International Law, Agricultural Biotechnology, and Infectious Disease (2007), 132–138.

541 ISPM 11 (n. 165), 8. On the application of ISPM 11 to LMOs, see *Lim/Lim* (n. 76), 52–53.

542 ISPM 11 (n. 165), 9.

control purposes.[543] With regard to phytosanitary risks related to gene flow, ISPM 11 recognizes that an LMO constitutes a potential vector for the introduction of a genetic construct of phytosanitary concern rather than a pest in and of itself.[544] Therefore, ISPM 11 proposes the term 'pest' to be understood to include the potential of an LMO to act as a vector for introducing genes presenting a potential phytosanitary risk into the environment.[545] Consequently, ISPM 11 also covers some risks involved with the unintentional dissemination of engineered gene drives.[546]

Although the IPPC does not establish substantive rules on the conditions under which LMOs may be released, ISPM 11 signifies a consensus among the parties to the Convention that LMOs may constitute plant pest vectors that require risk assessment and, if necessary, regulation. In this regard, ISPM 11 specifies – at least by way of *soft law* – requirements for risk assessments with regard to potential hazardous effects of LMOs on cultivated plants and wild flora that may be of particular relevance for LMOs with the capacity of self-propagation.[547]

E. World Organisation for Animal Health

The *World Organisation for Animal Health* (OIE) is an intergovernmental organization created to control the spread of animal diseases.[548] It was established by means of an international agreement concluded in 1924.[549] Today, the OIE has 182 member states, including all nations with major biotechnology industries.[550] Each member state is required to report animal diseases that it detects on its territory; such information is then disseminated to the other member states in order to allow them to take

543 *Ibid.*, 8.
544 *Ibid.*, 30.
545 *Ibid.*; cf. *Jackson* (n. 491), 210.
546 *Lim/Lim* (n. 76), 54.
547 Cf. *Angulo/Gilna* (n. 440), 281.
548 The organization, previously called *Office International des Epizooties*, was renamed in 2003 but retained its historical acronym *OIE* until recently, when the acronym was changed to *WOAH*.
549 Arrangement international pour la création, à Paris, d'un Office international des épizooties (25 January 1924; effective 11 June 1926), 57 LNTS 135.
550 Cf. OIE, Member Countries, available at: https://www.woah.org/en/who-we-are/members/ (last accessed 28 May 2022).

preventive action.[551] The OIE also facilitates the exchange of veterinary scientific information, encourages international solidarity in the control of animal diseases, and provides technical support to affected member states.[552] Besides, the OIE elaborates standards for international trade in animals and animal products which, like the ISPM developed under the IPPC,[553] formally only have *soft law* status but are recognized by the WTO as reference international sanitary rules under the SPS Agreement.[554]

Although the OIE has dealt with biotechnology-related matters from a number of perspectives,[555] it has not specifically addressed genetically modified animals.[556] Nevertheless, its *Terrestrial and Aquatic Animal Health Codes* contain guidelines for import risk analysis aimed at providing importing countries with an 'objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material'.[557] The stated purpose of risk assessments is to provide importing countries with clear reasons for the imposition of import conditions or refusal to import,[558] i.e. reasons that would withstand scrutiny under WTO law. In 2011, the OIE published *Guidelines for Assessing the Risk of Non-Native Animals Becoming Invasive*.[559] The purpose of these guidelines is to assist in determining whether imported animal species are likely to become harmful to the environment, animal or human health, or the economy.[560] Similar to ISPM 11 for invasive plants, these guidelines may provide guidance in determining the risks potentially associated with an LMO that could also be classified as an invasive, non-native species.[561]

551 OIE, Our Missions, available at: https://www.woah.org/en/who-we-are/mission/ (last accessed 28 May 2022).
552 *Ibid.*; see *Mariani* (n. 540), 124–125.
553 See *supra* section D.
554 OIE (n. 551); cf. SPS Agreement (n. 483), Annex A, para. 3(b).
555 See, e.g. OIE, Resolution No. XXVIII. Applications of Genetic Engineering for Livestock and Biotechnology Products. Adopted by the International Committee of the OIE During Its 73rd General Session (27 May 2005); OIE, Role of the OIE in Improving Animal Health by Using Biotechnologies: OIE Bulletin 2007–4, 3–14; cf. *Mariani* (n. 540), 124–127.
556 *Jackson* (n. 491), 210.
557 OIE, Terrestrial Animal Health Code (2019), Article 2.1.1.
558 *Ibid.*
559 Guidelines for Assessing the Risk of Non-Native Animals Becoming Invasive (n. 165).
560 *Ibid.*, 2.
561 Terrestrial Animal Health Code (n. 557), Article 2.1.1.

F. Codex Alimentarius

The *Codex Alimentarius* is a collection of standards, guidelines and recommendations on food, food production, and food safety.[562] Its texts are developed and maintained by the *Codex Alimentarius Commission*, which has been established by the *Food and Agriculture Organization of the United Nations* and the *World Health Organization* in 1963.[563] Although not legally binding in formal terms, the Codex texts are generally regarded as internationally recognized[564] and are referenced by the SPS Agreement as the relevant international standards on food safety.[565] The Codex Alimentarius Commission currently has 189 members, including all states which are major stakeholders in molecular biotechnology as well as the European Union.[566]

The Codex Alimentarius Commission has developed a number of documents relevant in the context of biotechnology,[567] including the *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*.[568] The purpose of these principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology.[569] However, the document expressly states that it 'does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods'.[570] These issues are outside the scope of the Codex Alimentarius, which is exclusively focused on food safety.

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562 See *Gerald G. Sander*, Codex Alimentarius Commission (CAC), in: Wolfrum/Peters (ed.), MPEPIL.

563 *Ibid.*

564 *Mariani* (n. 540), 62–63.

565 SPS Agreement (n. 483), Annex A, para. 3(a).

566 FAO/WHO, Codex Alimentarius: Members, available at: http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/ (last accessed 28 May 2022).

567 See *Mariani* (n. 540), 66–73; *Markus Böckenförde*, Genetically Modified Organisms, in: Wolfrum/Peters (ed.), MPEPIL, MN. 23; *Jackson* (n. 491), 208–209.

568 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (n. 165); see *Mariani* (n. 540), 66–69.

569 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (n. 165), para. 7. Notably, the definition of 'modern biotechnology' used by the Codex is identical to that of the Cartagena Protocol, cf. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (n. 165), para. 8.

570 *Ibid.*, para. 7.

Besides the aforementioned Principles, the Codex Alimentarius also contains Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants[571] and animals[572] or produced using recombinant-DNA microorganisms.[573] Moreover, the Codex contains provisions for the labelling of foods derived from modern biotechnology.[574]

G. *United Nations Convention on the Law of the Sea*

The *United Nations Convention on the Law of the Sea* of 1982 (UNCLOS)[575] does not directly address biotechnology, nor does the current draft for an implementing agreement on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction.[576] However, Article 196(1) UNCLOS requires states to take

> '*all measures necessary to prevent, reduce and control […] the intentional or accidental introduction of species, new or alien, to a particular part of the marine environment, which may cause significant and harmful changes thereto*'.

The meaning of the term 'alien species' corresponds to that of the same term in Article 8(h) CBD,[577] while 'new species' refers to those that have been bred traditionally or through modern biotechnology, which includes LMOs.[578] Article 196 UNCLOS extends to all activities under the jurisdic-

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571 Codex Alimentarius Commission, Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2008), CAC/GL 45–2003; see *Mariani* (n. 540), 69–71.

572 Codex Alimentarius Commission, Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (2008), CAC/GL 68–2008.

573 Codex Alimentarius Commission, Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (2003), CAC/GL 46–2003; see *Mariani* (n. 540), 72–73.

574 Codex Alimentarius Commission, Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology (2011), CAC/GL 76–2011.

575 See *supra* n. 112.

576 Cf. UNGA, Draft Text of an Agreement Under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction, UN Doc. A/CONF.232/2019/6, Annex (2019).

577 *Böckenförde* (n. 113), 261–262; *Czybulka*, Article 196 UNCLOS (n. 113), MN. 14.

578 *Böckenförde* (n. 113), 250–251; *Czybulka*, Article 196 UNCLOS (n. 113), MN. 14.

tion or control of states parties to the Convention, regardless of their geographical location.[579] Hence, the Convention requires its states parties to prevent the release of LMOs into the marine environment, provided that said LMOs 'may cause significant and harmful changes' to the marine environment. Moreover, the notion 'may' clearly indicates that the obligation is not only triggered when there is certainty about the adverse effects but already when there is a certain likeliness of damage. Consequently, the wording of Article 196(1) UNCLOS requires states to apply a precautionary approach and to carry out early risk assessments for relevant activities, in accordance with Article 206 UNCLOS.[580]

H. International Regulations on the Transport of Hazardous Goods

LMOs are also subject to international regulations concerning the transport of hazardous goods and substances.[581] The principal instrument in this context is the *UN Recommendations on the Transport of Dangerous Goods*, which is a non-binding *soft law* instrument developed by an expert committee of the *United Nations Economic and Social Council* (ECOSOC) and presented in the form of *Model Regulations*.[582] These Model Regulations contain a list of dangerous goods commonly subject to transport as well as provisions relating to their identification and classification, standards for packing and the design of packaging, as well as rules on consignment procedures and transport operations. The Model Regulations' *Dangerous Goods List* includes 'Genetically modified micro-organisms' (GMMs) and 'Genetically modified organisms' (GMOs).[583] The Model Regulations also contain a *Packing Instruction* specifically for GMMs and GMOs.[584] This Packing Instruction requires, *inter alia*, that packaging shall consist of multiple layers and must be leak-proof or sift-proof. Moreover, the Packing Instruction provides for a label that shall be attached to the outer packaging of GMMs or GMOs.[585] GMMs and GMOs packed and marked in accordance with these instructions are not subject to any other requirements

579 *Czybulka*, Article 196 UNCLOS (n. 113), MN. 13.
580 *Ibid.*, MN. 19.
581 See CBD Secretariat (n. 539), 29–56.
582 United Nations, Recommendations on the Transport of Dangerous Goods: Model Regulations, ST/SG/AC.10/1/Rev.22 (22nd ed. 2021).
583 *Ibid.*, section 2.9.2, vol. I at p. 170.
584 *Ibid.*, Packing Instruction P904, section 4.1.4.1, vol. II at page 94.
585 *Ibid.*

stipulated in the Model Regulations.[586] Moreover, GMMs and GMOs shall not be subject to the Model Regulations when they are 'authorized for use by the competent authorities of the countries of origin, transit and destination'.[587] However, when a GMM or GMO meets the definition of a *toxic substance* or an *infectious substance*, it is subject to the stricter requirements that apply to these types of substances.[588]

Based on the Model Regulations, several legally binding instruments have been developed to govern the international transport of hazardous goods and substances. At the universal level, instruments governing the transport of hazardous goods exist for transport by air[589] and by sea.[590] A number of similar instruments concerning transport by rail,[591] road,[592] and inland waters,[593] are geographically limited to Europe and neighbouring regions. All of these agreements largely mirror the rules in the Model Regulations and are usually harmonized with the amendments made to them.

586 *Ibid.*, section 3.3.1.219, vol. I at p. 322.
587 *Ibid.*, section 2.9.2, vol. I at p. 170.
588 *Ibid.*, section 3.3.1.219, vol. I at p. 322.
589 ICAO, Convention on International Civil Aviation, Annex 18: The Safe Transport of Dangerous Goods by Air, 4th edition 2011, incorporating all amendments adopted by the ICAO council effective as from 17 November 2011; ICAO, Technical Instructions for the Safe Transport of Dangerous Goods by Air, ICAO Doc. 9284, 2021–2022 edition.
590 IMO, International Maritime Dangerous Goods Code, 2020 edition, as amended by amendment 40–20 (effective 1 June 2020).
591 OTIF, Regulations Concerning the International Carriage of Dangerous Goods by Rail, Appendix C to the Convention Concerning International Carriage by Rail, with amendments as effective from 1 January 2021.
592 UNECE, European Agreement Concerning the International Carriage of Dangerous Goods by Road (30 September 1957; effective 29 July 1968), 619 UNTS 77, with amendments to Annexes A and B as applicable from 1 January 2021, consolidated version in UN Doc. ECE/TRANS/300, Vol. I and II.
593 UNECE, European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (26 May 2000; effective 29 February 2008), 2497–2500 UNTS, with amendments to the annexed Regulations as applicable from 1 January 2021, consolidated version in UN Doc. ECE/TRANS/301, Vol. I and II.

I. International Health Regulations

The *International Health Regulations* (IHR) become relevant when a product of biotechnology, such as a genetically modified virus, causes a disease in humans.[594] Last revised in 2005, the IHR are a legally binding instrument adopted by the World Health Assembly, the decision-making body of the *World Health Organization* (WHO), in accordance with Article 21(a) of the WHO's Constitution.[595] Since all UN member states except for Liechtenstein are also members of the WHO,[596] the IHR have a quasi-universal effect.

The IHR's objective is to prevent the international spread of diseases, while at the same time ensuring that public health responses are 'commensurate with and restricted to public health risks, and […] avoid unnecessary interference with international traffic and trade'.[597] Member states must notify the WHO about all events which may constitute a so-called 'public health emergency of international concern',[598] which is defined as

> *'an extraordinary event which is determined […] (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response'.*[599]

When the WHO determines that such an event occurs, it may issue temporary recommendations about specific health measures to be implemented by the state experiencing the outbreak.[600] It may also issue temporary recommendations to other states concerning measures to prevent or reduce the international spread.[601]

Although these recommendations are formally non-binding,[602] measures not recommended by the WHO 'shall be not more be more restric-

594 WHO, International Health Regulations (2005) (23 May 2005; effective 15 June 2007), WHO Doc. WHA58.3.
595 Constitution of the World Health Organization (22 July 1946; effective 07 April 1948), 14 UNTS 185, as last amended by resolution WHA39.6 of 16 May 1998 (effective 15 September 2015).
596 UN OLA, Status of the Constitution of the World Health Organization, available at: https://treaties.un.org/Pages/showDetails.aspx?objid=080000028002d899&clang=_en (last accessed 28 May 2022).
597 IHR 2005 (n. 594), Article 2.
598 *Ibid.*, Article 6(1).
599 *Ibid.*, Article 1(1).
600 *Ibid.*, Articles 15–18.
601 *Ibid.*, Article 15(2).
602 *Ibid.*, Article 1(1).

tive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection'.[603] Against this background, it has been argued that the imposition of travel restrictions not recommended by the WHO was in breach of international law.[604]

In principle, the IHR apply to any outbreak of a transmissible disease,[605] including such caused by pathogens modified through biotechnology. However, the practical effectiveness of the IHR has recently been called into question, since many developing states lack the necessary resources to implement surveillance systems to early identify outbreaks of transmissible diseases.[606] It has also been contended that states have repeatedly delayed notifications of disease outbreaks to avoid the imposition of restrictions harmful to their tourism and trade.[607] During the COVID-19 pandemic, the WHO was criticized for not reacting quickly enough, whereas states have only inconsistently complied with the WHO's recommendations.[608]

J. Disarmament and Humanitarian International Law

Finally, certain applications of biotechnology may fall within the scope of international law that prohibits both the acquisition of biological weapons and the conduct of 'environmental warfare', namely the Biologi-

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603 *Ibid.*, Article 43(1).

604 *Lawrence O. Gostin* et al., The International Health Regulations 10 Years on: The Governing Framework for Global Health Security, 386 (2015) The Lancet 2222, 2225; *Roojin Habibi* et al., Do Not Violate the International Health Regulations During the COVID-19 Outbreak, 395 (2020) The Lancet 664; *Benjamin M. Meier* et al., Travel Restrictions Violate International Law, 367 (2020) Science 1436.

605 *Morten Broberg*, A Critical Appraisal of the World Health Organization's International Health Regulations (2005) In Times of Pandemic: It Is Time for Revision, 11 (2020) European Journal of Risk Regulation 202, 205.

606 *Gostin* et al. (n. 604), 2223–2224; *Broberg* (n. 605), 206–207.

607 *Broberg* (n. 605), 207; *Lawrence O. Gostin* et al., Has Global Health Law Risen to Meet the COVID-19 Challenge? Revisiting the International Health Regulations to Prepare for Future Threats, 48 (2020) The Journal of Law, Medicine & Ethics 376, 378–379.

608 *Broberg* (n. 605), 205; *Barbara J.* von *Tigerstrom* et al., The International Health Regulations (2005) and the Re-Establishment of International Travel Amidst the COVID-19 Pandemic, 27 (2020) Journal of Travel Medicine 1; *Gostin* et al. (n. 607), 378–379.

cal Weapons Convention (I.), the ENMOD Convention (II.), and the rules of international humanitarian law (III.).

I. Biological Weapons Convention

The *Biological Weapons Convention* of 1972 (BWC)[609] is a disarmament treaty which prohibits the development, production, stockpiling, and other means of acquiring biological weapons or their means of delivery. It currently has 183 states parties, including all relevant states engaged in molecular biotechnology except Israel.[610] The obligation not to possess biological weapons is also part of customary international law,[611] as is their 'use', which is not explicitly prohibited by the BWC.[612] Pursuant to Article I(1) BWC,

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609 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) And Toxin Weapons and on Their Destruction (10 April 1972; effective 26 March 1975), 1015 UNTS 163; for a general introduction, see *Jozef Goldblat*, The Biological Weapons Convention: An Overview, 37 (1997) International Review of the Red Cross Archive 251.

610 UNOG, Lists of States Parties, Signatory States and Non-Signatory States of the Biological Weapons Convention, available at: https://www.un.org/disarmament/biological-weapons/about/membership-and-regional-groups (last accessed 28 May 2022). However, Israel is a party to the 1925 Geneva Protocol, see Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (17 June 1925; effective 09 May 1926), 94 LNTS 65; UN OLA, Status of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, available at: https://treaties.un.org/Pages/showDetails.aspx?objid=0800000280167ca8&clang=_en (last accessed 28 May 2022).

611 Cf. *Jean-Marie Henckaerts/Louise Doswald-Beck*, Customary International Humanitarian Law (2005), 256–258. Also note that the UN Security Council, acting under Chapter VII of the UN Charter (and thus acting with legislative powers binding all UN member states according to Article 25 of the UN Charter), decided in 2004 that all states shall refrain from providing any form of support to non-state actors that attempt to develop, acquire, or use chemical or biological weapons and their means of delivery, and that states shall take effective measures to prevent the proliferation of such weapons, see UNSC, Resolution 1540 (2004). Non-Proliferation of Weapons of Mass Destruction (28 April 2004), UN Doc. S/RES/1540 (2004), operative paras. 1–3.

612 Yet, states parties to the BWC have agreed that the use of biological weapons would be 'effectively a violation of Article I', cf. BWC Implementation Support Unit, Additional Understandings and Agreements Reached by Previous Review Conferences Relating to Each Article of the Convention: Background Informa-

> *'each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain*
> *(1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;*
> *(2) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict'.*

The Convention does not provide a definition of what constitutes a 'biological agent'. In a resolution adopted by the UN General Assembly in 1969 (i.e. before the BWC was adopted), the notion 'biological agents of warfare' was defined as

> *'living organisms, whatever their nature, or infective material derived from them, which are intended to cause disease or death in man, animals or plants, and which depend for their effects on their ability to multiply in the person, animal or plant attacked'.*[613]

According to this definition, a key characteristic of a biological warfare agent is that it multiplies in the target organism and thereby exerts its harmful effects. This would exclude from the scope of the BWC a range of applications of synthetic biology which do not rely on 'multiplication' in the target organism, such as engineered gene drives. But it is questionable whether this requirement applies to the BWC, because Article I(1) not only refers to microbial agents (i.e. microorganisms) but also includes 'other biological agents'. Indeed, there appears to be a wide consensus that the BWC is not limited to organisms that cause or spread diseases,[614] but also encompasses all other biological agents which can be used to harm or to cause death to humans, animals, or plants, insofar as these organisms are of types and quantities not justified for exclusively peaceful purposes.[615]

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tion Document for the Seventh Review Conference of the States Parties to the BWC, UN Doc. BWC/CONF.VII/INF.5 (2011), paras. 8–10; also see *William H. Boothby*, Weapons and the Law of Armed Conflict (2nd ed. 2016), 113.

613 UNGA, Resolution 2603 (XXIV). Question of Chemical and Bacteriological (Biological) Weapons, UN Doc. A/Res/2603(XXIV) (1969), para. (b).

614 See *Joseph P. Dudley/Michael H. Woodford*, Bioweapons, Biodiversity, and Ecocide: Potential Effects of Biological Weapons on Biological Diversity, 52 (2002) BioScience 583.

615 *Stefan Oeter*, Methods and Means of Combat, in: Dieter Fleck (ed.), The Handbook of International Humanitarian Law (3rd ed. 2013) 115, MN. 441; also see *Goldblat* (n. 609), 254, noting that there have never been disputes among the parties regarding the definition of biological agents or toxins.

Consequently, whether these effects are caused through multiplication in the target organism does not seem to be a constitutive element of a 'biological agent'. In fact, nothing in the BWC justifies the assertion that the notion of a 'biological agent' is limited to living organisms or 'biological materials'.[616] The BWC also applies to 'toxins',[617] which means 'artificial nonbiological materials that mimic biological effects that impair specific biological functions for malign purposes'.[618] Non-biological materials or substances that cause harmful effects to organisms are covered by the *Chemical Weapons Convention*.[619]

At the *Review Conferences* of the BWC, states parties have repeatedly affirmed that Article I BWC covers all scientific and technological developments relevant to the Convention.[620] The fourth Review Conference in 1996 concluded that the undertaking in Article I BWC also applied, *inter alia*, to applications of 'microbiology, biotechnology, genetic engineering and, any applications resulting from genome studies and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention'.[621]

The eighth Review Conference in 2017 noted that the Convention was comprehensive in its scope and covered 'all naturally or artificially created

616 But see *Durward Johnson/James Kraska*, Some Synthetic Biology May Not Be Covered by the Biological Weapons Convention (18 May 2020), available at: https://www.lawfareblog.com/some-synthetic-biology-may-not-be-covered-biological-weapons-convention (last accessed 28 May 2022), arguing that the BWC may not apply to certain application of synthetic biology, including so-called 'biomimetics'.

617 See *Goldblat* (n. 609), 253–254, noting that: 'Toxins are poisonous products of organisms; unlike biological agents, they are inanimate and not capable of reproducing themselves. The Convention applies to all natural or artificially created toxins, "whatever their origin or method of production" (Article I). It thus covers toxins produced biologically, as well as those produced by chemical synthesis.'

618 Cf. *Johnson/Kraska* (n. 616).

619 See Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction (03 September 1992; effective 29 April 1997), 1974 UNTS 45, Article II(2), which defines a toxic chemicals as '[a]ny chemical which through its chemical action on life processes can cause death, temporary incapacitation or permanent harm to humans or animals. This includes all such chemicals, regardless of their origin or of their method of production, and regardless of whether they are produced in facilities, in munitions or elsewhere'.

620 BWC Implementation Support Unit (n. 612), paras. 13–15.

621 BWC COP, Fourth BWC Review Conference: Final Declaration (1996), UN Doc. BWC/CONF.IV/9, p. 13, Article I, para. 6.

or altered microbial and other biological agents and toxins, as well as their components, regardless of their origin and method of production and whether they affect humans, animals or plants' that have no justification in accordance with Article I BWC.[622] The Conference also expressly reaffirmed that 'Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention'.[623] Notably, the ILC has cited the decisions of the BWC Review Conferences as examples of decisions embodying a 'subsequent agreement between the parties regarding the interpretation of a treaty' in the sense of Article 31(3)(a) VCLT.[624] Consequently, the notion of a biological agent under the BWC is broad and includes any types of organisms or parts thereof which are genetically modified or even synthetically produced.[625]

According to the so-called 'general purpose criterion',[626] the BWC prohibits the development, production, stockpiling etc., of biological agents and toxins 'of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes'. Hence, a party engaged in developing biological agents for which a hostile use case is plausible must present acceptable explanations that its research is justified by prophylactic, protective, or other peaceful purposes.[627]

However, it may at times be difficult to draw a clear line between research aimed at developing agents for civilian purposes (such as vaccines) and research that is not justifiable under the BWC.[628] If a military or hostile use appears more plausible than the stated peaceful purpose, mere claims of peaceful intentions may be insufficient.[629] In evidentiary terms, the wording of the prohibition as set out in the BWC does not require a claimant state to prove that a certain undertaking serves a military objective. Instead, the state engaging in the relevant conduct must substantiate

622 BWC COP, Eighth BWC Review Conference: Final Declaration (25 November 2016), UN Doc. BWC/CONF.VIII/4, p. 9, Article I, para. 1.

623 *Ibid.*, Article I, para. 2.

624 Cf. ILC, Draft Conclusions on Subsequent Agreements and Subsequent Practice in Relation to the Interpretation of Treaties, with Commentaries (2018), UN Doc. A/73/10, p. 12, Conclusion 11(2) and Commentary thereto, para. 16–18.

625 On the potential of synthetic biology to develop biological weapons, see *Alexander Kelle*, Prohibiting Chemical & Biological Weapons (2014), 37–40.

626 Cf. *ibid.*, 49.

627 See *Daniel M. Gerstein*, National Security and Arms Control in the Age of Biotechnology (2013), 87–90.

628 *Goldblat* (n. 609), 254–255; similarly *Kelle* (n. 625), 223.

629 *Silja Vöneky*, Limiting the Misuse of the Environment during Peacetime and War – The ENMOD Convention, FIP 5/2020 (2020), 14.

its claim that peaceful purposes justify its undertaking.[630] At the same time, however, there mere possibility of a 'dual use' does not *per se* give rise to a breach of the BWC.[631]

Against this background, the development of self-spreading genetic elements such as gene drives or genetically modified viruses may run the risk of being perceived as a violation of the BWC.[632] As shown above, a United States government agency funded the development of insect-delivered genetically modified viruses engineered to perform genome editing of susceptible crops in already-planted fields.[633] However, there is no clear regulatory pathway toward the use of such a technique in agriculture. In most national regulatory regimes, genetic homogeneity is a basic precondition for the authorization of releases of genetically engineered organisms; this is also an implied requirement in the rules on the transboundary movement of LMOs under the Cartagena Protocol.[634] But such homogeneity seems highly unlikely to achieve with the proposed method.[635] Nor will it be possible to confidently determine which plants have been infected by the genetically modified virus.[636] At the same time, a weaponization of the approach seems to be more realistic to achieve than the stated agricultural use.[637] For this reason, the program could be perceived as an effort to

630 See *Rüdiger Wolfrum/Mirka Möldner*, International Courts and Tribunals, Evidence, in: Wolfrum/Peters (ed.), MPEPIL, MN. 64; ICJ, Certain Activities Carried out by Nicaragua in the Border Area (Costa Rica v. Nicaragua), Compensation Owed by Nicaragua to Costa Rica, Judgment of 02 February 2018, ICJ Rep. 15, para. 147; ICJ, Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo), Merits Judgment of 30 November 2010, ICJ Rep. 639, para. 55.

631 *Vöneky* (n. 629), 15.

632 *R. Guy Reeves* et al., Agricultural Research, or a New Bioweapon System?, 362 (2018) Science 35.

633 Cf. DARPA, Broad Agency Announcement: Insect Allies: HR001117S000 (2016); see chapter 1, section D.

634 Cf. Annex I, para. h, and Annex III, para. 9(d) of the Cartagena Protocol.

635 *Reeves* et al. (n. 632), 36; also see *Samson Simon* et al., Scan the Horizon for Unprecedented Risks, 362 (2018) Science 1007, noting that the proposed application 'is beyond any risk assessment ever performed in the field of biotechnology'.

636 *Reeves* et al. (n. 632), 36.

637 *Ibid.*

develop biological agents for hostile purposes.[638] Similar concerns have been raised concerning research on engineered gene drives.[639]

II. ENMOD Convention

The *ENMOD Convention* of 1976[640] prohibits the use of environmental degradation as a weapon in armed conflict.[641] It currently has 78 states parties including China and the United States, but excluding many states in South-East Asia, Latin America, and Africa.[642]

Article I of the ENMOD Convention prohibits the military or any other hostile use of environmental modification techniques which have widespread, long-lasting or severe effects[643] as the means of destruction, damage or injury to any other state party. The term 'environmental modification technique' is defined in Article II of the Convention as

> *'any technique for changing – through the deliberate manipulation of natural processes – the dynamics, composition or structure of the Earth, including its biota, lithosphere, hydrosphere and atmosphere, or of outer space'.*

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638 *Ibid.*, 35; also see *Todd Kuiken*, DARPA's Synthetic Biology Initiatives Could Militarize the Environment: Is that Something We're Comfortable with? (28 March 2018), available at: http://www.slate.com/articles/technology/future_tense/2017/05/what_happens_if_darpa_uses_synthetic_biology_to_manipulate_mother_nature.html (last accessed 28 May 2022); *Simon* et al. (n. 635).

639 *David Gurwitz*, Gene Drives Raise Dual-Use Concerns, 345 (2014) Science 1010; *Kuiken* (n. 638); *Lim/Lim* (n. 76), 59–61.

640 Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques (10 December 1976; effective 05 October 1978), 1108 UNTS 151. For a general introduction, see *Boothby* (n. 612), 78–81; *Vöneky* (n. 629).

641 On the status of this prohibition in customary international law, see *Henckaerts/Doswald-Beck* (n. 611), 151–158.

642 UN OLA, Status of the Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques, United Nations Treaty Collection, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVI-1&chapter=26&clang=_en (last accessed 28 May 2022).

643 According to an 'understanding' attached to the ENMOD Convention, there was agreement during the negotiations that 'widespread' should be interpreted as encompassing an area on the scale of several hundred square kilometres, that 'long-lasting' should mean lasting for a period of months, or approximately a season; and that 'severe' should involve serious or significant disruption or harm to human life, natural and economic resources or other assets.

In its ordinary meaning, the term 'biota' refers to the collective animal and plant life.[644] Hence, the Convention also applies to techniques of molecular biotechnology in so far as they are deliberately used to manipulate animal and plant life in order to cause injury to another state party in armed conflict. This includes any military uses of self-spreading biotechnology, such as engineered gene drives or (potentially insect-delivered) genetically modified viruses employed to modify crop plants or other organisms to the detriment of an adversary state.[645] On the other hand, the Convention expressly provides in Article III(1) that it shall not hinder the use of environmental modification techniques for peaceful purposes in accordance with the general rules of international law concerning such use. This raises similar problems in the context of dual-use techniques as the BWC.[646]

III. International Humanitarian Law

The law of armed conflict (*ius in bello*) prohibits using the environment as a means of warfare. Under Article 35(3) of the Additional Protocol I to the Geneva Conventions,[647] it is 'prohibited to employ methods or means of warfare which are intended, or may be expected, to cause widespread, long-term and severe damage to the natural environment'.[648] Moreover, Article 55(1) prohibits the use of these means insofar as they inflict environmental damage which may prejudice the health and survival of the population.[649] The Protocol has 174 states parties, excluding, *inter alia*, India, Israel, and the United States.[650] However, the basic rule that

644 Cf. 'biota, n.', in: Oxford English Dictionary (n. 12).

645 Cf. *Lim/Lim* (n. 76), 63.

646 *Vöneky* (n. 629), 14–15; see *supra* section J.I.

647 Protocol Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of International Armed Conflicts (Protocol I) (08 June 1977; effective 07 December 1978), 1125 UNTS 3.

648 Cf. *Boothby* (n. 612), 81–83.

649 Also see ICJ, Legality of the Threat or Use of Nuclear Weapons, Advisory Opinion of 08 July 1996, ICJ Rep. 226, para. 31.

650 Switzerland, Département fédéral des affaires étrangères, Etats parties au Protocole additionnel aux Conventions de Genève du 12 août 1949 relatif à la protection des victimes des conflits armés internationaux, available at: https://www.eda.admin.ch/dam/eda/fr/documents/aussenpolitik/voelkerrecht/geneve/1977-PROT-1_fr.pdf (last accessed 28 May 2022).

'destruction of the natural environment may not be used as a weapon' appears to be universal customary international law.[651]

IV. Conclusions

Although the BWC, the ENMOD Convention and the provisions of international humanitarian law have significant differences both in focus and scope,[652] this does not diminish their relevance in the context of self-spreading biotechnology. Under all three, the development of techniques that have no plausible peaceful use is prohibited. Moreover, the use of biotechnology as a weapon in international armed conflict is prohibited at least where the (potential) damage would be widespread, long-term and severe.

K. Summary

The present chapter has analysed the rules of international law applicable to the development, transboundary movement, and use of products of biotechnology. The analysis of the Cartagena Protocol's scope has shown that recent scientific and technological development can make it hard to determine whether these new techniques and the products they yield are covered by the existing instruments. Yet, the definition of the term 'living modified organism' is significantly wider than the respective definition in other regulatory regimes, including that under EU law.[653] Consequently, organisms modified with recently developed genome editing techniques fall within the scope of the Cartagena Protocol even when the technique employed – unlike conventional methods of genetic engineering – does not involve the insertion of foreign genetic material into the target organism.[654] At the same time, there is no doubt that the Cartagena Protocol applies to modified organisms that carry foreign genetic elements, includ-

651 *Henckaerts/Doswald-Beck* (n. 611), 155–156.

652 See *Eric T. Jensen*, The International Law Environmental Warfare: Active and of Passive Damage During Armed Conflict, 38 (2005) Vanderbilt Journal of Transnational Law 145, 165–177; *Waldemar A. Solf*, Article 55 AP I, in: Michael Bothe/Karl J. Partsch/Waldemar A. Solf (eds.), New Rules for Victims of Armed Conflicts (2013), para. 2.6.

653 See *supra* section A.I.1 and A.IV.3.

654 See *supra* section A.I.1.e)aa).

ing, in particular, engineered or synthetic gene drives.[655] In order not to have to return to this discussion for each of the instruments analysed subsequently, their applicability was presumed and not discussed individually. Yet, where these instruments become practically relevant, answering the question of applicability will be not only inevitable but also difficult, as many instruments lack clear definitions of what they refer to as LMOs or GMOs.

The purpose of the Cartagena Protocol is to ensure that each party can take sovereign decisions on whether to allow the import and environmental release of LMOs in its territory. This is achieved by a comprehensive procedural framework for obtaining the so-called *Advance Informed Agreement* of the receiving state.[656] A significant challenge to the effectiveness of the AIA mechanism is the fact that its applicability depends on the (stated) intentions about whether or not an LMO will be released into the environment once it has been imported into the receiving state.[657] At the same time, the design of the AIA mechanism also reflects the fact that there is no consensus within the international community on whether techniques of genetic engineering should generally be seen as posing threats to biological diversity, human health etc.[658] Against this background, it is not surprising that the Cartagena Protocol's provisions on risk management and preparedness remain comparatively vague.[659] States are required to act with due diligence to prevent unintentional[660] or illegal[661] transboundary movements of LMOs but are largely free to decide how to regulate the development and use of LMOs in their own territory.[662] Yet, states are required to cooperate, especially in sharing information about potential hazards originating from LMOs.[663]

A notable exception is Article 25(2), which arguably imposes a strict obligation on the state of origin to dispose of an LMO illegally imported into another state. As the lawfulness of the import depends on whether

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655 See *supra* section A.I.1.e)bb) and cc).
656 See *supra* section A.II.1.
657 See *supra* section A.II.1.g).
658 Cf. *Mackenzie/Sands* (n. 170), 466. Interestingly, applications of the same techniques in human medicine seem to be much less controversial, and gene therapy applications appear to be only marginally addressed by international law.
659 See *supra* section A.II.2. Also see *Hill* (n. 153).
660 See *supra* section A.II.2.a)cc).
661 See *supra* section A.II.2.c).
662 See *supra* sections A.II.2.a) et seq.
663 See *supra* sections A.II.3 et seq.

the AIA mechanism, as well as the domestic laws of the receiving state, have been observed, this obligation is independent of any wrongdoing on the part of the state of origin. However, it remains questionable how this obligation can be implemented, especially when a (potentially self-spreading) LMO has already been released into the environment of the receiving state.[664]

Moreover, the freedom of each state to make its own decisions about whether to allow the import of LMOs into its territory may be considerably limited by international trade law, which provides that any restriction on international trade for the purpose of protecting the environment or human health must be based on scientific evidence about the risks that are to be averted.[665] In contrast to the Cartagena Protocol, states are not allowed to invoke scientific uncertainty about risks as a reason to restrict trade, but only insufficient scientific information that prevents a scientifically sound risk assessment altogether.[666] The WTO's dispute settlement mechanism, which is compulsory for all WTO member states, has yet to find a coherent approach on how to integrate WTO law into the wider body of international law.[667]

Besides the Cartagena Protocol, the provisions on biotechnology contained in the Convention on Biological Diversity remain relevant, particularly with regard to those states which have not ratified the Cartagena Protocol. At the same time, many of the obligations stipulated by the CBD are broad and unspecific, which makes it difficult to assess compliance. However, programmes aimed at completely eradicating a species within its native habitat range may be in breach of the CBD and thus be prohibited by international law altogether.[668] Moreover, the CBD and several other instruments address the risk of invasive species and it appears to be widely recognized that LMOs which may become invasive are covered by those provisions.[669] This is particularly relevant in the context of organisms equipped with self-spreading genetic elements, such as engineered gene drives or genetically modified viruses. There seems to be a universal consensus that states are obliged to prevent the spread of invasive species.

664 See *supra* section A.II.2.c)bb).
665 See *supra* section C.I.
666 See *supra* sections C.II.
667 See *supra* sections C.III.
668 See *supra* section B.
669 See *supra* sections B.V, C, E, and G.

Despite the widespread and persisting disagreement about whether LMOs are – as such and inherently – hazardous, the international treaties concerned with plant[670] and animal[671] health, food safety,[672] and international transport of hazardous goods[673] recognize that LMOs (or GMOs) may indeed pose certain risks. Yet, these instruments take a more pragmatic approach than the Cartagena Protocol by providing specific guidance on how to assess potential risks of LMOs in their specific context and on how to handle LMOs in ways that minimize these risks.

When a modified organism or pathogen causes a transmissible disease in humans, the WHO's International Health Regulations come into play. They require the state where the outbreak occurs to speedily inform the WHO, which can then issue recommendations to the affected states on how to mitigate the outbreak, and to non-affected states on how to prevent an international spread. However, the recent experience of the COVID-19 pandemic has shown that states may be reluctant to make early notifications to avert travel and trade restrictions, while non-affected states tend to implement the WHO's recommendations inconsistently.[674]

Finally, biotechnology may not necessarily be used for peaceful purposes. Fortunately, the pertinent instruments on biological weapons,[675] environmental modification techniques,[676] and international humanitarian law[677] provide rules which are broad enough to also cover more recent developments in biotechnology. Yet, ensuring compliance with these provisions remains a major challenge.

Challenges are also posed by the fact that the existing framework of international treaties and instruments may be insufficient to ensure that products of biotechnology do not cause adverse transboundary effects. As shown in the first chapter, the increasing development of self-spreading biotechnology, including engineered gene drives and modified viruses, have a high likelihood of spreading across political borders either through natural gene flow or (deliberately or inadvertently) transported by humans.[678] Although the obligation to prevent unintentional transboundary

670 See *supra* section D.
671 See *supra* section E.
672 See *supra* section F.
673 See *supra* section H.
674 See supra section I.
675 See *supra* section J.I.
676 See *supra* section J.II.
677 See *supra* section J.III.
678 See chapter 1, section C.IV.4.

movements is recognized in the Cartagena Protocol, the practical effectiveness of this obligation appears to be limited.[679] Moreover, a major shortcoming of the Cartagena Protocol is that it lacks participation by several 'key players' in the field of biotechnology, including the United States. This raises the question of whether the rules of universal customary international law on the prevention of transboundary environmental interference, which are analysed in the following chapter,[680] can fill these gaps. Subsequently, the debate on engineered gene drives is assessed as a current example of the difficulties involved in regulating emerging techniques that may have transboundary effects.[681]

679 See *supra* section A.II.2.a)cc).
680 See chapter 3.
681 See chapter 4.

Chapter 4: Prevention of Transboundary Harm from Biotechnology Under Customary International Law

The preceding chapter has shown that the existing international instruments may be insufficient to effectively prevent adverse transboundary effects of LMOs. For this reason, existing universal rules of customary international law may be particularly relevant in determining the rights and obligations of states in the prevention of transboundary harm.

As defined in Article 38(1) of the Statute of the *International Court of Justice* (ICJ),[1] rules of custom require a general practice of states carried by a corresponding conviction that their conduct is legally required.[2] The most fundamental obligation in international environmental law, and one of the cornerstones of modern international law generally, is the obligation of states to ensure that activities within their territory do not cause harm to the territory of other states (A.).

After assessing the material and spatial scope of this obligation (B.), the present chapter analyses the doctrine of due diligence, which is the standard of conduct in the fulfilment of this obligation (C.). Besides, the preventive obligation also entails more specific procedural obligations that must be observed by states (D.). Yet, identifying breaches of the obligation to prevent transboundary harm, which would entail the international responsibility of the source state, is prone to difficulties (E.).

A. *The Legal Foundation of the Obligation to Prevent Transboundary Harm*

The obligation not to cause significant transboundary environmental interference has its roots in the principle that the territorial sovereignty of states finds its limits where its exercise adversely affects the territorial sovereignty

1 Statute of the International Court of Justice (18 April 1946), 33 UNTS 993.
2 Cf. ICJ, North Sea Continental Shelf (Federal Republic of Germany v. Denmark; Federal Republic of Germany v. Netherlands), Judgment of 20 February 1969, ICJ Rep. 3, para. 77.

and integrity of other states.[3] This principle is, in turn, based on the even more fundamental principle of *sic utere tuo ut alienum non laedas*, which dictates that one shall use his own property so as not to harm that of another.[4] Although the obligation not to cause transboundary harm had been recognized in scholarly literature much earlier,[5] the first prominent expression of this principle was made by the arbitral tribunal in the *Trail Smelter* case, which concluded in 1939 that

> *'under the principles of international law […] no State has the right to use or permit the use of its territory in such a manner as to cause injury by fumes in or to the territory of another or the properties or persons therein, when the case is of serious consequence and the injury is established by clear and convincing evidence.'*[6]

Subsequently, the obligation not to cause transboundary harm was recognized and endorsed by the international community in numerous multilateral treaties and *soft law* declarations. While the Trail Smelter principle was still phrased in a prohibitive manner ('no State has the right'), the emphasis later shifted towards a positive obligation of states to proactively ensure that activities under their jurisdiction do not cause harm to other states.[7] This resulted in the so-called 'principle of prevention', which was first recognized on the universal level in Principle 21 of the *Stockholm Declaration* of 1972:

> *'States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause*

3 Cf. ICJ, Corfu Channel Case (United Kingdom v. Albania), Merits Judgment of 09 April 1949, ICJ Rep. 4, 22, noting that a state must not 'knowingly allow its territory to be used for acts contrary to the rights of other States'.

4 See *Leslie-Anne Duvic-Paoli*, The Prevention Principle in International Environmental Law (2018), 16–21.

5 Cf. *Lassa F. L. Oppenheim*, International Law: A Treatise (2nd ed. 1912), § 127, arguing that: 'A State, in spite of its territorial supremacy, is not allowed to alter the natural conditions of its own territory to the disadvantage of the natural conditions of the territory of a neighbouring State.'

6 Trail Smelter Case (United States v. Canada), Decision of 11 March 1941, III RIAA 1938, 1965; see *John E. Read*, The Trail Smelter Dispute, 1 (1963) Canadian YBIL 213.

7 See *Duvic-Paoli* (n. 4), 27–46.

damage to the environment of other States or of areas beyond the limits of national jurisdiction.'[8]

The parallel recognition of the states' sovereignty over their own resources on the one hand, and their obligation not to cause transboundary harm on the other, was subsequently reaffirmed in the *Rio Declarations* of 1992[9] and 2012.[10] It was also incorporated into a number of multilateral agreements on the environment,[11] including the *Convention on Biological Diversity*[12] and the *United Nations Convention on the Law of the Sea*.[13] Both conventions are virtually universally ratified.[14]

The obligation to prevent transboundary harm has also been recognized in international jurisprudence.[15] The ICJ first recognized the principle in

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8 Declaration of the United Nations Conference on the Human Environment (16 June 1972), UN Doc. A/Conf.48/14/Rev.1 (hereinafter 'Stockholm Declaration 1972'), Principle 21.

9 Rio Declaration on Environment and Development (14 June 1992), UN Doc. A/CONF.151/26/Rev.1 (Vol. I) (hereinafter 'Rio Declaration 1992'), Principle 2.

10 The Future We Want: Outcome Document of the United Nations Conference on Sustainable Development (22 June 2012), UN Doc. A/RES/66/288, Annex, paras. 14, 15, 227.

11 For an analysis of preventive obligations in treaty law, organized by types of risk, see *Duvic-Paoli* (n. 4), 66–76. For reiterations of the principle of prevention in regional treaties, see *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 209.

12 Cf. Convention on Biological Diversity (05 June 1992; effective 29 December 1993), 1760 UNTS 79 (hereinafter 'CBD'), Article 3.

13 Cf. United Nations Convention on the Law of the Sea (10 December 1982; effective 16 November 1994), 1833 UNTS 3 (hereinafter 'UNCLOS'), Article 194(2). On the jurisprudence of ITLOS on environmental matters, see *Jiang Xiaoyi/Zhang Jianwei*, Marine Environment and the International Tribunal for the Law of the Sea: Twenty Years' Practices and Prospects, 5 (2017) China Legal Science 84.

14 The only notable exception is the United States, which has not ratified either of the conventions (it has signed the CBD in 1993 but not ratified it since, and has neither signed nor acceded to the UNCLOS). However, the obligation not to cause significant transboundary harm is recognized in other environmental agreements to which the United States are a party, such as the United Nations Convention to Combat Desertification (14 October 1994; effective 26 December 1996), 1954 UNTS 3 (hereinafter 'UNCCD'), the Vienna Convention for the Protection of the Ozone Layer (22 March 1985; effective 22 September 1988), 2513 UNTS 293, and the United Nations Framework Convention on Climate Change (09 May 1992; effective 21 March 1994), 1771 UNTS 107 (hereinafter 'UNFCCC').

15 For an overview of relevant international case-law, see *Phoebe N. Okowa*, Responsibility for Environmental Damage, in: Malgosia A. Fitzmaurice/David Ong/

its advisory opinion on the *Legality of the Threat or Use of Nuclear Weapons* of 1996, in which it concluded that:

> *'The existence of the general obligation of States to ensure that activities within their jurisdiction and control respect the environment of other States or of areas beyond national control is now part of the corpus of international law relating to the environment.'*[16]

Since then, the Court has reiterated the principle of prevention in several cases, including the case concerning the *Gabčíkovo-Nagymaros Project*,[17] the *Pulp Mills* case,[18] and the *Certain Activities* case between Nicaragua and Costa Rica.[19] It is, therefore, safe to conclude that the obligation of states to prevent transboundary environmental harm is well established in both international treaties and customary international law, and forms one of the cornerstones of international environmental law.[20]

The *International Law Commission* (ILC),[21] which has been considering the issue of transboundary environmental harm since 1978, adopted *Draft*

Panos Merkouris (eds.), Research Handbook on International Environmental Law (2010) 303, 305–312; *Duvic-Paoli* (n. 4), 137–166.

16 ICJ, Legality of the Threat or Use of Nuclear Weapons, Advisory Opinion of 08 July 1996, ICJ Rep. 226, para. 29.

17 ICJ, Gabčíkovo-Nagymaros Project (Hungary v. Slovakia), Judgment of 25 September 1997, ICJ Rep. 7, para. 53.

18 ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment of 20 April 2010, ICJ Rep. 14, para. 193.

19 ICJ, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) and Construction of a Road in Costa Rica along the San Juan River (Nicaragua v. Costa Rica), Merits Judgment of 16 December 2015, ICJ Rep. 665, para. 118. For an overview of the Court's jurisprudence relating to the environment, see *Alan E. Boyle/Catherine Redgwell*, Birnie, Boyle, and Redgwell's International Law and the Environment (4th ed. 2021), 156–158.

20 *Rebecca M. Bratspies*, State Responsibility for Human-Induced Environmental Disasters, 55 (2012) German YBIL 175, 185; *Sands* et al. (n. 11), 207; *Duvic-Paoli* (n. 4), 174–175.

21 The ILC was established by the UN General Assembly in 1947 in order to promote the codification and progressive development of international law, accordance with Article 13(1)(a) of the UN Charter, cf. UNGA, Resolution 174 (II). Establishment of an International Law Commission (21 November 1947), UN Doc. A/RES/174(II). The ILC prepares draft conventions (commonly referred to as 'draft articles') on subjects which have not yet been regulated by international law or in regard of which the law has not yet been sufficiently developed in state practice, see Statute of the International Law Commission (21 November 1947), UN Doc. A/RES/174(II), last amended by UNGA resolution 36/39 of 18 November 1981, Article 15. The ILC's draft articles are often regarded as codify-

Articles on the Prevention of Transboundary Harm from Hazardous Activities in 2001.[22] The Articles stipulate that states shall take 'appropriate measures to prevent significant transboundary harm or at any event to minimize the risk thereof' from being caused by hazardous activities carried out under their jurisdiction.[23] This pivotal obligation is further specified in a set of detailed rules on both procedural and substantive aspects of prevention. The core of these rules is widely recognized as representing customary international law,[24] although it is questionable whether the Articles in their entirety can be regarded as a codification of custom.[25] As shown subsequently, the precise legal content and the specific duties flowing from the obligation to prevent transboundary harm are still unsettled.[26]

B. Scope of the Obligation to Prevent Transboundary Harm

Before discussing the substantive content of the obligation to prevent transboundary harm, it is necessary to clarify the scope of this obligation. The ILC's Articles on Prevention, which are the 'text of reference' to analyse the scope of the preventive obligation,[27] apply to 'activities not prohibited by international law which involve a risk of causing significant transboundary harm through their physical consequences'.[28]

Thus, the obligation applies to harm (I.) in a transboundary context (II.), provided that such harm is caused through the 'physical consequences' of an activity (III.). The obligation is triggered whenever there is a 'risk of significant transboundary harm', which is a combined threshold incorpo-

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ing the pertinent rules of customary international law, see *Fernando L. Bordin*, Reflections of Customary International Law: The Authority of Codification Conventions and ILC Draft Articles in International Law, 63 (2014) ICLQ 535.

22 ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148 (hereinafter 'ILC, Articles on Prevention').

23 *Ibid.*, Article 3.

24 See *Boyle/Redgwell* (n. 19), 154.

25 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge Donoghue, para. 19, warning that 'their role in the assessment of State practice and *opinio juris* must not be overstated'. For a detailed analysis, including of comments by states in the Sixth Committee of UNGA, see *Duvic-Paoli* (n. 4), 101–104.

26 *Bratspies* (n. 20), 185.

27 *Duvic-Paoli* (n. 4), 234.

28 ILC, Articles on Prevention (n. 22), Article 1.

rating both the potential magnitude of harm (IV.) and the probability that harm will occur (V.). In situations where risk cannot be clearly anticipated, it is questionable whether the precautionary principle mandates or even requires preventive action (VI.). Finally, it is assessed whether these criteria capture transboundary risks arising from products of modern biotechnology such as living modified organisms (VII.).

I. Harm

There is no consistent terminology to describe the subject matter of the obligation of prevention.[29] Instead, terms like 'transboundary impacts', 'transboundary pollution', 'transboundary adverse effects', and 'transboundary environmental interference' are often used interchangeably.[30] The ILC has distinguished between 'transboundary harm' and 'transboundary damage', using 'harm' to denote the adverse effects that may ensue from a hazardous activity and 'damage' for those consequences once they have materialized.[31] 'Damage' is also the term which is commonly used in international instruments on environmental liability.[32] But in the context of preventive obligations, the ILC has rather referred to

29 Also see *James Crawford*, Fourth Report on State Responsibility, UN Doc. A/CN.4/517 and Add.1 (2001), para. 30.

30 See, e.g., *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 8–10; *Hanqin Xue*, Transboundary Damage in International Law (2003), 3–10.

31 *Julio Barboza*, The Environment, Risk and Liability in International Law (2011), 10; cf. ILC, Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, with Commentaries (2006), YBILC 2006, vol. II(2), p. 56 (hereinafter 'ILC, Allocation of Loss Principles'), Commentary to Principle 1, para. 11; also see *Joanna Kulesza*, Due Diligence in International Law (2016), 205.

32 See e.g. International Convention on Civil Liability for Oil Pollution Damage (29 November 1969; effective 19 June 1975), 973 UNTS 3, as amended by the Protocol of 27 November 1992 (effective 30 May 1996), 1956 UNTS 255, Article 1(6); Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal (10 December 1999; not yet in force), UNEP/CHW.5/29, p. 88, Article 2(2)(c); ILC, Allocation of Loss Principles (n. 31), Principles 1 and 2(a); Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64 (hereinafter 'Supplementary Protocol'), Article 2(2)(b).

'harm'.[33] Interestingly, the ILC's Articles on Prevention do not provide a comprehensive definition of this term, but merely state that it shall include 'harm caused to persons, property and the environment'.[34] English dictionaries also provide no abstract definition of the term but only refer to synonyms such as *injury*, *loss*, or *damage*.[35] Consequently, the preventive obligation is not limited to 'environmental harm' (a term which involves its own definitional problems[36]), but in principle covers any type of transboundary interference that has adverse or injurious consequences.[37]

II. Transboundary Harm

'Transboundary harm' is commonly understood as harm which is caused by an activity in one state and which materializes in the territory of another state.[38] Contrary to what the term might imply, transboundary harm can occur whether or not the states concerned share a common border.[39] However, the notion of transboundary harm may raise problems when the harm does not originate from a place under the jurisdiction or control of a state (1.), or when harm is caused to an area beyond the limits of national jurisdictions (2.) or to 'global commons' (3.).

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33 See ILC, Articles on Prevention (n. 22), Article 2(b).

34 See. *ibid.*, Commentary to Article 2, para. 8, assuming that this was 'self-explanatory'.

35 Cf. 'harm, n.' in: *James Murray* et al., Oxford English Dictionary, Online Edition, available at: http://www.oed.com/ (last accessed 28 May 2022); *Bryan A. Garner* (ed.), Black's Law Dictionary (11th ed. 2019), 861.

36 The term 'environment' is not defined in the Articles on Prevention, but in the ILC's *Principles on Allocation of Loss*, where the environment is broadly defined as including 'natural resources, both abiotic and biotic, such as air, water soil, fauna and flora, and the interaction between the same factors, and the characteristic aspects on the landscape', cf. ILC, Allocation of Loss Principles (n. 31), Principle 2(b); see *Duvic-Paoli* (n. 4), 180. Also see the introduction to chapter 11.

37 *Ibid.*, 66–67; also see *R. D. Munro/Johan G. Lammers* (eds.), Environmental Protection and Sustainable Development (1987), 38, which define the term 'environmental interference' as 'any impairment of human health, living resources, ecosystems, material property, amenities or other legitimate uses of a natural resource or the environment caused, directly or indirectly, by man through polluting substances, ionizing radiation, noise, explosions, vibrations or other forms of energy, plants, animals, diseases, flooding, sand-drift or other similar means'.

38 Cf. ILC, Articles on Prevention (n. 22), Article 2(c) and (d), and commentary, para. 9; *Lefeber* (n. 30), 10; *Xue* (n. 30), 8–9.

39 ILC, Articles on Prevention (n. 22), Article 2(c).

1. 'Extraterritorial' Transboundary Harm

It is recognized that transboundary harm may also originate from locations outside the territory of a state, provided that the activity is conducted under the 'jurisdiction or control' of that state.[40] The notion 'jurisdiction' refers to all situations in which the state is authorized by international law to exercise governmental authority, such as over ships or aircraft flying its flag.[41]

The notion 'control' has been used to refer to situations in which a state is exercising *de facto* jurisdiction, such as in cases of unlawful intervention, occupation, and unlawful annexation.[42] Hence, the meaning of 'control' in the present context appears to be different from that of the same term under the international law of state responsibility. According to Article 8 of the ILC's *Articles on State Responsibility*,[43] the conduct of a non-state actor 'shall be considered an act of a State' if that person or group is in fact acting under the 'control' of that state. It is recognized that this implies a higher threshold than mere control of a state over its territory and the persons residing therein.[44] Compared to this, the notion of 'jurisdiction or control' in the context of transboundary harm refers not to control over individuals and their activities, but to control over territory in the sense

40 *Ibid.*, Article 2(d) and commentary to Article 1, para. 9. *Vice versa*, transboundary harm may not only affect the territory of another state but also other places under its jurisdiction or control, see ILC, Articles on Prevention (n. 22), Article 2(c) and commentary thereto, para. 9.

41 *Ibid.*, Commentary to Article 1, para. 10; *Lefeber* (n. 30), 11.

42 ILC, Articles on Prevention (n. 22), Commentary to Article 1, para. 12; *Lefeber* (n. 30), 11–12; see *Markus Vordermayer*, The Extraterritorial Application of Multilteral Environmental Agreements, 59 (2018) Harv. Int'l L. J. 59, 65, noting that '[i]n the environmental context, no specific jurisdiction rules have so far emerged; states thus need to resort to the general rules of jurisdiction, notably the territoriality principle, in order to regulate and control, for example, the activities of foreign companies'.

43 ILC, Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries (2001), YBILC 2001, vol. II(2), p. 31 (hereinafter 'ARSIWA').

44 ICJ, Corfu Channel (Merits) (n. 3), 18; cf. ARSIWA (n. 43), Commentary to Article 8, para. 3.

of *de facto jurisdiction*,[45] which does not require that a state is aware of the relevant activities or even has 'effective' control over them.[46]

Nevertheless, there may be situations where a state has 'control' over the conduct of non-state actors even though it does not exercise 'jurisdiction or control' over the place where the conduct is carried out. This could be the case where non-state actors acting under a state's control operate in areas beyond national jurisdiction or – illegally – in the territory of another state, for instance by releasing LMOs.[47] In such situations, it could be argued that the obligation to prevent transboundary harm did not apply because the relevant activities did not occur under the (territorial) 'jurisdiction or control' of the responsible state.[48] However, to avoid fragmentation as well as *lacunae* in responsibility, the notion of 'control' in the context of transboundary harm should be construed as also including all situations within the ambit of Article 8 of the Articles on State Responsibility. Whenever a state exercises 'control' over an activity, regardless of whether by means of territorial control or control over the conduct of individuals,[49] it is required to ensure that the activity does not cause harm to other states.[50]

2. Harm to Areas Beyond National Jurisdiction

The obligation to prevent transboundary harm not only applies to harm caused to other states but also to harm caused to areas beyond the limits of national jurisdiction.[51] This has been recognized in the *Stockholm* and

45 See ILC, Articles on Prevention (n. 22), Commentary to Article 1, paras. 9–12, citing ICJ, Legal Consequences for States of the Continued Presence of South Africa in Namibia, Advisory Opinion of 21 June 1971, ICJ Rep. 16, para. 118.

46 The term 'effective' is often used to qualify the notion of 'control' in the context of attribution, cf. ICJ, Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States of America), Merits Judgment of 27 June 1986, ICJ Rep. 14, para. 115; ARSIWA (n. 43), Commentary to Article 8, paras. 4–8.

47 On the conditions for attributing such conduct to a state, see chapter 9, section A.II.2.a)cc).

48 See *Vordermayer* (n. 42), 85–86.

49 See *supra* fn. 46.

50 On the question whether multilateral environmental agreements create extraterritorial obligations even beyond this scope, see *Vordermayer* (n. 42), 87–124.

51 See *ibid.*, 116–118.

Rio Declarations[52] as well as the multilateral treaties governing these areas, namely the high seas and the deep seabed,[53] the Antarctic,[54] and outer space.[55] Article 3 of the CBD also provides that states have the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of areas beyond the limits of national control.[56]

Interestingly, the scope of the ILC's Prevention Articles does not cover the prevention of harm to areas beyond national jurisdiction but is expressly limited to damage to the territory of other states (or other places under the latter's jurisdiction or control).[57] This could be explained by the fact that extending the preventive obligation to areas beyond national jurisdiction significantly modifies the rationale of this obligation, as the focus is shifted from avoiding external infringements of national sovereignty towards protecting the environment *per se*.[58] But there is no doubt that the obligation to prevent harm to areas beyond national jurisdiction is now part of customary law.[59] This was also recognized by the ICJ in its *Nuclear Weapons* advisory opinion.[60]

3. Harm to 'Global Commons'

States can also be required to prevent certain forms of environmental harm even when there is no clear impact on specific states or specific areas beyond national jurisdiction. This primarily relates to issues of 'global concern' such as global warming, deforestation, desertification, and the

52 Stockholm Declaration 1972 (n. 8), Principle 21; Rio Declaration 1992 (n. 9), Principle 2.
53 UNCLOS (n. 13), Articles 145 and 192.
54 Protocol on Environmental Protection to the Antarctic Treaty (04 October 1991; effective 14 January 1998), 30 ILM 1455, Article 2.
55 Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies (27 January 1967; effective 10 October 1967), 610 UNTS 205, Article IX.
56 See chapter 3, section B.II.
57 Cf. ILC, Articles on Prevention (n. 22), Article 2(c).
58 *Duvic-Paoli* (n. 4), 239–240; also see *Barboza* (n. 31), 87, suggesting that the issue of damage to areas beyond the limits of national jurisdiction was left aside by the ILC in order not to further increase the complexity of the work before it.
59 *Xue* (n. 30), 10; *Duvic-Paoli* (n. 4), 239–240; *Sands* et al. (n. 11), 206; *Boyle/Redgwell* (n. 19), 161–162.
60 Cf. ICJ, Nuclear Weapons (n. 16), para. 29.

loss of global biodiversity.[61] These issues are difficult to assess from a legal perspective because they are caused cumulatively by the international community through legitimate exercises of territorial sovereignty by individual states and, for this reason, cannot be easily attributed to any particular state.[62] At the same time, further harm can only be prevented effectively by joint action of all states, as individual states alone are unable to reverse the course of degradation.[63] Moreover, damage to global commons raises questions related to the enforcement of responsibility, especially with regard to the standing to make claims.[64]

Some authors in legal scholarship have distinguished between the responsibility not to cause significant transboundary harm on the one hand and the preventive principle on the other, arguing that the latter required states to prevent environmental harm regardless of whether or not there are transboundary impacts.[65] Indeed, a number of environmental treaties create preventive obligations that are not focused on transboundary effects but on environmental issues which, despite primarily concerning each state party's own environment, ultimately constitute a 'common concern'.[66] It can, therefore, be assumed that states are not only required to prevent transboundary harm but also to prevent harm to values of 'common concern'.[67] However, in its generality, this obligation remains

61 See *Boyle/Redgwell* (n. 19), 143–145.
62 *Xue* (n. 30), 16.
63 *Ibid.*
64 *Ibid.*, 237–250; see chapter 9, section C.I.
65 *Sands* et al. (n. 11), 212; *Alexandre Kiss/Dinah Shelton*, Guide to International Environmental Law (2007), 91; *Boyle/Redgwell* (n. 19), 143.
66 Cf., e.g., the obligation to protect and preserve the marine environment stipulated in Article 192 of UNCLOS (n. 13), which international jurisprudence confirmed to apply 'to all maritime areas' (ITLOS, Request for an Advisory Opinion Submitted by the Sub-regional Fisheries Commission, Advisory Opinion of 02 April 2015, Case No. 21, ITLOS Rep. 4, para. 120). Also see the references in *Boyle/Redgwell* (n. 19), 143; *Duvic-Paoli* (n. 4), 246–247.
67 *Xue* (n. 30), 250; *Duvic-Paoli* (n. 4), 241; *Boyle/Redgwell* (n. 19), 143–145; also see *Roda Verheyen*, Climate Change Damage and International Law (2005), 166–168, specifically addressing the no-harm rule in the context of climate change and arguing that 'neither the decades of ILC debates on the issue of prevention of environmental harm nor international jurisprudence provide evidence that complex instances of environmental change are not be covered by the general duty to prevent harm and minimize the risk thereof'.

difficult to grasp and needs to be operationalized by more specific provisions in multilateral treaties.[68]

The aforementioned conclusions also hold true in the context of the present study. In principle, the CBD does not stipulate an obligation of states to prevent the global long-term loss of biological diversity.[69] But at the same time, the CBD expressly applies to all activities under the jurisdiction of states parties, regardless of where their effects occur.[70] Consequently, the obligation to regulate and control LMOs under Article 8(g) CBD and the obligation to control invasive alien species that threaten ecosystems, habitats and species stipulated in Article 8(h) CBD are not limited to effects that might negatively affect biodiversity in individual states, but potentially also apply to the global impacts of such organisms. The Cartagena Protocol, on the other hand, is limited to regulating the transboundary movements of LMOs (in terms of movements between states) but does not apply to the release of LMOs in areas beyond the limits of national jurisdictions.[71] However, as shown earlier, Article 196(1) UNCLOS requires all states parties to prevent the environmental release of LMOs that may cause significant and harmful changes to the marine environment; this obligation also applies on the high seas beyond national jurisdiction.[72]

III. Harm Caused by ‘Physical Consequences’

As shown above, transboundary harm is generally construed as harmful effects which originate in one state and, after being subject to an undelib-

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68 See, in particular, *Alexander Zahar*, Methodological Issues in Climate Law, 5 (2015) Climate Law 25.

69 See Article 3 CBD, which merely reiterates the general obligation of states to ensure that their activities do not cause damage to the environment of other states or of areas beyond national jurisdiction. But see *Daniela M. Schmitt*, Staatenverantwortlichkeit für Schäden an der biologischen Vielfalt (2018), 292–296, who argues that, because the conservation of global biodiversity is a ‘common concern’, the obligation to prevent harm should be read extensively as requiring states to also prevent harm to the biodiversity in their own territory.

70 Cf. Article 4(b) CBD.

71 See chapter 3, section A.I.3.

72 *Detlef Czybulka*, Article 196 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017), MN. 13; see chapter 3, section G.

erate transboundary movement, cause damage in another state.[73] However, it has been controversial which types of effects are covered by this obligation.

During the ILC's deliberation of the topic, one of the major debates was whether the topic should be confined only to environmental harm, or whether it should cover all kinds of transboundary harm including those arising from economic, financial and trade activities, such as the devaluation of a state's currency.[74] The ILC ultimately agreed to limit the scope of the Articles on Prevention to harm caused by the 'physical consequences' of activities, which was meant to rule out harm caused by state policies in monetary, socio-economic or similar fields.[75] At the same time, the ILC agreed that the term 'physical' was to be understood broadly,[76] and that 'physical consequences' could encompass any consequence 'which does or may arise out of the very nature of the activity or situation in question, in response to a natural law'.[77] Consequently, a transboundary spread of LMOs or transboundary adverse effects caused an LMO could be regarded as 'physical consequences' of their release.[78]

Environmental harm may also be caused following the deliberate transfer of hazardous technology or substances into another state. In that case, both the adverse effects and the act ultimately causing these effects take place in the same country, but the actual responsibility nonetheless lies with a foreign actor.[79] As opposed to *transboundary* harm, these situations can be referred to as cases of *transnational* harm:[80]

> *'The "transnational" case is where the activity and the physical damage all occur within one country, but nonetheless there is a transnational involvement, for example, because capital (including technological know-how) has*

73 ILC, Articles on Prevention (n. 22), Article 2(c); see *supra* section B.II.
74 *Xue* (n. 30), 5; *Barboza* (n. 31), 83.
75 ILC, Articles on Prevention (n. 22), Commentary to Article 1, para. 16.
76 Also see 'physical, adj.', in: Oxford English Dictionary (n. 35), sect. III.7.a; Black's Law Dictionary (n. 35), 1386.
77 ILC, Report of the Working Group on International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law, YBILC 1996, vol. II(2), p. 100 (1996), Commentary to Article 1, para. 25.
78 Similar questions are raised in the context of cyber-attacks, see *Beatrice A. Walton*, Duties Owed: Low-Intensity Cyber Attacks and Liability for Transboundary Torts in International Law, 126 (2017) Yale L.J. 1460, 1478–1484.
79 *Xue* (n. 30), 9.
80 See, e.g., *Michael Mason*, The Governance of Transnational Environmental Harm: Addressing New Modes of Accountability/Responsibility, 8 (2008) Global Environmental Politics 8.

been exported from another country in order to make possible the activity which has caused environmental damage and, presumably, any profits realized from such exported capital will be returned in one way or another to its country of origin.'[81]

It has been argued that state-centred accountability regimes are unfit to adequately address transnational environmental harm.[82] Developing countries in particular are often unable to adequately regulate externally-generated threats to the well-being of their population, both due to their limited regulatory capabilities as well as the high thresholds international law sets for lawful restrictions on international trade.[83] At the same time, the states of origin of the hazardous techniques or substances are often either unwilling or unable to appropriately control the extraterritorial activities of their nationals.[84] But contrary to what has been suggested by some authors,[85] there is no general responsibility of developed states for injury caused by their nationals in the territory of other (especially developing) states.[86] After all, this would require the exercise of extraterritorial jurisdiction, which could be regarded as an interference with the domestic affairs of the affected states.[87] However, responsibility could be assumed in exceptional cases when the exporting state retains control (in terms of Article 8 ARSIWA) over the hazardous activity in the receiving state.[88]

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81 Hague Conference on Private International Law, Note on the Law Applicable to Civil Liability for Environmental Damage: Preliminary Document No 9 of May 1992, in: Hague Conference on Private International Law (ed.), Proceedings of the Seventeenth Session 10 to 29 May 1993, Tome I (1995) 187, 189.

82 *Mason* (n. 80), 11.

83 See *Lefeber* (n. 30), 12; *Mason* (n. 80), 11; *Boyle/Redgwell* (n. 19), chapter 13.

84 *Lefeber* (n. 30), 12.

85 Cf. *Günther Handl/Robert E. Lutz*, An International Policy Perspective on the Trade of Hazardous Materials and Technologies, 30 (1989) Harv. Int'l L. J. 351, 371; *Francesco Francioni*, Exporting Environmental Hazard Through Multinational Enterprises: Can the State of Origin Be Held Responsible?, in: Francesco Francioni/Tullio Scovazzi (eds.), International Responsibility for Environmental Harm (1991) 275, 289.

86 *Peter-Tobias Stoll*, Transboundary Pollution, in: Fred L. Morrison/Rüdiger Wolfrum (eds.), International, Regional, and National Environmental Law (2000) 169, 175; *Susanne Förster*, Internationale Haftungsregeln für schädliche Folgewirkungen gentechnisch veränderter Organismen (2007), 207–208; *Vordermayer* (n. 42), 118–121.

87 *Lefeber* (n. 30), 12.

88 Cf. ILC, Report of the Commission to the General Assembly on the Work of the Thirty-Fourth Session, UN Doc. A/37/10, YBILC 1982, Vol. II, Pt. 2, p. 86, para. 113, referring to cases of 'substantial control' of the state of origin, which

In the context of biotechnology, comparable transnational situations may arise in cases in which an LMO is deliberately moved into a country and, once released, causes harm there. As shown earlier, it is not an unusual phenomenon that LMOs are developed in countries other than those where they are ultimately released.[89] But even when the import of the LMO – or even its release – occurs without the permission of the affected state and subsequently causes harm, it appears difficult to assume a situation of *transboundary harm*.[90] Instead, such a case could give rise to a violation of the *Advance Informed Agreement* mechanism under the Cartagena Protocol.[91] Moreover, a deliberate release of LMOs into a foreign territory could also give rise to breaches of other norms of international law, such as the prohibition of aggression[92] or the prohibition of the use of biological weapons.[93]

However, as soon as the receiving state has validly consented to the import of a particular LMO, it becomes the sole bearer of the risk.[94] After all, the transboundary movement of hazardous technologies or substances is rather an issue of international trade than a problem of environmental harm.[95] Hence, occurrences of *transnational* harm are generally not covered by the regime on *transboundary* harm in international law.

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seems to be identical to cases of effective control within the meaning of Article 8 ARSIWA. But see ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 113, where the Court concluded that there is no case of transboundary harm when a state causes harm by conducting activities in breach of another state's territorial sovereignty. Also see *supra* section B.II.1.

89 See chapter 3, section A.II.1.g).

90 *Förster* (n. 86), 205–209.

91 Cf. Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 January 2000; effective 11 September 2003), 2226 UNTS 208 (hereinafter 'Cartagena Protocol'), Article 7(1); see chapter 3, section A.II.1.

92 See *Anikó Raisz*, GMO as a Weapon – a.k.a. a New Form of Aggression?, 2 (2014) Hungarian Yearbook of International Law and European Law 275, 284–285.

93 Cf. Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) And Toxin Weapons and on Their Destruction (10 April 1972; effective 26 March 1975), 1015 UNTS 163, Article I, see *R. Guy Reeves* et al., Agricultural Research, or a New Bioweapon System?, 362 (2018) Science 35, 36.

94 *Förster* (n. 86), 209.

95 *Xue* (n. 30), 9.

IV. The Threshold of 'Significant' Harm

It is generally recognized that international law does not prohibit the causation of transboundary environmental interference under all circumstances. Instead, transboundary impacts are considered to be tolerable and lawful as long as they do not reach a certain threshold.[96]

In contemporary[97] international law, this threshold is usually described as that of 'significant' transboundary harm.[98] The threshold applies in two different ways: *Ex ante*, it is part of the assessment of whether there is a risk that triggers the obligation to prevent harm, whereas *ex post*, it serves to determine whether the damage that has occurred is wrongful.[99] Consequently, the concept is found both in instruments dealing with the prevention of harm[100] and in instruments on responsibility or liability for damage that has actually occurred.[101] However, in both dimensions (*ex ante* and *ex post*) it is difficult to define in general terms when the threshold of 'significant' harm or risk thereof is reached. According to the ILC,

96 ILC, Articles on Prevention (n. 22), Commentary to Article 2, para. 5; *Lucas Bergkamp*, Liability and Environment (2001), 276–278.

97 Earlier practice and jurisprudence has referred to other criteria, including that of 'serious' consequences or prejudice (see Affaire du Lac Lanoux (Spain v. France), 16 November 1957, XII RIAA 281, 293; Trail Smelter Case, Decision of 1941 (n. 6), 1965). In the ILC, some preferred the notion of 'appreciable' harm, which was later given in favour of the term 'significant' harm.

98 For a detailed account of the threshold of 'significant harm', see *K. Sachariew*, The Definition of Thresholds of Tolerance for Transboundary Environmental Injury Under International Law: Development and Present Status, 37 (1990) Netherlands International Law Review 193.

99 *Duvic-Paoli* (n. 4), 184–185.

100 See, e.g., UNECE, Convention on Environmental Impact Assessment in a Transboundary Context (25 February 1991; effective 10 September 1997), 1989 UNTS 309, as last amended by the Second Amendment to the Convention (4 June 2004; effective 23 October 2017), UN Doc. ECE/MP.EIA/6, p. 93 (hereinafter 'Espoo Convention'), Article 2(1); CBD (n. 12), Article 14(1)(a); Convention on the Law of the Non-Navigational Uses of International Watercourses (21 May 1997; effective 17 August 2014), UN Doc. A/RES/51/229 (hereinafter 'International Watercourses Convention'), Article 7; Vienna Convention for the Protection of the Ozone Layer (n. 14), Article 1(2); UNCLOS (n. 13), Article 196.

101 See, e.g., ILC, Allocation of Loss Principles (n. 31), Article 2(a); Supplementary Protocol (n. 32), Article 2(3); Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty: Liability Arising from Environmental Emergencies (14 June 2005; not yet in force), ATCM Measure 1 (2005), Article 2(b).

'"significant" is something more than "detectable" but need not be at the level of "serious" or "substantial". The harm must lead to a real detrimental effect on matter such as, for example, human health, industry, property, environment or agriculture in other States. Such detrimental effects must be susceptible of being measured by factual and objective standards.'[102]

The ILC acknowledged that the concept is not without ambiguity and that a determination in specific cases may involve more factual than legal considerations.[103] Yet, some international instruments provide more detailed legal criteria as to when harm is deemed to be significant.[104] For instance, the *Nagoya-Kuala Lumpur Supplementary Protocol* contains a detailed definition of what constitutes 'significant' adverse effects of LMOs on biological diversity. The definition refers to criteria such as the permanence, quality, and quantity of changes to biological diversity, and the effects of such changes on human health.[105]

International jurisprudence has acknowledged the threshold of 'significant' harm in several cases,[106] but so far offered little guidance on how to determine whether the threshold is reached. This is aptly demonstrated by the judgment of the ICJ in the *Certain Activities* case between Costa Rica and Nicaragua.[107] The case concerned a border dispute between both

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102 ILC, Articles on Prevention (n. 22), Commentary to Article 2, para. 4.

103 *Ibid.*

104 On internationally set dose levels for radioactivity, see *Sands* et al. (n. 11), 744–745.

105 Supplementary Protocol (n. 32), Article 3(3); see chapter 6, section B.II.3.

106 See, e.g., PCA, Iron Rhine Arbitration (Belgium v. Netherlands), Award of 24 May 2005, Case No. 2003–02, XXVII RIAA 35, para. 59; ICJ, Pulp Mills (n. 18), para. 101; ITLOS, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, Advisory Opinion of 01 November 2011, Case No. 17, ITLOS Rep. 10, para. 116; ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 104; PCA, South China Sea Arbitration (Philippines v. People's Republic of China), Award of 12 July 2016, PCA Case No. 2013–19, para. 941.

107 ICJ, Certain Activities Carried out by Nicaragua in the Border Area (Costa Rica v. Nicaragua), Compensation Owed by Nicaragua to Costa Rica, Judgment of 02 February 2018, ICJ Rep. 15; for commentaries on the judgment, see *Tomme R. Young*, Recognition of "Environmental Services" in the ICJ's First Award of Compensation for International Environmental Damage, 48 (2018) Environmental Policy and Law 36; *Jason Rudall*, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica V. Nicaragua), 112 (2018) AJIL 288; *Jefferi H. Sendut*, The International Court of Justice and Compensation for Environmental Harm: A Missed Opportunity?, 1 (2018) De Lege Ferenda 17. The ICJ had already confirmed in the *Gabčíkovo-Nagymaros* case that Hungary was

states, which also led to reciprocal allegations about transboundary harm, or a risk thereof, caused by the activities of both parties in the disputed territory.[108] In its judgment on the merits of the case, the ICJ discussed the threshold of significant harm both from the *ex ante* and the *ex post* perspectives. Concerning the existence of a risk of significant harm caused by Nicaragua's excavation of channels in the disputed wetland area, the Court referred to expert evidence to conclude that there was no such risk.[109]

At the same time, with regard to the construction of a road in the border area by Costa Rica, the Court found that there was indeed a risk of significant harm, which it derived from the 'nature and magnitude of the project and the context in which it was to be carried out'.[110] However, addressing the question of whether significant transboundary harm had actually occurred, the Court held that a two percent increase in the sediment load of a shared river (i.e. the amount of solid matter carried by the river) that was caused by the activity in question did not reach the threshold of significant harm.[111] The Court gave no indications on the basis of which criteria it came to this finding.[112] The only conclusion that can be drawn from the judgment is that the ICJ seems to concur with the ILC that harm must be 'more than detectable' in order to be considered significant.[113] But apart from this, the Court 'remained opaque on the method and criteria' it used to assess the threshold of significant harm or a risk thereof.[114]

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entitled to 'compensation for the damage sustained as a result of the diversion of the Danube', although the Court did not specifically indicate that this included reparation for purely environmental damage, cf. ICJ, Gabčíkovo-Nagymaros (n. 17), paras. 151–152; see *Sands* et al. (n. 11), 754.

108 For the background of the dispute, see *Stefan Geens*, About Costa Rica, Nicaragua, Their Mutual Border, and Google, Ogle Earth, 07 November 2010, available at: https://ogleearth.com/2010/11/about-costa-rica-nicaragua-their-border-and-google/ (last accessed 28 May 2022); *Jacob K. Cogan*, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica V. Nicaragua); Construction of a Road in Costa Rica Along the San Juan River (Nicaragua V. Costa Rica), 110 (2016) AJIL 320.

109 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 105.

110 *Ibid.*, paras. 154–156.

111 *Ibid.*, para. 186.

112 Cf. *Kerryn A. Brent*, The Certain Activities Case: What Implications for the No-Harm Rule?, 20 (2017) Asia Pac. JEL 28, 53.

113 Cf. *ibid.*

114 *Diane Desierto*, Evidence but not Empiricism? Environmental Impact Assessments at the International Court of Justice in Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) and Con-

In any event, it appears to be widely recognized that the threshold of significant harm is lowered when the affected environment is particularly fragile.[115] For instance, the environmental panel of the *UN Compensation Commission*[116] held that damage that might otherwise be characterized as insignificant can nevertheless be significant when it is caused to an area of 'special ecological sensitivity'.[117] Similarly, the ICJ recognized that the proximity of wetlands protected under the *Ramsar Convention*[118] 'heightens the risk of significant damage because it denotes that the receiving environment is particularly sensitive'.[119]

Moreover, the threshold of significance could be influenced by the environmental standards in the country of origin.[120] This roots in the understanding that states shall not discriminate between domestic and transboundary environmental interferences.[121] Support for this approach is also found in Article 15 of the ILC's Prevention Articles, which provides that a state shall not discriminate against persons seeking legal protection against significant harm on the grounds that the harm would occur outside its jurisdiction.[122] Consequently, when the release of a particular LMO (or of LMOs generally) is illegal under the national laws of a state, that

struction of a Road in Costa Rica Along the San Juan River (Nicaragua v. Costa Rica), EJIL: Talk!, 26 February 2016, available at: http://www.ejiltalk.org/evidence-but-not-empiricism-environmental-impact-assessments-at-the-international-court-of-justice-in-certain-activities-carried-out-by-nicaragua-in-the-border-area-costa-rica-v-nicaragua-and-con/ (last accessed 28 May 2022); also see *Cameron A. Miles*, Introductory Note to Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua)/Construction of a Road in Costa Rica Along the San Juan River (Nicaragua v. Costa Rica) (I.C.J.), 55 (2016) ILM 417, 421.

115 Cf. Espoo Convention (n. 100), Appendix III, para. 1(b); ILC, Draft Articles on the Law of Transboundary Aquifers, with Commentaries, YBILC 2008, vol. II(2) (2008), Commentary to Article 6, para. 3; see *Duvic-Paoli* (n. 4), 186–187.

116 See chapter 11, section B.I.3.

117 UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the Third Instalment of "F4" Claims, UN Doc. S/AC.26/2003/31 (2003), para. 36.

118 See Convention on Wetlands of International Importance Especially as Waterfowl Habitat (02 February 1971; effective 21 December 1975), 996 UNTS 245.

119 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 155.

120 *Duvic-Paoli* (n. 4), 188.

121 WCED Expert Group on Environmental Law, Legal Principles and Recommendations (n. 37), Article 13 and commentary thereto, p. 88–90; OECD, Recommendation of the Council on Principles Concerning Transfrontier Pollution (14 November 1974), Doc. OECD/LEGAL/0133, Annex, Title C.

122 ILC, Articles on Prevention (n. 22), Article 15 and commentary thereto, para. 3.

state cannot argue that an unintentional spread of that LMO into the environment of another state was insignificant.

V. Risk of Harm

A core element of the principle of prevention is that of risk anticipation. In addition to the *magnitude* of potential harm, the *probability* that such harm occurs is the second criterion that defines whether there is a risk of transboundary harm which requires the state of origin to take preventive measures.[123]

The ILC summarized this concept in the notion 'risk of significant transboundary harm', which it defined as including 'risks taking the form of a high probability of causing significant transboundary harm and a low probability of causing disastrous transboundary harm'.[124] Consequently, it is the combined effect of the probability of a harmful event and the magnitude of its injurious impact which triggers the obligation to take preventive measures.[125] Contrary to what the definition may imply, the obligation is not limited to 'high risk of impact' and 'low risk of high impact' situations. Instead, the ILC intended to provide a spectrum within which the preventive obligation is triggered.[126] Therefore, the obligation also includes situations involving a moderate risk of significant (but not catastrophic) transboundary harm.[127] At the same time, activities involving a very low probability of causing only significant but not more serious harm fall outside the scope of the obligation.[128]

VI. Foreseeability of Harm and the Role of Precaution

1. Foreseeability as a Precondition of Prevention

Both the determination of the probability of harm and its potential magnitude presuppose that the causation of harm is at all *foreseeable*, i.e. that it

123 *Ibid.*, Commentary to Article 2, para. 2.
124 *Ibid.*, Article 2(a).
125 *Ibid.*, Commentary to Article 2, para. 2.
126 *Ibid.*, Commentary to Article 2, para. 3.
127 *Duvic-Paoli* (n. 4), 182.
128 ILC, Articles on Prevention (n. 22), Commentary to Article 2, para. 2.

is possible to identify plausible, albeit unlikely, scenarios in which harm would occur. It is generally accepted that a state cannot be held responsible for damage that could have not reasonably been foreseen.[129] This is logically inherent in the idea that a risk of significant harm triggers an obligation to take preventive measures: only when the risk is known to the parties concerned can it entail positive legal obligations.[130]

The reference point for the foreseeability of harm is the *best scientific knowledge* at the time when preventive action is required.[131] However, the obligation to prevent transboundary harm does not require the causation of harm to be established by 'clear and convincing evidence' as suggested by the arbitral tribunal in the *Trail Smelter* case.[132] If such a high threshold was required, irreversible or very serious harm would often occur before the causes were fully understood and preventive action could be initiated.[133]

2. The Precautionary Principle (or Approach)

States could be required to take preventive action already when there are indications, but no proof (or scientific certainty) that an activity might lead to significant transboundary harm. Such an obligation might be derived from the precautionary principle (or approach[134]). In essence, the principle provides that preventive measures can be justified – or even required – even when there is no scientific certainty whether an activity or substance is harmful to the environment. On the international level, the principle found express recognition for the first time in Principle 15 of the Rio Declaration, which provides:

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129 *Boyle/Redgwell* (n. 19), 171; also see ICJ, Corfu Channel (Merits) (n. 3), 18–22; ICJ, Application of the Convention on the Prevention and Punishment of the Crime of Genocide (Bosnia and Herzegovina v. Serbia and Montenegro), Judgment of 26 February 2007, ICJ Rep. 43, para. 432.

130 Cf. ILC, Articles on Prevention (n. 22), Commentary to Article 3, para. 18; see *Duvic-Paoli* (n. 4), 181–183; *Bergkamp* (n. 96), 261.

131 *Boyle/Redgwell* (n. 19), 171.

132 Cf. Trail Smelter Case, Decision of 1941 (n. 6), 1965.

133 *Boyle/Redgwell* (n. 19), 171.

134 The terms 'precautionary principle' and 'precautionary approach' are more or less interchangeable; the latter term concerns goes back to concerns by the United States and others that the term 'principle' would imply a normative character, see *ibid.*, 172–173.

> *'Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'.*[135]

Subsequently, the precautionary principle has been recognized in numerous international environmental agreements[136] and domestic jurisdictions.[137] However, there are substantial variations in how the principle is understood and applied.[138] In some contexts, it embodies a positive obligation to take preventive action (*obligatory function*).[139] In others, it is only used to justify restrictive or cost-incurring measures that cannot be fully based on scientific evidence (*facilitative function*).[140] The fact that there are 'strong' and 'weak' versions (or interpretations) of the principle is

135 Rio Declaration 1992 (n. 9), Principle 15, see *Antônio A. Cançado Trindade*, Principle 15, in: Jorge E. Viñuales (ed.), The Rio Declaration on Environment and Development: A Commentary (2015) 403.

136 See, e.g. Vienna Convention for the Protection of the Ozone Layer (n. 14), Preambular para. 5; CBD (n. 12), Preambular para. 9; Convention on the Protection and Use of Transboundary Watercourses and International Lakes (17 March 1992; effective 06 October 1996), 1936 UNTS 269 (hereinafter 'UNECE Watercourses Convention'), Article 2(5)(a); UNFCCC (n. 14), Article 3(3); 1996 Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 1972 (07 November 1996; effective 24 March 2016), 36 ILM 1, Article 3(1); Cartagena Protocol (n. 91), Articles 1, 10(6), and 11(8); for more references, see *Cançado Trindade*, Principle 15 (n. 135), 414–417; *Boyle/Redgwell* (n. 19), 175.

137 Unlike often asserted in the European legal discourse, this is even true for the United States, see *Jonathan B. Wiener/Michael D. Rogers*, Comparing Precaution in the United States and Europe, 5 (2002) Journal of Risk Research 317.

138 *Sands* et al. (n. 11), 234.

139 See, e.g., CJEU, Alpharma Inc. v. Council of the European Union, Judgment of 11 September 2002, T-70/99, ruling that under the precautionary principle as embodied in EU law, 'a public authority *may be required* to take action even before adverse effects have become apparent' (emphasis added). Also see Convention for the Protection of Marine Environment of the Baltic Sea Area (09 April 1992; effective 17 January 2000), 2099 UNTS 197, Article 3(2), which provides that states parties '*shall* […] *take preventive measures* when there is reason to assume that substances or energy […] may create hazards to human health, harm living resources and marine ecosystems, […] even when there is no conclusive evidence of a causal relationship between inputs and their alleged effects' (emphasis added).

140 See *Arie Trouwborst*, Precautionary Rights and Duties of States (2006), 120–124; *Daniel Bodansky*, Deconstructing the Precautionary Principle, in: David D. Caron/Harry N. Scheiber (eds.), Bringing New Law to Ocean Waters (2010) 381, 383–386.

often used to challenge the concept as a whole.[141] As a result, and despite its ubiquity, the status of precaution as a rule of customary international law, as well as its specific meaning, remain some of the most controversial topics in contemporary international environmental law.[142]

International courts and tribunals have also been hesitant to expressly recognize the precautionary principle as a rule of custom.[143] For instance, the World Trade Organization's *Dispute Settlement Body* has repeatedly questioned its customary status.[144] At the same time, the DSB recognized that the principle of precautionary action was reflected in Article 5(7) of the SPS Agreement,[145] although it applied a high threshold for when this provision can be invoked to justify trade restrictions.[146]

The *International Tribunal on the Law of the Sea* (ITLOS) has repeatedly relied on the precautionary principle, although without expressly referring to it.[147] Moreover, the jurisprudence of ITLOS must be seen in the context

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141 See *Daniel Steel*, Philosophy and the Precautionary Principle (2015), 3–43 with further references.

142 See, e.g., *Bergkamp* (n. 96), 445–450; *Arie Trouwborst*, Evolution and Status of the Precautionary Principle in International Law (2002), 260–284; *Gerhard Hafner/Isabelle Buffard*, Obligations of Prevention and the Precautionary Principle, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 521, 530–532; *Daniel Kazhdan*, Precautionary Pulp: Pulp Mills and the Evolving Dispute Between International Tribunals over the Reach of the Precautionary Principle, 38 (2011) ELQ 527; *Ole W. Pedersen*, From Abundance to Indeterminacy: The Precautionary Principle and Its Two Camps of Custom, 3 (2014) Transnational Environmental Law 323; *Cançado Trindade*, Principle 15 (n. 135), 412–414; *Maria Monnheimer*, Due Diligence Obligations in International Human Rights Law (2021), 147–149.

143 For an overview, see *Tullio Treves*, Environmental Impact Assessment and the Precautionary Approach: Why Are International Courts and Tribunals Reluctant to Consider Them as General Principles of Law?, in: Mads T. Andenæs/Malgosia A. Fitzmaurice et al. (eds.), General Principles and the Coherence of International Law (2019) 379; *Cançado Trindade*, Principle 15 (n. 135), 417–421.

144 WTO DSB, EC Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body of 16 January 1998, WT/DS26/AB/R, WT/DS48/AB/R, para. 123; WTO DSB, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Report of the Panel of 29 September 2006, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.89.

145 Cf. WTO DSB, EC-Hormones, Appellate Body report (n. 144), para. 125; see Agreement on the Application of Sanitary and Phytosanitary Measures (15 April 1994), 1867 UNTS 493, Article 5(7), also see chapter 3, section C.II.

146 Cf. WTO DSB, EC-Biotech (n. 144), para. 7.89.

147 Instead, ITLOS based its provisional measures on considerations of 'prudence and caution', cf. ITLOS, Southern Bluefin Tuna Cases (New Zealand v. Japan; Australia v. Japan), Provisional Measures, Order of 27 August 1999, ITLO cases

of UNCLOS as a multilateral treaty and thus cannot be construed as a recognition of a customary status of the principle.[148] Nevertheless, the Seabed Disputes Chamber of ITLOS observed in 2011 that the precautionary principle had been incorporated into a growing number of international treaties and other instruments, which, in the view of the Chamber, had 'initiated a trend towards making this approach part of customary international law'.[149]

The ICJ, on its part, has not yet adopted a conclusive stand on the status of the precautionary principle. Although the principle was invoked by parties in the 1995 revision of the *Nuclear Tests* case[150] and in the *Gabčíkovo-Nagymaros* case, the Court made no reference to it in either of the cases.[151] In *Pulp Mills*, the ICJ merely recognized that the 'precautionary approach may be relevant in the interpretation and application of the provisions of the [disputed treaty]'.[152] In its 2015 merits judgment in the *Certain Activities* case, the ICJ again remained silent on the role of the precautionary principle.[153]

Nos. 3 and 4, ITLOS Rep. 288, paras. 77–79; ITLOS, The MOX Plant Case (Ireland v. United Kingdom), Order of 03 December 2001, Case No. 10, ITLOS Rep. 89, para. 84; ITLOS, Case concerning Land Reclamation by Singapore in and around the Straits of Johor (Malaysia v. Singapore), Provisional Measures, Order of 08 October 2003, Case No. 12, ITLOS Rep. 10, para. 99. However, the Seabed Dispute Chamber of ITLOS later acknowledged the 'implicit link between an obligation of due diligence and the precautionary approach' in the Court's order in *Southern Bluefin Tuna*, cf. ITLOS, Responsibilities and Obligations of States (n. 106), para. 132.

148 *Boyle/Redgwell* (n. 19), 178.

149 ITLOS, Responsibilities and Obligations of States (n. 106), para. 135; see *Silja Vöneky/Felix Beck*, Article 145 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017) 1007, MN. 40–41.

150 But see ICJ, Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgment of 20 December 1974 in the Nuclear Tests (New Zealand v. France) Case, Order of 22 September 1995, ICJ Rep. 288, Dissenting Opinion of Judge Weeramantry, p. 342–344.

151 Cf. *Sands* et al. (n. 11), 234–236.

152 ICJ, Pulp Mills (n. 18), para. 164; but see ICJ, Pulp Mills (n. 18), Separate Opinion of Judge ad hoc Vinuesa, p. 152.

153 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 218.

3. Precaution and the Burden of Proof

In principle, the party which asserts a certain fact bears the burden of proof, which means that it has to adduce evidence to establish the existence of the said fact.[154] Hence, a state opposing another state's hazardous activity has to prove that the activity will cause – or is likely to cause – significant transboundary harm.[155] This can be difficult for a number of reasons, but may prove impossible when there is scientific uncertainty as to whether the activity in question is likely to cause harm at all. For this reason, it has sometimes been asserted that the application of the precautionary principle shifted the burden of proof onto the state which intends to undertake or authorize a hazardous activity.[156] In this case, the latter would be required to prove that the activity will not cause transboundary harm, either because it does not pose a risk of doing so or because the state has taken sufficient measures to avert the risk.[157] In his separate opinion in the *MOX Plant* case, ITLOS Judge *Wolfrum* even assumed that a reversal of the burden of proof was the only tangible content of the precautionary principle.[158]

However, this position appears not to be supported by the jurisprudence of international courts and tribunals, which have generally required the party asserting a risk of environmental harm to adduce enough evidence to establish at least a *prima facie* case.[159] In the *Pulp Mills* case, the ICJ expressly underlined that the precautionary approach did not operate as a

154 Cf. ICJ, Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States of America), Judgment on Jurisdiction and Admissibility of 26 November 1984, ICJ Rep. 392, para. 101; ICJ, Bosnian Genocide (n. 129), para. 204; ICJ, Pulp Mills (n. 18), para. 216.

155 ICJ, Pulp Mills (n. 18), para. 216.

156 This argument was made in a number of international cases, including by New Zealand in the 1995 revision of the *Nuclear Tests* case (cf. ICJ, Nuclear Tests Case 1995 (New Zealand v. France) (n. 150), para. 34), by Argentina in the Pulp Mills case (cf. ICJ, Pulp Mills (n. 18), para. 160), and by Ireland in the *MOX Plant* case (cf. ITLOS, The MOX Plant Case (Ireland v. United Kingdom) (n. 147), para. 71). See *Caroline E. Foster*, Science and the Precautionary Principle in International Courts and Tribunals (2011), 240–277; *Sands* et al. (n. 11), 234; *Boyle/Redgwell* (n. 19), 176–177.

157 *Sands* et al. (n. 11), 234, for a critical position, see *Bergkamp* (n. 96), 445–446.

158 ITLOS, The MOX Plant Case (Ireland v. United Kingdom) (n. 147), Separate Opinion of Judge Wolfrum, p. 134.

159 Cf. WTO DSB, EC-Hormones, Appellate Body report (n. 144), paras. 97–109; ITLOS, Land Reclamation (n. 147), para. 96, see *Boyle/Redgwell* (n. 19), 176.

reversal of the burden of proof.[160] What remains is that precaution has the effect of 'lowering the knowledge threshold to a significant extent'.[161] At the same time, when the evidence is sufficiently conclusive and leaves little or no room for uncertainty in the calculation of risk, there is no need to apply the precautionary principle at all.[162]

4. Precaution in the Area of Biosafety

In the area of biosafety, the same result follows from the provisions of the Cartagena Protocol. Although the Cartagena Protocol requires the party of export to carry out a risk assessment of an LMO intended for transboundary movement,[163] it does not require the exporting party to prove that the LMO in question is 'safe' – instead, it is for the importing party alone to decide, based on the information made available to it, whether it approves or denies the transboundary movement of the LMO.[164]

When there is a lack of scientific certainty about the potential adverse effects of the LMO in question, the party of import may invoke the precautionary principle when denying the transboundary movement 'in order to avoid or minimize such potential adverse effects'.[165] However, it is left to each party of import to decide whether and to what extent it invokes the precautionary principle to justify denials of imports. After all, such decisions must also be in compliance with other obligations incumbent on that state, including international trade law which imposes strict requirements for the lawfulness of invoking the insufficiency of scientific evidence to justify trade restrictions.[166]

VII. Living Modified Organisms and the Risk of Transboundary Harm

During the negotiations of the Cartagena Protocol, an argument against the inclusion of provisions on liability was that the existing rules of state

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160 ICJ, Pulp Mills (n. 18), para. 164.
161 *Monnheimer* (n. 142), 149.
162 *Boyle/Redgwell* (n. 19), 174; cf. ITLOS, The MOX Plant Case (Ireland v. United Kingdom) (n. 147), paras. 71–81.
163 Cartagena Protocol (n. 91), Articles 10(1) and 15, see chapter 3, section A.II.1.c).
164 *Boyle/Redgwell* (n. 19), 176–177.
165 Cartagena Protocol (n. 91), Article 10(6) see chapter 3, section A.II.1.d).
166 On this problem, see chapter 3, section C.

responsibility were sufficient to address possible occurrences of harm.[167] But interestingly, the question of whether – and if so, to what extent – the obligation to prevent transboundary harm applies to the transboundary effects caused by LMOs has so far only received limited attention in legal scholarship.[168]

1. Scholarly Opinions

In one of the first scholarly treatments of the topic, *Cripps* argued in 1980 that there was 'room for doubt regarding the application of recognized general principles of state responsibility to the release of genetically engineered viruses and organisms which traverse national boundaries'.[169] In her view, the conventions and declarations existing at that time were insufficient to address the potential transboundary effects involved with the development of genetically modified organisms.[170] At the same time, Cripps recognized that the *Stockholm Declaration* of 1972 would be relevant for genetic engineering activities which cause damage in other states.[171]

More recently, the majority of writers appear to acknowledge that the risks posed by LMOs fall within the scope of the obligation to prevent significant transboundary harm. According to *Ascencio*, 'the general obligation of due diligence is applicable in respect of any damage to the environment and biological diversity resulting from the deliberate or unintended transboundary movements of LMOs.'[172] As an example, he refers to a case where an unintended propagation of LMOs across national

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167 See *Kate Cook*, Liability: 'No Liability, No Protocol', in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 371, 374; *Gurdial S. Nijar*, The Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges, 13 (2013) Int. Environ. Agreements 271, 278–279.

168 See *Heidi J. Mitchell/Detlef Bartsch*, Regulation of GM Organisms for Invasive Species Control, 7 (2020) Front. Bioeng. & Biotechnol. 927, 4, assuming that whether the customary international law on state responsibility 'may apply for negative effects caused by GD releases is – as far as the authors know – not completely solved yet'.

169 *Yvonne Cripps*, A New Frontier for International Law, 29 (1980) ICLQ 1, 6.

170 *Ibid.*, 10.

171 *Ibid.*, 7.

172 *Alfonso Ascencio*, The Transboundary Movement of Living Modified Organisms: Issues Relating to Liability and Compensation, 6 (1997) RECIEL 293, 295.

boundaries damages wild relatives of important crop plants.[173] Similarly, *Förster* assumes that the obligation to prevent significant transboundary harm applies to the environmental spread of LMOs which cause harmful effects to foreign territory in the same manner as it applies to harm caused by toxic or hazardous substances.[174] In the view of *Lefeber*, cases of *unintentional* transboundary movements can result in transboundary damage when the LMO in question 'is likely to have significant adverse effects on biological diversity'.[175] However, he assumes that cases of *intentional* transboundary movements are not covered by the customary obligation to prevent transboundary harm, as in this case harm was not caused by the 'physical consequences' of an activity.[176]

2. Transboundary Effects of LMOs and the Notion of 'Significant Harm'

In order to determine whether the obligation to prevent significant transboundary harm is applicable to transboundary effects of LMOs, several scenarios need to be distinguished.

First of all, intentional transboundary movements, regardless of their legality, do not fall under the obligation to prevent transboundary harm. In such cases, there is no *transboundary* harm which is caused by the *physical consequences* of an activity.[177] As shown above, adverse effects that follow from the deliberate movement of LMOs are less an issue of international environmental law than of international trade law.[178] An obligation of states to prevent deliberate transboundary movements carried out without the prior agreement of the importing state is laid down in the Cartagena Protocol,[179] but is not yet established as a general rule of customary international law.

Secondly, situations where an LMO is subject to an unintentional transboundary movement and subsequently causes harm in the territory of the receiving state clearly constitute situations of transboundary harm. In

173 *Ibid.*
174 *Förster* (n. 86), 166.
175 *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 77.
176 *Ibid.*, 82.
177 *Ibid.*
178 See *supra* section B.III and chapter 3.
179 Cf. Cartagena Protocol (n. 91), Article 25(1); see chapter 3, section A.II.2.c)aa).

principle, this is true for all kinds of harm, regardless whether it affects persons, property, or the environment (in terms of the biological diversity in the territory of other states or in areas beyond the limits of national jurisdiction). As noted earlier, adverse effects of LMOs can be regarded as 'physical consequences' of their release: there is no essential difference between such harm and other types of harm caused by hazardous substances, pollution, or other forms of transboundary environmental interference. This also applies to LMOs that are not released intentionally, but accidentally. If a state engages in research involving hazardous biological agents such as infectious viruses,[180] it must employ due diligence to prevent such agents from escaping or, at least, from spreading beyond its own territory.[181] However, proving a laboratory accident as the source of a new virus will often be difficult, as shown by attempts to trace the origins of the SARS-CoV-2 coronavirus that caused the COVID-19 pandemic.[182]

More difficult issues arise, *thirdly*, when an LMO uncontrolledly spreads in the environment of another state but does not cause any substantial damage (to persons, property, or the environment) there. In these situations, the decisive question is whether the *mere presence* of an LMO in a foreign territory constitutes significant transboundary harm. As shown earlier, the notion of harm has no specific meaning in international law, which means that it is capable of covering any form of transboundary environmental interference. In fact, under some jurisdictions, already the mere environmental release of LMOs (or GMOs) is deemed to constitute damage to the environment.[183] However, it is questionable whether the

180 See, for instance, *Sander Herfst* et al., Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets, 336 (2012) Science 1534; see chapter 1, section E.I.

181 On international standards for containment and laboratory biosafety, see chapter 5, section C.III.

182 See *Kristian G. Andersen* et al., The Proximal Origin of SARS-CoV-2, 26 (2020) Nature Medicine 450.

183 See United Kingdom, Environmental Protection Act, 1990 c, 43, as amended, Section 107(3), which provides that: '"Damage to the environment" is caused by the presence in the environment of genetically modified organisms which have (or of a single such organism which has) escaped or been released from a person's control and are (or is) capable of causing harm.' The notion 'harm' is broadly defined in Section 107(6) as 'adverse effects as regards the health of humans or *the environment*' (emphasis added). Moreover, see Constitution of the Republic of Hungary (18 April 2011; effective 01 January 2012), Unofficial English translation available in Oxford Constitutions of the World, Article XX(2), which provides that Hungary shall promote the exercise of the right of every person to physical and mental health by, inter alia, by 'making sure that its agriculture remains free from any genetically modified organism'.

mere presence of an LMO meets the threshold of *significant* harm, which requires such harm to be 'more than detectable'. As shown above, to be regarded as significant, the harm must lead to a 'real detrimental effect' on matters such as human health, industry, property, environment or agriculture.[184] Moreover, the detrimental effects must also be 'susceptible of being measured by factual and objective standards'.[185] For these reasons, it appears difficult to assume that the mere presence of an LMO in the environment of another state *per se* constitutes transboundary harm as long as the LMO does not cause any 'real detriment'. This result is in line with the *Nagoya – Kuala Lumpur Supplementary Protocol*: while unintentional transboundary movements are explicitly included in the Protocol's scope,[186] a case of damage is assumed only when a transboundary movement results in adverse effects that are both measurable and significant.[187] Similarly, the obligation to notify other states about unintentional transboundary movements only applies when the LMO concerned is 'likely to have significant adverse effects' on biological diversity.[188]

Fourthly, a closely related issue is whether there is a case of transboundary harm when LMOs do not cause physical injury but economic damage, for instance by contaminating agricultural commodities which can then be no longer sold as 'GMO-free'.[189] Here, on the one hand, the affected farmers suffer damage that is measurable by factual and objective standards, namely by comparing the market value of conventional crops with that of GMO-free or organic crops. On the other hand, it could be argued that damage does not result from the *physical consequences* of the LMO, but rather from economic or regulatory policies in the affected state that discriminate against products of modern biotechnology. Still, contamination with LMOs undermines the ability of states to determine for themselves

184 ILC, Articles on Prevention (n. 22), Commentary to Article 2, para. 4; see *supra* section B.IV.
185 *Ibid.*
186 See Supplementary Protocol (n. 32), Article 3(3) and chapter 6, section B.III.2.
187 See *ibid.*, Article 2(2)(b) and chapter 6, section B.II.3.
188 Cartagena Protocol (n. 91), Article 17(1).
189 *Förster* (n. 86), 177; see *R. Guy Reeves/Martin Phillipson*, Mass Releases of Genetically Modified Insects in Area-Wide Pest Control Programs and Their Impact on Organic Farmers, 9 (2017) Sustainability 59. For an assessment of the private international law aspects of this scenario, see *Thomas Kadner Graziano/Matthias Erhardt*, Cross-Broder Damage Caused by Genetically Modified Organisms: Jurisdiction and Applicable Law, in: Bernhard A. Koch (ed.), Damage Caused by Genetically Modified Organisms (2010) 784.

how to regulate the use of modern biotechnology.[190] Therefore, a case of significant transboundary harm could be presumed at least when there is a large-scale introduction of LMOs into the environment of another state or contamination of large amounts of agricultural commodities.[191]

3. Anticipation of Risk

One of the main features of the obligation to prevent transboundary harm is the anticipation of risk. Hence, any invocation of state responsibility requires that the occurrence of harm is objectively foreseeable at the time when the relevant activity, such as the release of LMOs, is carried out. In this regard, *Lefeber* argued that the release of LMOs into the environment was unlikely to constitute a 'hazardous activity' as governments would be expected not to approve such releases if the risk assessment revealed either a high probability of causing significant transboundary damage or a low probability of causing disastrous transboundary damage.[192] But this confuses the question of whether a risk exists and the question of whether a state has lived up to its duties that follow from such a risk: a hazardous activity remains objectively hazardous even when appropriate measures are put in place to prevent the risk from materializing.

VIII. Conclusions

In sum, the obligation to prevent transboundary harm generally applies to unintended transboundary effects of LMOs. This includes unintentional transboundary movements, although the mere presence of an LMO in foreign territory as such is unlikely to be considered *significant* harm. The precautionary principle provides that a lack of scientific certainty does not justify taking no preventive measures, although the principle should not be misunderstood as requiring action when the alleged risks remain purely theoretical and are not supported at least by *prima facie* evidence.

Harm resulting from LMOs after they have been deliberately introduced into the receiving state is not covered by the obligation to prevent trans-

190 *Alison Peck*, The New Imperialism: Toward an Advocacy Strategy for GMO Accountability, 21 (2008) Geo. Int'l Envtl. L. Rev. 37, 39.
191 *Förster* (n. 86), 177.
192 *Lefeber* (n. 175), 82.

boundary harm, as there are no physical transboundary consequences. Yet, states are still under the general obligation to not knowingly allow their territory to be used for acts contrary to the rights of other states,[193] which also applies to unauthorized transboundary movements of LMOs.

C. Prevention of Transboundary Harm as an Obligation of 'Due Diligence'

Once it is established that the obligation to prevent transboundary harm applies to a given situation, the question of the content of this obligation arises. While it is possible to flesh out a number of specific procedural duties related to prevention,[194] determining the substantive content of the obligation is more difficult. Most importantly, the obligation to prevent transboundary harm is not absolute, which means that not every occurrence of harm is unlawful.[195] On the other hand, states are not only expected to refrain from harmful conduct but also to take proactive steps to prevent harm. In international treaties, this two-fold obligation is usually described as an obligation to take 'appropriate measures'. For instance, the ILC's Prevention Articles provide that states shall 'take all appropriate measures to prevent significant transboundary harm or at [sic] any event minimize the risk thereof'.[196] Similarly, the Cartagena Protocol requires states to 'take appropriate measures to prevent unintentional transboundary movements of living modified organisms'.[197] Comparable expressions can be found in many other instruments relating to the prevention of transboundary or environmental harm.[198]

Obligations to take *appropriate measures* or *reasonable steps* towards a given aim (such as to prevent harm or to provide for operator liability in certain cases) are often characterized as obligations of 'due diligence'.[199]

193 Cf. ICJ, Corfu Channel (Merits) (n. 3), 22.
194 See *infra* section D.
195 ILC, Articles on Prevention (n. 22), Commentary to Article 3, para. 7.
196 *Ibid.*, Article 3.
197 Cartagena Protocol (n. 91), Article 16(3).
198 See, e.g., UNCLOS (n. 13), Article 194(2); Espoo Convention (n. 100), Article 2(1); International Watercourses Convention (n. 100), Article 7(1), also see *Riccardo Pisillo-Mazzeschi*, The Due Diligence Rule and the Nature of the International Responsibility of States, 35 (1992) German YBIL 9, 36–41.
199 See, e.g., ILC, Articles on Prevention (n. 22), Article 3, commentary para. 7; *Boyle/Redgwell* (n. 19), 163–164. In the ILC, it was assumed that the terms 'all appropriate measures' and 'due diligence' were synonymous, cf. ILC, Report of the International Law Commission on the Work of Its Fifty-Second Session,

According to its ordinary meaning, the term *due diligence* refers to the degree of care reasonably expected from a person in order to discharge an obligation.[200] Consequently, obligations of due diligence do not require states to guarantee a particular result (i.e. 'no harm occurs') but to implement a certain conduct (i.e. 'appropriate measures to prevent harm are being taken').[201] This takes account of the fact that most hazardous activities are not carried out by the states themselves, but by private actors whose actions cannot be generally attributed solely because they are committed within the state's jurisdictional sphere.[202] For the same reason, obligations of due diligence can also be found in many other areas of international law including human rights law, humanitarian law, and international investment law,[203] although the role of due diligence varies depending on the respective context and the pertinent primary norms.[204]

While the precise nature of the due diligence standard in international law remains subject to scholarly and judicial debate,[205] it appears that due diligence is not an obligation in itself, but rather a legal standard of conduct which serves to determine whether a state has complied with a particular (primary) rule.[206] In the context of international environmental law, the pertinent key primary rule is the obligation to prevent significant transboundary harm.[207] In this regard, due diligence requires a standard of care which is 'generally considered to be appropriate and proportional

YBILC 2000, vol. II(2) (2000), para. 718. Also see *Pisillo-Mazzeschi* (n. 198), 46–49; *Monnheimer* (n. 142).

200 Cf. 'diligence' and 'due diligence', in: Black's Law Dictionary (n. 35), 573.

201 See *Constantin P. Economides*, Content of the Obligation: Obligations of Means and Obligations of Result, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 373; *James Crawford*, State Responsibility: The General Part (2013), 227–228.

202 *Duvic-Paoli* (n. 4), 201; see chapter 9, section A.II.2.b).

203 See *Kulesza* (n. 31), 55–113; ILA, ILA Study Group on Due Diligence in International Law: First Report (2014), 6–31.

204 *Neil McDonald*, The Role of Due Diligence in International Law, 68 (2019) ICLQ 1041, 1044–1054; *Duvic-Paoli* (n. 4), 201.

205 See e.g. *Pisillo-Mazzeschi* (n. 198); *Kulesza* (n. 31), 262–270; *McDonald* (n. 204).

206 *McDonald* (n. 204), 1044–1049; but see *Duvic-Paoli* (n. 4), 206–207, who concludes that there is still disagreement on whether due diligence is a discrete obligation or a standard of care. Also see ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge ad hoc Dugard, paras. 9–10, pointing out that '[t]he duty of due diligence […] is the standard of conduct required to implement the principle of prevention.'

207 See *Kulesza* (n. 31), 91–105; see *supra* section A.

to the degree of risk of transboundary harm in the particular instance'.[208] In contrast to what was suggested by the United Kingdom in the *Alabama Arbitration* of 1872,[209] due diligence is an objective standard and does not depend on the degree of care employed by the respective government in its domestic concerns.[210] Instead, due diligence requires what can reasonably be expected from a responsible government (or 'good' government[211]) under normal conditions.[212]

In the context of prevention, the state is required to 'act in exact proportion to the risks'.[213] Hence, the required standard of care depends on the probability that harm might occur, and the nature and scope of such harm.[214] The more hazardous the activity, or the more severe the potential damage, the higher the duty of care will be.[215] Some scholars have even argued that certain 'ultra-hazardous' activities could be forbidden altogether if they involve a risk of catastrophic damage that cannot be entirely averted.[216] However, this point of view seems not to correspond with the *opinio juris* of states, especially considering the multitude of ultra-hazardous activ-

208 ILC, Articles on Prevention (n. 22), Article 3, commentary para. 11.

209 Cf. Alabama Arbitration (United States v. Great Britain), reported in: Moore (ed.), History and Digest of the International Arbitrations to Which the United States Has Been a Party, vol. I (1898), p. 495, 610.

210 *Xue* (n. 30), 163; see Alabama Arbitration (United States v. Great Britain) (n. 209), 572–573; cf. ICJ, Military and Paramilitary Activities in and against Nicaragua (n. 46), para. 157; ICSID, Asian Agricultural Products Ltd. v. Republic of Sri Lanka, Award of 27 June 1990, ICSID Case No. ARB/87/3, para. 77.

211 Cf. *Pierre-Marie Dupuy*, Due Diligence in the International Law of Liability, in: OECD (ed.), Legal Aspects of Transfrontier Pollution (1977) 369, 369–370, who assumes that 'Due diligence […] is the diligence expected from a "good government"'; ILA, ILA Study Group on Due Diligence in International Law: Second Report (2016), 9–10.

212 ILC, Articles on Prevention (n. 22), Article 3, commentary para. 17; see *Xue* (n. 30), 162–164.

213 Alabama Arbitration (United States v. Great Britain) (n. 209), 654.

214 ILC, Articles on Prevention (n. 22), Article 3 MN. 11; *Günther Handl*, Transboundary Impacts, in: Daniel Bodansky/Jutta Brunnée/Ellen Hey (eds.), The Oxford Handbook of International Environmental Law (2007) 531, 540; ITLOS, Responsibilities and Obligations of States (n. 106), paras. 117–120.

215 ILC, Articles on Prevention (n. 22), Commentary to Article 3, para. 18; ITLOS, Responsibilities and Obligations of States (n. 106), para. 117.

216 *Günther Handl*, An International Legal Perspective on the Conduct of Abnormally Dangerous Activities in Frontier Areas: The Case of Nuclear Power Plant Siting, 7 (1978) ELQ 1, 47–48; *Boyle/Redgwell* (n. 19), 168.

ities that are regularly conducted by states and generally deemed lawful, such as the operation of nuclear power plants.[217]

The standard of due diligence does not *per se* prescribe specific measures that a state must take. Due diligence is a 'variable concept'[218] which grants the states concerned significant 'autonomy and flexibility'[219] in choosing their means of preventing harm, based on their individual circumstances, policy preferences, and the characteristics of the risk.[220] Due to this flexibility, it remains difficult to describe in precise terms what the content of due diligence obligations is,[221] and in consequence, what measures will be considered 'appropriate' or 'reasonable' in a particular situation.[222] Hence, it may be difficult for states to ascertain 'clearly, and in advance, that they are satisfactorily meeting – and continuing to meet – their obligations of conduct'.[223] Consequently, whether or not a state has acted with due diligence is often assessed only after the harm that was to be prevented has (allegedly) already occurred.[224] The due diligence standard in the prevention of transboundary harm has thus rightfully been described as an '*ex post* framework for an anticipatory obligation'.[225] As will be seen below, this is an important caveat for determining breaches of the obligation to prevent transboundary harm.[226]

D. Procedural Duties in the Context of Prevention

The previous section has shown that the specific requirements ensuing from the due diligence standard depend on the individual circumstances of each case, which makes it difficult to define in abstract terms what

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217 *Alan E. Boyle*, State Responsibility and International Liability for Injurious Consequences of Acts Not Prohibited by International Law: A Necessary Distinction?, 39 (1990) ICLQ 1, 12–14; *Phoebe N. Okowa*, Procedural Obligations in International Environmental Agreements, 67 (1997) BYIL 275, 314–320; see *Handl* (n. 214), 540.
218 ITLOS, Responsibilities and Obligations of States (n. 106), para. 117.
219 ILA, Second Report on Due Diligence (n. 211), 2.
220 *Duvic-Paoli* (n. 4), 201.
221 ITLOS, Responsibilities and Obligations of States (n. 106), para. 117.
222 *Duvic-Paoli* (n. 4), 201.
223 ILA, Second Report on Due Diligence (n. 211), 7.
224 *Duvic-Paoli* (n. 4), 332.
225 *Ibid.*
226 See *infra* section E.

measures a state must adopt in order to comply with the required standard of care.

Nevertheless, a number of – mostly procedural – obligations have emerged in both international treaties and customary law, which contribute to a 'minimum standard of conduct' in the prevention of transboundary harm.[227] These obligations include a requirement to adopt and implement an effective domestic regulatory framework to prevent harm from being caused by private actors (I.), the requirement to carry out environmental impact or risk assessments for hazardous activities (II.), the use of the best available technologies and compliance with internationally agreed standards (III.), the duty to cooperate with potentially affected states (IV.) a requirement to allow for public participation from the potentially affected population (V.). Besides, additional duties arise when damage is imminent or has already occurred (VI.).

I. Adoption and Enforcement of Effective Domestic Regulation

First and foremost, the effective prevention of significant transboundary harm requires that states adopt and implement national legislative and administrative frameworks to regulate the conduct of (private or public) actors which may cause such harm.[228] Where available, such legislation shall incorporate accepted international standards, which can 'constitute a necessary reference point' to determine whether domestic measures are appropriate.[229] In the absence of relevant international standards, states are free to decide on the nature and design of their national laws and regulations, provided that these laws and regulations are capable of effectively preventing transboundary harm.[230]

In addition to adopting appropriate legal measures at the national level, states must also ensure that these measures are effectively implemented

227 *Xue* (n. 30), 165. On the question whether these duties are elements of the due diligence standard or self-standing obligations of customary international law, see *infra* section E.III.
228 Rio Declaration 1992 (n. 9), Principle 11; ILC, Articles on Prevention (n. 22), Article 5; see *Boyle/Redgwell* (n. 19), 164.
229 ILC, Articles on Prevention (n. 22), Article 3, commentary para. 3; cf. ICJ, Pulp Mills (n. 18), para. 197.
230 ITLOS, Sub-Regional Fisheries Commission (n. 66), para. 138; *Duvic-Paoli* (n. 4), 208–209.

and enforced.[231] In the *Pulp Mills* case, the ICJ underscored that the obligation to employ due diligence

> '*is an obligation which entails not only the adoption of appropriate rules and measures, but also a certain level of vigilance in their enforcement and the exercise of administrative control applicable to public and private operators, such as the monitoring of activities undertaken by such operators, to safeguard the rights of the other party.*'[232]

Similarly, the ILC's Prevention Articles provide that states shall take the necessary legislative, administrative or other action, 'including the establishment of suitable monitoring mechanisms', to discharge their obligation to prevent transboundary harm.[233] The commentary emphasizes the 'continuing character of the obligations, which require action to be taken from time to time to prevent transboundary harm'.[234] This includes, in particular, the obligation to require prior authorization for activities that may involve a risk of significant transboundary harm.[235]

Consequently, a state may not only be internationally responsible for not enacting appropriate laws, but also for not sufficiently implementing and enforcing these laws, for not preventing or terminating an illegal activity, or for not punishing the person responsible for it.[236]

II. Environmental Impact (or Risk) Assessment

One of the cornerstones of international law relating to the prevention of transboundary harm is the requirement of environmental impact assessments (EIA) or risk assessments.[237] Characterized as an 'obligation

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231 *Xue* (n. 30), 164.

232 ICJ, Pulp Mills (n. 18), MN. 197; also see ITLOS, Sub-Regional Fisheries Commission (n. 66), paras. 138–139; ICJ, Gabčíkovo-Nagymaros (n. 17), para. 185; PCA, South China Sea Arbitration (Philippines v. People's Republic of China) (n. 106), paras. 961, 964, and 974.

233 ILC, Articles on Prevention (n. 22), Article 5.

234 *Ibid.*, Article 5, commentary para. 1.

235 *Ibid.*, Article 6 and commentary, para. 2; also see *McDonald* (n. 204), 1045.

236 ALI, Restatement of the Law Third: Foreign Relations of the United States, Volume 2 (1987), p. 105, section 601, comment (d); ILC, Draft Articles on the Law of the Non-Navigational Uses of International Watercourses and Commentaries Thereto, YBILC 1994, vol. II(2), p. 89 (1994), Article 7, commentary para. 4.

237 See generally *Neil Craik*, The International Law of Environmental Impact Assessment (2008). Note that there is no clear distinction between the terms

to acquire knowledge',[238] the overall purpose of such assessments is to evaluate the potential effects of an activity, including their likeliness and magnitude, on persons, property and the environment.[239] Therefore, they are a 'central means' for states to determine the potential environmental consequences of hazardous activities and, consequently, the required degree of care in ensuring that no harm is caused by these activities.[240]

1. Legal Status

Numerous multilateral treaties require that the environmental impacts of potentially harmful activities be assessed before such activities are authorized.[241] The most comprehensive elaboration of EIA requirements in international law can be found in the *Espoo Convention*,[242] which provides detailed rules on EIAs for hazardous activities that may cause transboundary harm but which binds only 45 (mostly European) states.[243] At the universal level, Principle 17 of the Rio Declaration calls for environmental impact assessments to be undertaken for 'proposed activities that are likely to have a significant adverse impact on the environment'.[244] The ILC's Articles on Prevention also provide that decisions concerning the authorization of hazardous activities shall be based on an assessment of

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'risk assessment' and 'environmental impact assessment'. Article 7 of the ILC's Prevention Articles refers to 'an assessment of the possible transboundary harm […], including any environmental impact assessment', which implies the former term to denote the more general concept and the latter to be more specific. But it appears to largely depend on the context which of the terms is used. The present study will treat the terms EIA and risk assessment synonymously as referring to the study of the potential adverse effects of LMOs.

238 *Monnheimer* (n. 142), 150.

239 Cf. ILC, Articles on Prevention (n. 22), Commentary to Article 7, para. 8; see *Kulesza* (n. 31), 104–105.

240 *Duvic-Paoli* (n. 4), 211.

241 See, e.g., UNCLOS (n. 13), Article 206; Espoo Convention (n. 100); Protocol on Environmental Protection to the Antarctic Treaty (n. 54), Article 8; UNFCCC (n. 14), Article 4(1)(f); CBD (n. 12), Article 14. For references to regional agreements, see *Xue* (n. 30), p. 165, n. 12.

242 Espoo Convention (n. 100).

243 UN OLA, Status of the Convention on Environmental Impact Assessment in a Transboundary Context, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-4&chapter=27&clang=_en (last accessed 28 May 2022).

244 Rio Declaration 1992 (n. 9), Principle 17.

the possible transboundary harm caused by that activity, 'including any environmental impact assessment'.[245]

The obligation to conduct an EIA has also found recognition in international jurisprudence. In its judgment in the *Pulp Mills* case, the ICJ held it 'may now be considered a requirement under general international law' to undertake an EIA where a proposed industrial activity may have significant adverse transboundary impacts.[246] Moreover, the Court expressly held that 'due diligence, and the duty of vigilance and prevention which it implies, would not be considered to have been exercised' if a party planning a hazardous activity likely to have transboundary effects did not undertake an environmental impact assessment on the potential effects of the activity.[247] This position was reaffirmed in the *Certain Activities* case, where the Court also clarified that the obligation to conduct an EIA is not limited to industrial activities, but applies 'generally to proposed activities which may have a significant adverse impact in a transboundary context'.[248]

A still controversial issue is whether the requirement to carry out an EIA is an independent customary obligation[249] or whether it constitutes a manifestation of the due diligence standard.[250] This distinction is not merely an academic problem but has considerable practical implications,[251] including for the question of whether a failure to conduct an EIA does by itself constitute a violation of international law even when no damage has occurred (yet).[252] Moreover, the legal status of the EIA requirement

245 ILC, Articles on Prevention (n. 22), Article 7.

246 ICJ, Pulp Mills (n. 18), para. 204; also see ILC, Articles on Prevention (n. 22), Article 7; *Handl* (n. 214), 541–542.

247 ICJ, Pulp Mills (n. 18), para. 204.

248 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 104.

249 Cf. ITLOS, Responsibilities and Obligations of States (n. 106), para. 145; ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge ad hoc Dugard, para. 9.

250 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge Donoghue, para. 1; also see *Duvic-Paoli* (n. 4), 213–215; *Justine Bendel/James Harrison*, Determining the Legal Nature and Content of EIAs in International Environmental Law: What Does the ICJ Decision in the Joined Costa Rica v Nicaragua/Nicaragua v Costa Rica Cases Tell Us?, 42 (2017) QIL 13, 14–18.

251 *Bendel/Harrison* (n. 250), 17.

252 *Jutta Brunnée*, International Environmental Law and Community Interests: Procedural Aspects, in: Eyal Benvenisti/Georg Nolte/Keren Yalin-Mor (eds.), Community Interests Across International Law (2018) 151, 158–159; see *infra* section E.II.

also has ramifications on the obligation to notify other states potentially affected by a hazardous activity.[253]

2. Triggers of the Obligation

Another fundamental question is when exactly the obligation to carry out an EIA is triggered. On the one hand, the performance of an EIA shall be required whenever an activity might have significant adverse effects; on the other hand, the very purpose of EIAs is to determine whether a risk of adverse effects exists at all.[254] Some international instruments try to solve this 'circularity problem'[255] by requiring an EIA for specific activities or substances because they are (legally) presumed to involve a risk of adverse effects.[256] This approach is also reflected in the Cartagena Protocol, which provides for a mandatory risk assessment whenever there is a transboundary movement of an LMO intended for introduction into the environment.[257] Where international law does not provide such specific guidance, states are required to ascertain whether there is a risk of significant transboundary harm which would trigger the requirement to carry out an EIA.[258] Consequently, they must ensure that there are criteria or preliminary assessment procedures in their domestic authorization procedures to determine whether a proposed activity should be subject to an EIA.[259]

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253 See *infra* section D.IV.1.
254 *Duvic-Paoli* (n. 4), 211–212; *Boyle/Redgwell* (n. 19), 191.
255 *Duvic-Paoli* (n. 4), 212.
256 Espoo Convention (n. 100), Appendix I; Cartagena Protocol (n. 91), Articles 10(1) and 15.
257 Cartagena Protocol (n. 91), Article 10(1), 15.
258 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 104, see *Brent* (n. 112), 53, observing that the Court affirmed a 'new procedural obligation'.
259 *Duvic-Paoli* (n. 4), 212; ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 154; *Boyle/Redgwell* (n. 19), 192–193. Also see Protocol on Environmental Protection to the Antarctic Treaty (n. 54), Annex I, Article 2, which provides for a dedicated 'Initial Environmental Evaluation' to determine whether a more detailed assessment is required; moreover, see UNEP, Goals and Principles of Environmental Impact Assessment (1987), UN Doc. UNEP/GC.14/17, Annex III (adopted by UNEP GC decision 14/25, contained in UN Doc. A/42/25, p. 77), Principle 2, which proposes an 'initial environmental evaluation' besides other mechanisms to determine whether an EIA is required.

3. Process and Content of EIAs

Once the requirement to conduct an EIA has been established, the question arises of what should be the process and content of such an assessment. In this regard, it is widely assumed that international law prescribes neither a specific methodology nor a catalogue of aspects that should be considered.[260] In the commentaries of its Articles on Prevention, the ILC assumed that the 'specifics of what ought to be the content of assessment is left to the domestic laws of the state conducting such assessment'.[261] Similarly, the ICJ held in *Pulp Mills* that 'it is for each state to determine in its domestic legislation […] the specific content of the environmental impact assessment required in each case, having regard to the nature and magnitude of the proposed development and its likely adverse impact on the environment.'[262] This principle was reaffirmed in the *Certain Activities* case, where the Court added that the content of the EIA should be determined 'in light of the specific circumstances of each case'.[263]

But this does not mean that international law does not make any prescriptions as to how the process and content of EIAs should be designed.[264] A wide array of international legal sources indicate that there are at least certain minimum requirements that states must meet in order to satisfy their due diligence obligations.[265] Such requirements can be found, for instance, in the *Goals and Principles on Environmental Impact Assessment* adopted by the Governing Council of the UN Environment Programme in 1987.[266] The Goals and Principles contain a list of the issues that should at least be addressed by an EIA.[267] The list includes an assessment of the likely or potential impacts of the proposed activity, a discussion of available measures to mitigate adverse impacts, an indication of gaps in knowledge, as well as an indication of whether the activity is likely to affect the environment of other states or areas beyond national jurisdic-

260 See, e.g., *Xue* (n. 30), 167; *Duvic-Paoli* (n. 4), 216.
261 ILC, Articles on Prevention (n. 22), Commentary to Article 7, paras. 7.
262 ICJ, Pulp Mills (n. 18), para. 205.
263 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 104; also see ITLOS, Responsibilities and Obligations of States (n. 106), para. 149.
264 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Seperate Opinion of Judge ad hoc Dugard, para. 18.
265 See *Craik* (n. 237), 90–111.
266 UNEP, Goals and Principles of EIA (n. 259).
267 *Ibid.*, Principle 4.

tion.[268] Minimum requirements and other standards for EIAs have also been developed, both in treaties and *soft law* instruments, with regard to specific types of hazardous activities or substances.[269]

4. Standards for Risk Assessments of LMOs/GMOs

Standards for the risk assessment of LMOs or GMOs can be found, *inter alia*, in Annex III to the Cartagena Protocol, in a dedicated *Guidance on Risk Assessment and Monitoring of LMOs* elaborated by a working group established by the meeting of parties to the Cartagena Protocol,[270] and in the respective documents developed under the auspices of the International Plant Protection Convention,[271] the World Organization for Animal Health,[272] and the Codex Alimentarius Commission.[273] It can be assumed that these standards, where applicable, will be referred to by international courts and tribunals when examining EIAs in particular cases.[274] However, it is questionable to what extent the existing risk assessment frameworks are sufficient to capture the particular risks posed by LMOs capable of self-propagation, such as gene drives.[275]

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268 *Ibid.*

269 See, e.g., the Espoo Convention (n. 100), the Regulations and Recommendations adopted by the International Seabed Authority (cf. *Vöneky/Beck*, Article 145 UNCLOS (n. 149), MN. 45–47; ITLOS, Responsibilities and Obligations of States (n. 106), para. 149); and ISO, Risk Management – Risk Assessment Techniques, ISO/IEC 31010:2019 (2019).

270 AHTEG on Risk Assessment, Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment, UN Doc. UNEP/CBD/BS/COP-MOP/8/8/Add.1, Annex (2016); see chapter 5, section C.II.1.b)aa).

271 See chapter 3, section D.

272 See chapter 3, section E.

273 See chapter 3, section F.

274 *Duvic-Paoli* (n. 4), 217.

275 Cf. *Marion Dolezel* et al., Beyond Limits – The Pitfalls of Global Gene Drives for Environmental Risk Assessment in the European Union, 15 (2020) BioRisk 1; *Jennifer Kuzma*, Procedurally Robust Risk Assessment Framework for Novel Genetically Engineered Organisms and Gene Drives, 15 (2021) Regulation & Governance 1144.

5. Conclusions

In conclusion, the requirement to conduct an environmental impact (or risk) assessment for activities that may have significant transboundary effects is well-established in international law. The precise process and content of these assessments largely depend on the context, whether there are internationally agreed standards in the relevant field, and on the domestic legislation of the state concerned. However, in the context of biotechnology multiple instruments provide detailed scientific standards on the methodology and content of risk assessments. Moreover, the content of EIAs can be assessed against the general obligation of states to employ due diligence to prevent transboundary harm.[276] For instance, in *Pulp Mills* the ICJ assessed whether Uruguay failed to exercise due diligence by not considering alternative locations for the disputed pulp mills in its EIA.[277] The WTO Dispute Settlement Body has also reviewed the adequacy of risk assessments in several cases.[278]

III. Use of the Best Available Technologies

Another expression of the due diligence standard is the requirement to ensure that the operators of hazardous activities make use of 'the best available technologies that minimize significant risks to nature or other adverse effects'.[279] Under the *UNECE Watercourses Convention*, the term

276 *Duvic-Paoli* (n. 4), 217.

277 Cf. ICJ, Pulp Mills (n. 18), paras. 207–214.

278 Cf. WTO DSB, Australia – Measures Affecting Importation of Salmon, Report of the Appellate Body of 20 October 1998, WT/DS18/AB/R, para. 135; WTO DSB, EC-Hormones, Appellate Body report (n. 144), para. 199; WTO DSB, Japan – Measures Affecting the Importation of Apples, Report of the Appellate Body of 26 November 2003, WT/DS245/AB/R, para. 202; also see chapter 3, section C.II.

279 UNGA, World Charter for Nature, UN Doc. A/RES/37/7, Annex (1982), para. 11; cf. UNECE Watercourses Convention (n. 136), Annex I, para. 1; Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (22 March 1989; effective 05 May 1992), 1673 UNTS 57 (hereinafter 'Basel Convention'), Article 2(8) and 4(2)(b); Convention for the Protection of the Marine Environment of the North-East Atlantic (22 September 1992; effective 25 March 1998), 2354 UNTS 67, Article 2(3)(b) and Appendix 1; but see *Kiss/Shelton* (n. 65), 120–121, who argue that the requirement to use the best available technology or the best practical means 'can be seen as

'best available technology' has been defined as 'the latest stage of development of processes, facilities or methods of operation which indicate the practical suitability of a particular measure for limiting discharges, emissions and waste'.[280] The Convention also recognizes that what is 'best available technology' for a particular process will change over time in light of technological advances and changes in scientific knowledge and understanding.[281]

Some earlier instruments limit the obligation insofar that states must only use the best technology *actually at their disposal*.[282] It has also been discussed whether the degree of care expected under the due diligence standard is variable, depending on the technical and economical capabilities of the state concerned.[283] Indeed, the obligation to employ due diligence is generally reflective of the means actually available to the state in question.[284] At the same time, however, it is doubtful whether states with a comparatively low level of economic development are allowed to operate hazardous activities at a lower standard of care than other, better-developed states. In the commentary to its Prevention Articles, the ILC expressly stated:

> *'The economic level of States is one of the factors to be taken into account in determining whether a State has complied with its obligation of due diligence. But a State's economic level cannot be used to dispense the State from its obligation under the present articles.'*[285]

This view has also been adopted in international case law. In the *Pulp Mills* case, the ICJ held that the mills erected by Uruguay (a developing state)

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deriving in part from the customary international obligation of 'due diligence' to prevent environmental harm.'

280 UNECE Watercourses Convention (n. 136), Annex I, para. 1.

281 *Ibid.*, Annex I, para. 2.

282 See e.g., Stockholm Declaration 1972 (n. 8), Principle 23; Convention on Long-Range Transboundary Air Pollution (13 November 1979; effective 16 March 1983), 1302 UNTS 217 (hereinafter 'LRTAP'), Article 6; UNCLOS (n. 13), Article 194(1); Montreal Protocol on Substances that Deplete the Ozone Layer (16 September 1987; effective 01 January 1989), 1522 UNTS 3, as last amended by the Meeting of Parties in 2018, Article 5; Rio Declaration 1992 (n. 9), Principles 6 and 7.

283 Cf. WCED Expert Group on Environmental Law, Legal Principles and Recommendations (n. 37), 80; see *Lefeber* (n. 30), 68–69; *Duvic-Paoli* (n. 4), 287–291.

284 Cf. ICJ, United States Diplomatic and Consular Staff in Tehran, Judgment of 24 May 1980, ICJ Rep. 3, paras. 61 and 63.

285 ILC, Articles on Prevention (n. 22), Commentary to Article 3, para. 13.

had to be operated in line with the highest international standards.[286] Similarly, the ITLOS Seabed Disputes Chamber held that the provisions concerning the responsibilities and liability of state sponsoring activities in the international seabed area applied equally to all sponsoring states, as otherwise commercial enterprises could choose states 'of convenience' with lower environmental standards.[287] Hence, while the actual capabilities of a state may be taken into account when assessing a state's compliance with its obligation to employ due diligence in preventing transboundary harm,[288] this does not result in a generally lowered standard of care applicable to developing states.[289]

IV. Cooperation

The duty of states to cooperate with each other in the prevention of environmental harm is widely recognized as a 'fundamental principle' of international law.[290] It is generally viewed as a procedural obligation that extends to all phases of planning and implementation of a (potentially) hazardous activity.[291] The general duty to cooperate finds its expression in three core obligations, namely a duty to notify (1.), a duty to exchange relevant information (2.), and an obligation to consult and negotiate (3.).

1. Notification

The obligation to notify other states has been characterized by the ILC as an 'indispensable part of any system designed to prevent harm'.[292] It generally takes two different forms: The first, which will be addressed in the present section, is that states which engage in hazardous activities that may have significant transboundary effects shall inform the states which

286 Cf. ICJ, Pulp Mills (n. 18), paras. 220–228.
287 ITLOS, Responsibilities and Obligations of States (n. 106), para. 159.
288 ILA, Second Report on Due Diligence (n. 211), 22; see *Duvic-Paoli* (n. 4), 202.
289 *Boyle/Redgwell* (n. 19), 166–167.
290 ICJ, Pulp Mills (n. 18), para. 77; ITLOS, The MOX Plant Case (Ireland v. United Kingdom) (n. 147), para. 81; PCA, South China Sea Arbitration (Philippines v. People's Republic of China) (n. 106), para. 985.
291 ILC, Articles on Prevention (n. 22), Commentary to Article 4, para. 1.
292 *Ibid.*, Commentary to Article 8, para. 2; see *Okowa* (n. 217), 289–300.

may potentially be affected by those effects.[293] The second form, which is a notification in cases of imminent damage, will be addressed separately below.[294]

The duty to notify other states about hazardous activities that may have significant transboundary effects has been reiterated in numerous international instruments[295] as well as in international case law.[296] It can now be regarded as a general obligation of customary international law that has 'gained pre-eminence in the context of environmental protection'.[297] At the same time, however, the duty to notify faces a number of unsettled questions and problems.

a) Timing

The first problem concerns the question as to when exactly the potentially affected states have to be notified and, more specifically, how the notification relates to the obligation to conduct a risk assessment or EIA.[298] In this respect, the Espoo Convention and the ILC's Articles on Prevention follow contradictory approaches. According to the *Espoo Convention*, parties are required to notify potentially affected states *before* conducting the EIA so as to allow these states to contribute to the assessment.[299] But the ILC's Prevention Articles provide that potentially affected states shall only be notified '[i]f the risk assessment indicates a risk of causing significant transboundary harm',[300] which implies that the duty to notify is only triggered *after* the risk assessment has been conducted and has revealed the existence of a risk.[301]

In the *Certain Activities* case, the ICJ apparently followed the latter approach.[302] Because it had already established that Costa Rica had violated

293 Rio Declaration 1992 (n. 9), Principle 19; *Xue* (n. 30), 169.
294 See *supra* section D.VI.1.
295 See, e.g., LRTAP (n. 282), Article 5; Espoo Convention (n. 100), Article 5; Rio Declaration 1992 (n. 9), Principle 19; International Watercourses Convention (n. 100), Article 12.
296 ICJ, Pulp Mills (n. 18), para. 113; ICJ, Corfu Channel (Merits) (n. 3), 22.
297 *Duvic-Paoli* (n. 4), 219.
298 See *Okowa* (n. 217), 291; *Xue* (n. 30), 170–172.
299 Espoo Convention (n. 100), Article 3(3).
300 ILC, Articles on Prevention (n. 22), Article 8(1).
301 *Duvic-Paoli* (n. 4), 226.
302 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 104.

its obligation to carry out an EIA for its construction of a road in the border area with Nicaragua, the Court saw no need to examine whether Costa Rica had also violated its obligation to notify Nicaragua about the project.[303] Thus, the Court implied that it considered the obligation to notify to be contingent upon a prior finding of risk through an EIA.[304]

After all, international law seems to provide no specific guidance as to when the notification must be made, except for the vague indications that it should be 'timely'[305] or 'as early as possible'.[306] In particular, there is no general rule that potentially affected states shall be given the opportunity to participate in the EIA process.

b) Addressees

The second issue relates to the recipients of the notification, i.e. the question of which states should be notified about a proposed hazardous activity.[307] In principle, a notification must be made to all states that are 'likely to be affected' by transboundary harm.[308] This largely depends on the nature of the activity and the types of risk it involves.[309] For instance, an undesired spread of a highly invasive gene drive may not only affect the neighbouring states but all states in which the relevant species is present as well as other states which may be affected by secondary ecosystem effects.[310] Hence, the question of who should be notified is closely linked to the issue of when the duty of notification is triggered in the first place.[311]

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303 *Ibid.*, para. 168; see *Duvic-Paoli* (n. 4), 224–225.
304 *Ibid.*, 226; *Brunnée* (n. 252), 158; but see ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Seperate Opinion of Judge Donoghue, paras. 21–23, who pointed out that she did not understand the judgment to mean that the obligation to notify only applied when an EIA found a risk of significant transboundary harm.
305 ILC, Articles on Prevention (n. 22), Article 8(1).
306 Espoo Convention (n. 100), Article 3(1); see *Duvic-Paoli* (n. 4), 225.
307 See *Okowa* (n. 217), 290–291.
308 ILC, Articles on Prevention (n. 22), Article 8(1).
309 *Duvic-Paoli* (n. 4), 220.
310 See chapter 1, section C.IV.4.
311 *Xue* (n. 30), 172.

c) Content

The third issue concerns the content of a notification.[312] In principle, the state undertaking the hazardous activity is required to provide all relevant information on the nature of the activity, the risks involved and the injury it may cause, so as to allow the potentially affected states to make their own evaluation of the situation.[313] When the state of origin has already conducted an EIA, it appears reasonable to assume that it will have to submit the assessment itself as well as any relevant information on which the assessment is based.[314]

d) Procedure

Finally, it is questionable whether states need to observe any particular procedure when making the notification. In this regard, the ILC's Prevention Articles set out detailed rules on the procedure of notification, including a six-month waiting period during which the state of origin may not proceed with the activity until it has received a response from the notified state.[315]

Moreover, the Articles stipulate a right of the potentially affected state to request information about activities which it believes involve a risk of causing significant transboundary harm.[316] While these provisions are based on examples contained in treaties,[317] they seem to go beyond existing customary law and should rather be qualified as an instance of *progressive development* of international law.[318] As with the content of EIAs, the details of the notification procedure are left for each state to decide.[319]

312 See *Okowa* (n. 217), 291–293.
313 *Ibid.*, 291; *Duvic-Paoli* (n. 4), 219.
314 ILC, Articles on Prevention (n. 22), Article 8(1).
315 *Ibid.*, Article 8(2); on the failure to respond to notification, see *Okowa* (n. 217), 297–299.
316 ILC, Articles on Prevention (n. 22), Article 11.
317 See Espoo Convention (n. 100), Article 3(7); International Watercourses Convention (n. 100), Articles 13 and 18.
318 *Duvic-Paoli* (n. 4), 219; see Statute of the International Law Commission (n. 21), Article 1(1).
319 See *Duvic-Paoli* (n. 4), 219, noting that as a general rule, states will directly contact the other states through diplomatic channels.

2. Exchange of Information

The obligation to exchange relevant information on the hazardous activity is, to a certain extent, inherent in the obligation to notify, which requires disclosure of the 'available technical and all other relevant information'.[320] The exchange of information was characterized as a 'routine process' in international environmental law, especially in the context of activities that might have transboundary or global impacts.[321] Numerous international instruments provide for some form of information exchange, although with large differences in the degree of detail concerning both the content of the information and the process of exchange.[322] Usually, a distinction is made between information exchange in the planning period of an activity[323] and at the time during which the activity is undertaken.[324]

The exchange of information can be performed either directly between the states concerned or by using a competent international organization as an intermediary.[325] The latter is usually advisable when the information is relevant for a larger number of states or where appropriate mechanisms for information-sharing have already been established.[326]

For instance, the exchange of information regarding living modified organisms is facilitated by the *Biosafety Clearing-House* (BCH), which is a dedicated internet platform established under the Cartagena Protocol and maintained by the CBD Secretariat.[327] As shown above, parties to the Cartagena Protocol are legally required to submit certain information to the BCH, including decisions on the transboundary movement and release of LMOs, and underlying environmental reviews generated by their regulatory processes.[328]

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320 ILC, Articles on Prevention (n. 22), Commentary to Article 8, para. 6.

321 *Duvic-Paoli* (n. 4), para. 220.

322 See, e.g., UNCLOS (n. 13), Article 200; Espoo Convention (n. 100), Article 4(2) and Appendix II; CBD (n. 12), Article 17.

323 ILC, Articles on Prevention (n. 22), Article 8(1), which provides that the notification of potentially affected states shall include the 'available technical and all other relevant information on which the [risk] assessment is based'.

324 *Ibid.*, Article 12, see *Duvic-Paoli* (n. 4), 220.

325 ILC, Articles on Prevention (n. 22), Commentary to Article 12, para. 4; see *Okowa* (n. 217), 300–301.

326 ILC, Articles on Prevention (n. 22), Commentary to Article 12, para. 4.

327 Biosafety Clearing-House, available at: http://bch.cbd.int/ (last accessed 28 May 2022).

328 See chapter 3, section A.II.3.

As the BCH is open to states which are not parties to the Cartagena Protocol,[329] the BCH may also serve as an appropriate means to discharge the obligation to exchange information under general international law. However, in situations specifically affecting certain other states, it may not be sufficient to simply upload the information to the BCH, but it may be necessary to expressly inform the affected states that the relevant information has been made available on the BCH and how it can be retrieved.

3. Consultations and Negotiations

As a third element, the duty to cooperate entails an obligation to enter into consultations and negotiate with the potentially affected states.[330] As stipulated in Article 9(2) ARSIWA, the purpose of such consultations is to accommodate the interests of the potentially affected states and to find mutually acceptable solutions for how the risk of adverse transboundary impacts can be limited.[331]

Article 10 ARSIWA provides a catalogue of factors that the states concerned shall take into account in order to achieve an equitable balance of interests. Besides factors such as the degree of risk of transboundary and environmental harm, and the availability of means to minimize the risk or to repair resulting harm, the catalogue also specifies 'the importance of the activity […] for the State of origin in relation to the potential harm for the State likely to be affected' as a factor for the equitable balancing of interests.[332] While the Article does not indicate how the 'importance' of activity could be objectively established, it suggests that hazardous activities carried out to address serious public health issues, such as the use of engineered gene drives to suppress vectors of dreadful diseases, may be given more consideration than activities only carried out for economic purposes. The Article also expressly recognizes the need to consider alternatives to the activity.[333]

329 Cartagena Protocol (n. 91), Article 24(2).

330 ILC, Articles on Prevention (n. 22), Article 9; Rio Declaration 1992 (n. 9), Principle 19.

331 Cf. ILC, Articles on Prevention (n. 22), Commentary to Article 9, para. 5; *Okowa* (n. 217), 302.

332 ARSIWA (n. 43), Article 10(b).

333 Cf. *ibid.*, Article 10(e).

It is generally recognized that consultations shall be carried out 'at an early stage and in good faith'.[334] In the *Lac Lanoux* arbitration between France and Spain, the tribunal held that consultations 'must be genuine, must comply with the rules of good faith and must not be mere formalities'.[335] The tribunal also provided examples of behaviour that would violate the obligation to negotiate, including an unjustified termination of the discussions, abnormal delays, disregard of agreed procedures, and a systematic refusal to take into consideration adverse proposals or interests.[336]

The responsible state should not move forward with the project while negotiations are still ongoing.[337] But at the same time, this does not grant the potentially affected state a right to veto the proposed hazardous activity.[338] The obligation to consult remains a purely procedural duty that does not require the states concerned to reach an agreement before any action can be taken. State practice clearly indicates that proposed hazardous activities are not subject to the consent of the potentially affected states.[339] Still, the ILC's Articles on Prevention provide that even when negotiations fail to produce an agreed solution, the state of origin shall 'take into account' the interests of the potentially affected states as expressed in the negotiations.[340] Although the ILC has characterized this obligation as a 'measure of self-regulation',[341] it cannot be construed as resulting in a change to the substantive obligations of the state of origin.[342]

Consultations and negotiations can be conducted bilaterally among the states concerned or by using existing international bodies, such as international organizations or meetings of parties to multilateral conventions.[343] The ILC's Prevention Articles expressly provide that states shall seek the assistance of 'competent international organizations' in preventing significant transboundary harm.[344] The requirement to involve relevant interna-

334 Rio Declaration 1992 (n. 9), Principle 19.
335 Affaire du Lac Lanoux (Spain v. France) (n. 97), 310; also see ICJ, North Sea Continental Shelf (n. 2), para. 85; ICJ, Gabčíkovo-Nagymaros (n. 17), para. 141.
336 Affaire du Lac Lanoux (Spain v. France) (n. 97), 307; see *Okowa* (n. 217), 306–307.
337 *Duvic-Paoli* (n. 4), 222.
338 *Ibid.; Okowa* (n. 217), 314–316.
339 *Xue* (n. 30), 174; see Affaire du Lac Lanoux (Spain v. France) (n. 97), 306; ILC, Articles on Prevention (n. 22), Commentary to Article 9, para. 10.
340 ILC, Articles on Prevention (n. 22), Article 9(3) and commentary, para. 10.
341 *Ibid.*, Commentary to Article 9, para. 10.
342 *Duvic-Paoli* (n. 4), 222; *Boyle/Redgwell* (n. 19), 205–206.
343 *Duvic-Paoli* (n. 4), 222–224.
344 ILC, Articles on Prevention (n. 22), Article 4.

tional bodies has also been acknowledged in international case law.[345] Hence, whether a state reasonably engaged with relevant international organizations is a factor to determine whether it complied with the due diligence standard.[346]

V. Public Participation

Public participation in decision-making processes on environmental matters is increasingly recognized as an important element of prevention.[347] It has been expressly recognized in the Rio Declaration[348] and in a number of multilateral instruments.[349] The *Aarhus Convention* stipulates detailed obligations with regard to three 'pillars' of public participation, namely access to information, participation in decision-making, and access to justice,[350] although its membership is comprised of European and Central Asian states only.[351] At the universal level, the ILC's Articles on Prevention stipulate that states shall provide the public likely to be affected with relevant information about the activity, the risk involved, and the harm which

345 ICJ, Certain Activities Carried out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) (Provisional Measures), Order of 08 March 2011, ICJ Rep. 6, para. 80; ICJ, Certain Activities Carried out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) (Provisional Measures), Order of 22 November 2013, ICJ Rep. 354, para. 54; ITLOS, Responsibilities and Obligations of States (n. 106), paras. 124 and 142; ITLOS, Sub-Regional Fisheries Commission (n. 66), para. 210.

346 *Duvic-Paoli* (n. 4), 223.

347 See generally *Jonas Ebbesson*, Public Participation in Environmental Matters, in: Wolfrum/Peters (ed.), MPEPIL.

348 Rio Declaration 1992 (n. 9), Principle 10.

349 See, e.g., Espoo Convention (n. 100), Articles 2(6) and 3(8); UNFCCC (n. 14), Article 6; UNCCD (n. 14), Article 3(a).

350 Cf. Convention on Access to Information, Public Participation and Decision Making and Access to Justice in Environmental Matters (25 June 1998; effective 30 October 2001), 2161 UNTS 447 (hereinafter 'Aarhus Convention'), Articles 4, 6 and 9; see *Leslie-Anne Duvic-Paoli*, The Status of the Right to Public Participation in International Environmental Law: An Analysis of the Jurisprudence, 23 (2012) YB Int'l Env. L. 80, 90–96.

351 Cf. UN OLA, Status of the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=XXVII-13&chapter=27&clang=_en (last accessed 28 May 2022).

might result.[352] With regard to the participation of the affected public, the Articles merely provide that states shall 'ascertain their views',[353] but do not explain this obligation further.

1. Legal Status Under General International Law

Whether or not there is an obligation in customary international law to ensure (meaningful) public participation in decisions about projects that may have adverse environmental impacts is still an unsettled question. In the *Pulp Mills* case, the ICJ rejected the argument that such a customary obligation could arise from, *inter alia*, the Aarhus Convention, the ILC Prevention Articles, or the UNEP Goals and Principles on EIA.[354] However, it could be argued that access to information and public participation in environmental decision-making processes is an element of the obligation to exercise due diligence, at least with regard to activities that may have transboundary impacts.[355]

Moreover, minimum requirements for the participation of the affected populations may arise from international human rights law.[356] For instance, the *European Court of Human Rights* has repeatedly held that individuals affected by decisions relating to the environment have a right to access to information as well as a right to seek judicial redress against such decisions.[357] Similar jurisprudence does also exist from other international human rights bodies.[358]

352 ILC, Articles on Prevention (n. 22), Article 13.
353 *Ibid.*
354 ICJ, Pulp Mills (n. 18), para. 216; cf. UNEP, Goals and Principles of EIA (n. 259); see *Duvic-Paoli* (n. 350), 84–85.
355 *Duvic-Paoli* (n. 4), 229–230.
356 For an assessment of the jurisprudence of human rights bodies on the right to participate in environmental decision-making, see *Duvic-Paoli* (n. 350), 96–105.
357 Cf. e.g. ECtHR, Tătar v. Romania, Judgment of 21 January 2009, Application no. 67021/01, paras. 122–125; ECtHR, Taşkın et al. v. Turkey, Judgment of 20 March 2005, Application no. 46117/99, paras. 118–119.
358 For a detailed assessment, see *Duvic-Paoli* (n. 350), 96–105.

2. Public Participation Under the Cartagena Protocol

As regards public participation in the context of modern biotechnology, Article 23(2) of the Cartagena Protocol requires its parties to consult the public in the decision-making process regarding LMOs and to make the results of such decisions available to the public. However, parties are only required to do so 'in accordance with their respective laws and regulations', and while respecting confidential information.[359] Consequently, the scope, extent and methods for public participation under the Cartagena Protocol are subject to the parties' national laws and regulations.[360]

3. GMOs Under the Aarhus Convention

a) Status Quo

Rules on public participation in decisions pertaining to LMOs can also be found in the aforementioned *Aarhus Convention*. According to Article 6(11) of the Convention, parties shall apply the Convention's rules on public participation also to decisions on whether to permit the deliberate release of genetically modified organisms into the environment, but only 'within the framework of their national laws' and 'to the extent feasible and appropriate'. These limitations, which essentially leave it to the states parties to decide whether or not to allow for public participation, go back to a compromise in the negotiations of the Aarhus Convention, during which no agreement could be reached on the extent to which the convention should apply to GMOs.[361]

359 Cartagena Protocol (n. 91), Article 23(2).

360 *Ruth Mackenzie* et al., An Explanatory Guide to the Cartagena Protocol on Biosafety (2003), MN. 596–597; also see *Christine Toczeck Skarlatakis/Julian Kinderlerer*, The Importance of Public Participation, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 111, 119–121.

361 UNECE, The Aarhus Convention: An Implementation Guide (2nd ed. 2014), 160.

b) The GMO Amendment

In 2005, the meeting of the parties to the Aarhus Convention adopted an Amendment to the Convention introducing specific rules on public participation in decisions concerning the environmental release and placing on the market of GMOs.[362] According to these rules, which shall apply instead of the Aarhus Convention's general provisions, each party shall make arrangements in its regulatory framework to provide for effective information and public participation in these decisions.[363] This includes the release of information, a transparent decision-making process and adequate opportunities for the public to comment on the proposed decisions. Moreover, parties shall ensure that 'due account is taken of' the outcome of the public participation procedure.[364]

Compared to the procedural rules already existing in the Aarhus Convention, the GMO Amendment does not appear to introduce any significant new obligations.[365] However, the Amendment significantly reduces the parties' margin of appreciation, as the minimum standards provided in the amendment are no longer subject to compatibility with existing national frameworks or a test of feasibility and appropriateness.[366] Moreover, the Amendment expressly provides that certain information about the GMO in question shall in no case be considered confidential and shall thus not be withheld from the public.[367] The Amendment also recognizes potential overlaps with the Cartagena Protocol by providing that the national implementing measures should be 'consistent with objectives of the

362 Amendment to the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (27 May 2005; not yet in force), ECE/MP.PP/2005/2/Add.2 (hereinafter 'GMO Amendment to the Aarhus Convention').

363 *Ibid.*, Article 6 bis, para. 1, and Annex I bis, para. 1.

364 *Ibid.*, Annex I bis, para. 7.

365 For a detailed analysis of the obligations provided in the GMO amendment, see UNECE, Aarhus Implementation Guide (n. 361), 165–172; also see *Balázs Horváthy*, New Impulses: Aarhus Convention and Genetically Modified Organisms, in: Hanna Müllerová (ed.), Public Participation in Environmental Decision-Making: Implementation of the Aarhus Convention (2013) 29, 50–51, pointing out that the amendment does not mention judicial review and, in this regard, steps back from the requirements under the previous Article 6(11) of the Aarhus Convention.

366 For a comparison of differences, see *ibid.*, 38.

367 GMO Amendment to the Aarhus Convention (n. 362), Annex I bis, para. 4.

Cartagena Protocol on Biosafety'.[368] The Amendment has not yet entered into force, as this requires one further ratification to reach the required threshold of three quarters of those parties that were already party to the Aarhus Convention when the amendment was adopted.[369]

c) The Lucca Guidelines

The 2005 amendment was preceded by the so-called *Lucca Guidelines*,[370] which is a set of formally non-binding recommendations on how the Aarhus Convention can be applied to GMOs. Unlike Article 6(11) of the Convention, the Guidelines also apply to the contained use of GMOs. Moreover, compared to the formal GMO amendment to the Aarhus Convention, the Lucca Guidelines contain much more detailed rules and are not limited to public participation in decision-making, but also address access to information pertaining to GMOs and access to justice. The Guidelines can thus be seen as a valuable *soft law* document which formulates a best practice standard regarding public participation in the context of modern biotechnology.[371]

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368 *Ibid.*, Article 6 bis, para. 2. In Decision II/1 of the Meeting of Parties to the Aarhus Convention, which adopted the GMO amendment, the need for collaboration both with the Cartagena Protocol and between the secretariats of both instruments was explicitly recognized. So far, three joint workshops on access to information and public participation with respect to GMOs have been held in 2008, 2010, and 2019; see UNECE, The Aarhus Convention's GMO Amendment (12 March 2020), available at: http://www.unece.org/env/pp/gmos.html (last accessed 28 May 2022).

369 Cf. Aarhus Convention (n. 350), Article 14(4); see UN OLA, Status of the GMO Amendment to the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=XXVII-13-b&chapter=27&clang=_en (last accessed 28 May 2022).

370 Meeting of the Parties to the Aarhus Convention, Guidelines on Access to Information, Public Participation and Access to Justice with Respect to Genetically Modified Organisms (23 October 2002), UN Doc. ECE/MP.PP/2003/3, adopted by decision I/4 (UN Doc. ECE/MP.PP/2/Add.5), para. 1.

371 *Horváthy* (n. 365), 36.

VI. Obligations When Damage Is Imminent or Inevitable

In situations where significant transboundary harm is imminent or inevitable, the responsible state is obliged to take all available measures to ensure that the damage is limited. In particular, it must notify the states likely to be affected (1.) and take available measures to mitigate the damage as much as possible (2.).

1. Notification in Emergency Situations

When there is an emergency situation that causes or is likely to cause transboundary harm, the state of origin must immediately notify the states affected or likely to be affected. This obligation has found recognition in the Rio Declaration,[372] the ILC's Prevention Articles,[373] and in many international agreements including the CBD.[374] Moreover, Article 17 of the Cartagena Protocol requires parties to notify potentially affected states about any release of a living modified organism that leads, or may lead, to an unintentional transboundary movement. The common rationale behind these obligations is to allow the affected state(s) to take measures to minimize or mitigate the damage to the greatest extent possible.[375] For this reason, notification shall be made 'without delay and by the most expeditious means' as soon as the responsible state learns about the emergency.[376]

A problem related to the obligation to notify is that international law often does not indicate a clear threshold above which damage is 'imminent' and the obligation to notify is triggered.[377] This problem also exists in the international biosafety regime: The aforementioned obligation in

372 Rio Declaration 1992 (n. 9), Principle 18; also see *Phoebe N. Okowa*, Principle 18, in: Jorge E. Viñuales (ed.), The Rio Declaration on Environment and Development: A Commentary (2015) 471.

373 Cf. ILC, Articles on Prevention (n. 22), Article 17.

374 Cf. CBD (n. 12), Article 14(1(d); UNCLOS (n. 13), Article 188; Basel Convention (n. 279), Article 13(1); International Watercourses Convention (n. 100), Article 28(2); for further instances, see *Okowa*, Principle 18 (n. 372), 484–488.

375 ILC, Articles on Prevention (n. 22), Commentary to Article 17, para. 2; see *Xue* (n. 30), 168; *Okowa* (n. 217), 296–297.

376 ILC, Articles on Prevention (n. 22), Commentary to Article 17, para. 2.

377 *Okowa* (n. 217), 296–297, points out that under the 1986 Convention on Early Notification of a Nuclear Accident, it is left to the source state to determine whether an incident is of 'radiological safety significance for another State' and thus subject to the obligation to notify.

the Cartagena Protocol is contingent on the LMO being 'likely' to have significant adverse effects on biodiversity, which may be uncertain or even disputed among the states concerned.[378] Considering the objective of the present obligation, notification should be made about any unintentional release of LMOs containing self-spreading genetic elements that may be subject to a transboundary movement.

2. Obligation to Control and Mitigate Damage

In situations in which damage can no longer be prevented, states are required to take measures to control, reduce or mitigate damage to the largest extent possible. This obligation is recognized in various international agreements, which often do not clearly distinguish between the *prevention* of damage and the *mitigation* of damage.[379] Indeed, it is questionable whether it is necessary (or even possible) to sharply distinguish between both obligations, as both are corollaries of the fundamental principle of *sic utere*.[380] The obligation to prevent undue transboundary interference does not cease to exist when such interference occurs.[381] Rather, its focus is shifted to minimizing those adverse that can no longer be averted. Hence, the obligation to prevent does not only operate *ex ante*, i.e. prior to the occurrence of damage, but also *ex post* as an obligation to prevent further damage.[382] Yet, it must not be confused with obligations to ensure compensation or reparation (whether as primary obligations or as a consequence of responsibility for wrongful conduct), which operate in a different realm.[383]

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378 See chapter 3, section A.I.2; see *Mackenzie* et al., IUCN Guide (n. 360), MN. 484–485.

379 UNCLOS (n. 13), Article 194; UNFCCC (n. 14), Artiicle 3(3); CBD (n. 12), Article 14(1)(d).

380 *Shinya Murase*, Third Report on the Protection of the Atmosphere, UN Doc. A/CN.4/692 (2015), para. 15.

381 See ARSIWA (n. 43), Article 14(3).

382 *Duvic-Paoli* (n. 4), 193–194.

383 *Ibid.*, 194.

VII. Conclusions

It has been observed that 'environmental treaties tend to stipulate procedural obligations that are narrower and more concrete than their relatively amorphous substantive obligations.'[384] This observation also holds true in the realm of customary international law on the prevention of environmental harm: while the substantive obligation to prevent the causation of significant harm to the environment of other states and areas beyond national jurisdiction remains a difficult to grasp obligation of 'due diligence', the entailing procedural obligations are more specific and compliance is easier to determine.

The cornerstone of procedural environmental law is the obligation to conduct an EIA to determine the likely consequences of a project, which enjoys general recognition as a requirement under customary international law. This obligation is an important entry-point for international 'soft law' standards since by informing the EIA, these standards can guide the decision-making process without unduly interfering with the sovereign decision whether to approve a project or not. Yet, as will be seen in the following section, deficits in the EIA do not necessarily allow to conclude that a state has also breached its substantive obligation to prevent harm.

E. Establishing Breaches of the Obligation to Prevent Transboundary Harm

As elaborated above, the content of the due diligence obligation to prevent transboundary harm is largely context-dependent, which means that the specific measures required from a state which undertakes or authorizes a hazardous activity significantly depend on the circumstances of the particular situation.[385] Consequently, it can be difficult to clearly determine whether or not a state has breached its obligation.

This is aggravated by a number of dogmatic uncertainties concerning the nature of the preventive obligation: First, it is generally assumed that the occurrence of transboundary harm does not necessarily indicate a breach of the obligation to prevent such harm (I.). But at the same time, it is also unclear whether the preventive obligation can be breached even when harm has not (yet) occurred (II.). The third problem concerns the

384 *Bratspies* (n. 20), 194.
385 See *supra* section C.

relationship between the substantive obligation to prevent harm and the associated procedural duties (III.).

I. Occurrence of Harm as an Indication of a Breach

It could be assumed that the obligation to prevent significant transboundary harm is breached whenever such harm actually occurs. This seems to be supported by Article 14(3) of the ILC's Articles on State Responsibility, which specifically addresses obligations to prevent a given event:

> *'The breach of an international obligation requiring a State to prevent a given event occurs when the event occurs and extends over the entire period during which the event continues and remains not in conformity with that obligation.'*

If the occurrence of transboundary harm was understood to be the 'given event' that the state is required to prevent, it could be assumed that the obligation is breached whenever transboundary harm occurs.

But in fact, it is generally agreed that preventive obligations in international law do not require the responsible state to guarantee that the undesired event occurs under no circumstances.[386] This was also pointed out by the ICJ in the *Bosnian Genocide* case: with regard to the obligation to prevent and punish genocide under the Genocide Convention,[387] the Court recognized that this obligation was one of conduct and not one of result, 'in the sense that a State cannot be under an obligation to succeed, whatever the circumstances, in preventing the commission of genocide'.[388] Instead, the Court held that states are required to employ all means reasonably available to them, but do not incur responsibility simply because the desired result is not achieved.[389] However, a state would incur responsibility when it 'manifestly failed' to take all measures which were within its power and which might have contributed to preventing genocide.[390] This

386 See *supra* section C.

387 Convention on the Prevention and Punishment of the Crime of Genocide (09 December 1948; effective 12 January 1951), 78 UNTS 228, Article 1.

388 ICJ, Bosnian Genocide (n. 129), para. 430.

389 *Ibid.*

390 *Ibid.* Interestingly, the Court seems not to require but-for causality (a state only incurs responsibility if the genocide would have actually been prevented by the measures the state was required but failed to take), but finds it sufficient that the omitted measures 'might have contributed to preventing' the undesired event.

is also generally recognized regarding the obligation to prevent significant transboundary harm:

> *'The duty of due diligence […] is not intended to guarantee that significant harm be totally prevented, if it is not possible to do so. In that eventuality, the State of origin is required, as noted above, to exert its best possible efforts to minimize the risk. In this sense, it does not guarantee that the harm would not occur.'*[391]

Consequently, the obligation to prevent significant transboundary harm is not necessarily violated simply because damage has occurred. Rather, in order to hold another state responsible for a breach of due diligence, a claimant state would need to demonstrate that the state has violated its due diligence obligation by not taking 'all appropriate measures', and that there is a causal link between this obligation and the occurrence of harm in the territory of the claimant state. In many cases, this will require an *ex post* determination of what measures would have been appropriate in the individual case from an *ex ante* perspective.[392] This will often be difficult, especially since it requires evidence of what information was available to the responsible party at the time when the action necessary to prevent harm should have been taken.

For this reason, it has been proposed to reverse the burden of proof in the event of damage by requiring the responsible state to demonstrate that it has taken all preventive measures that were objectively required.[393] However, as with the burden of proof concerning the existence of a risk, there is no general consensus that the burden of proof should be reversed in the event that damage has occurred.[394]

391 ILC, Articles on Prevention (n. 22), Article 3, commentary para. 7.

392 Cf. *Pierre-Marie Dupuy*, Reviewing the Difficulties of Codification: On Ago's Classification of Obligations of Means and Obligations of Result in Relation to State Responsibility, 10 (1999) EJIL 371, 381; *Bergkamp* (n. 96), 269; *Ulrich Beyerlin/Thilo Marauhn*, International Environmental Law (2011), 42–43.

393 Cf. *Stephen C. McCaffrey*, The Law of International Watercourses (2019), 501; *Beyerlin/Marauhn* (n. 392), 43; similarly *Bergkamp* (n. 96), 270–271, who suggests that the injured party would only need to bring *prima* facie evidence of a breach of due diligence, which the defendant state would then have to rebut; also see *Schmitt* (n. 69), 204.

394 See *supra* section B.VI.

II. Occurrence of Harm as a Prerequisite of a Breach

The preceding section has established that the mere occurrence of transboundary harm does not *per se* indicate a violation of the preventive obligation. But *vice versa*, it is also questionable whether a breach of the preventive obligation can only be assumed when harm has actually occurred, or whether a state can incur responsibility for not taking appropriate measures to prevent harm even though no damage has occurred (yet).

In the *Bosnian Genocide* case, the ICJ expressly ruled that a state can only be held responsible for breaching the obligation to prevent genocide when genocide was actually committed.[395] The Court referred to Article 14(3) ARSIWA to point out that 'it is at the time when commission of the prohibited act […] begins that the breach of an obligation of prevention occurs'.[396] Consequently, the Court held that a state cannot incur responsibility *a posteriori* for an omission to act when the apprehended event did not actually occur.[397]

It is questionable whether this conclusion can also be applied to the obligation to prevent transboundary harm. Notably, the ICJ itself stated that it did not purport to establish a general jurisprudence applicable to all cases concerning an obligation to prevent certain acts.[398] However, the Court's jurisprudence in environmental matters appears to go in a similar direction. In the *Pulp Mills* case, the ICJ held that there was neither conclusive evidence that Uruguay had not acted with due diligence, nor that the discharges from the disputed mills had actually caused harm to the river shared with Argentina.[399] Moreover, in the *Certain Activities* case, the Court dismissed Nicaragua's claim that Costa Rica had breached its substantive preventive obligations expressly because the disputed activity had not actually caused significant transboundary harm.[400] Hence, it seems that the Court is willing to assume a violation of the obligation to prevent transboundary harm only when such harm actually occurs.[401] If this interpretation of the obligation to prevent significant transboundary harm pre-

395 ICJ, Bosnian Genocide (n. 129), para. 431.
396 *Ibid.*
397 *Ibid.*
398 *Ibid.*, para. 429.
399 ICJ, Pulp Mills (n. 18), para. 265.
400 *Ibid.*, para. 217.
401 *Hafner/Buffard* (n. 142), 523; *Brent* (n. 112), 55; *Brunnée* (n. 252), 158–159.

vailed, the capacity of the rule to respond to contemporary environmental challenges would be significantly inhibited.[402]

According to a different position, the obligation to prevent transboundary harm is breached whenever a state does not act with due diligence, regardless of whether or not the breach results in actual harm.[403] This is because the obligation to prevent transboundary harm is not a (negative) obligation of result, but an obligation of conduct that continuously requires acting with due diligence. If the occurrence of harm was construed as a prerequisite for a breach of this obligation, it would be impossible to hold a state responsible for not taking all appropriate measures unless and until harm actually occurs. The legal consequences of state responsibility other than reparation, namely the obligation to cease the wrongful conduct[404] and the obligation to offer appropriate assurances and guarantees of non-repetition,[405] would be inapplicable. But whether a state is required to cease a wrongful conduct by returning to diligent action does not depend on the occurrence of harm, which is only relevant to the question of whether the responsible state must also make reparation for any harm caused during the period of non-compliance.[406] This was aptly summarized by judge *Donoghue* in her separate opinion to the merits judgment in the *Certain Activities* case:

> *'In the planning phase, a failure to exercise due diligence to prevent significant transboundary environmental harm can engage the responsibility of the State of origin even in the absence of material damage to potentially affected States. […] If, at a subsequent phase, the failure of the State of origin to exercise due diligence in the implementation of a project causes significant transboundary harm, the primary norm that is breached remains one of due diligence, but the reparations due to the affected State must also address the material damage caused to the affected State.'*[407]

This also appears to be in line with the ILC's position. As mentioned earlier, Article 14 ARSIWA addresses the temporal dimension of breach-

402 *Brent* (n. 112), 55.
403 *Lefeber* (n. 30), 85–86; *Crawford* (n. 201), 227; *Duvic-Paoli* (n. 4), 335–336; ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge Donoghue, para. 9.
404 ARSIWA (n. 43), Articles 29 and 30(a).
405 *Ibid.*, Article 30(b); see chapter 9, section B.I.
406 *Duvic-Paoli* (n. 4), 336.
407 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge Donoghue, para. 9.

es of international obligations. In this respect, the Article distinguishes between obligations which have or do not have a continuing character. Article 14(3), which addresses international obligations 'requiring a State to prevent a given event', provides that the breach 'extends over the entire period during which the event continues and remains not in conformity with that obligation'. But the ILC expressly recognized in its commentary that 'not all obligations directed at preventing an act from occurring will be of this kind'.[408] Indeed, the ILC recognized that there is a difference between obligations to prevent a given event, which are construed as (negative) obligations of result, and obligations of due diligence, which the ILC describes as 'best efforts obligations, requiring States to take all reasonable or necessary measures to prevent a given event from occurring, but without warranting that the event will not occur'.[409]

Consequently, there is a difference between obligations of prevention *strictu sensu* on the one hand and preventive obligations of due diligence on the other.[410] While the former are (negative) obligations of result, which are deemed to be breached whenever the apprehended event occurs,[411] due diligence obligations are obligations of conduct which can be breached independently from whether the event to be averted actually

408 ARSIWA (n. 43), Commentary to Article 14, para. 14.

409 *Ibid.*, Article 14, para. 14; but see *Economides* (n. 201), 378, who appears to regard due diligence obligations as obligations of result, as 'their common feature is their general formulation and their lack of precise stipulation of the means to achieve the specified result'. Moreover, *Economides* (n. 201), 374, cites the obligation to take all appropriate measures to prevent significant transboundary harm as enshrined in Article 3 of the ILC's Articles on Prevention (n. 22) as an example for an obligation of prevention.

410 *Crawford* (n. 201), 227.

411 It may be questioned whether such obligations (i.e. '"negative" obligations of result') do exist at all. The commentary to Draft Article 23 (ILC, Report of the International Law Commission on the Work of Its Thirtieth Session, UN Doc. A/33/10, YBILC 1978, Vol. II, Pt. 2 (1978), 81) cites Article 22(2) of the Vienna Convention on Diplomatic Relations (18 April 1961; effective 24 April 1964), 500 UNTS 95, which provides that the state receiving a diplomatic mission 'is under a special duty to take all appropriate steps to protect the premises of the mission […] and to prevent any disturbance of the peace of the mission'. However, as shown by *Crawford* (n. 201), 228–229, this obligation is equally an obligation of conduct (and, essentially, also one of due diligence). Interestingly, the Draft Article 23 was deleted altogether, and the final ARSIWA only mention obligations of prevention in Article 14(3) in the context of the temporal elements of a breach, see *Crawford* (n. 201), 230; *Hafner/Buffard* (n. 142), 523. On a side note, obligations of prevention refer to the prevention of acts by third parties (or private actors) and must not be confused with negative obligations

occurs.[412] The wrongful conduct giving rise to a breach of a due diligence obligation is the state's failure to take the required measure. A state is not allowed to argue, retrospectively, that because no harm has occurred at the time of the legal proceeding, there was no duty of due diligence at the time the project was planned.[413] The due diligence obligation to prevent harm arises whenever there is a risk of significant transboundary harm.

Therefore, a breach occurs whenever and as long as the state fails to act with due diligence, but regardless of whether the breach causes the undesired event (such as transboundary harm) to occur.[414] Proving the existence of a risk from an *ex post* perspective in cases in which the risk has not materialized may be associated with difficulties. But this is more of an evidentiary issue than a legal problem. Consequently, the obligation to prevent transboundary harm is breached whenever the state does not act with due diligence, regardless of whether transboundary harm has (already) occurred.[415]

III. Relationship Between Procedural and Substantive Obligations of Prevention

The third problem concerns the relationship between the substantive obligation to prevent transboundary harm and the corresponding procedural obligations, in particular the obligation to carry out an EIA. In particular, it is unclear whether the breach of a procedural obligation automatically entails a breach of the substantive obligation to prevent transboundary harm. This depends on whether the procedural obligations are regarded as expressions of the due diligence standard required to prevent transboundary harm or as independent obligations of customary international law.

The ICJ's jurisprudence on this matter is rather ambiguous. In the *Pulp Mills* case, the ICJ considered the obligation to undertake an EIA to be 'a requirement under general international law'.[416] But the Court also stated

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that require a state to refrain from a certain conduct (see *Economides* (n. 201), 373–374).

412 But see *Dupuy* (n. 392), 380, arguing that obligations of prevention should always be viewed as a sub-category of obligations of conduct.

413 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge ad hoc Dugard, para. 10.

414 See ILC (n. 411), fn. 397 on p. 81; cf. *Dupuy* (n. 392), 382.

415 Cf. *Crawford* (n. 201), 227.

416 ICJ, Pulp Mills (n. 18), 204.

that 'due diligence, and the duty of vigilance and prevention which it implies, would not be considered to have been exercised' when a state has failed to carry out an EIA.[417] At the same time, however, the Court sharply distinguished between procedural and substantive obligations contained in the bilateral treaty which governed the dispute. In this regard, the Court expressly held that a breach of a procedural obligation does not automatically entail the breach of substantive obligations.[418] Likewise, it stated that the fact that the parties have complied with their substantive obligations does not mean that they are deemed to have complied *ipso facto* with their procedural obligations, or were excused from doing so.[419]

Similarly, in the *Certain Activities* case, the ICJ concluded that Costa Rica had breached its obligation to conduct an EIA. This procedural obligation was triggered by the risk that Costa Rica's activity posed to Nicaragua's environment.[420] Nonetheless, the ICJ found that Costa Rica had not violated its substantive obligation to prevent transboundary harm.[421] Thus, the judgment affirms that the fact that no significant transboundary harm has occurred does not exonerate a state for its failure to carry out an EIA in the first place, but also that such a failure is irrelevant for the assessment as to whether the substantive obligation was breached.[422] Consequently, the Court treats alleged breaches of procedural obligations entirely independently from the question of whether the substantive obligation to prevent transboundary harm has been breached.[423]

The ICJ's position is plausible, particularly in view of the fact that the Court seems to hold that the substantive prevention obligation can only be breached if damage has actually occurred.[424] However, the strict distinction between substantive and procedural obligations is problematic. Most crucially, the position disregards the fact that respect for procedural obligations can serve as an 'essential indicator' of whether substantive obli-

417 *Ibid.*
418 *Ibid.*, para. 78.
419 *Ibid.*; see *Duvic-Paoli* (n. 4), 337.
420 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), para. 162.
421 *Ibid.*, para. 217.
422 Cf. *ibid.*, Separate Opinion of Judge ad hoc Dugard, para. 19.
423 *Duvic-Paoli* (n. 4), 337; also see ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge ad hoc Dugard, para. 9, stressing that the obligation to conduct an EIA is an 'independent obligation' which is not dependent on the obligation to exercise due diligence in preventing significant transboundary harm.
424 See *supra* section E.II.

gations were breached or not.[425] Non-compliance with procedural duties will often have direct effects on the substantive elements of prevention. For instance, a duly performed EIA could reveal means to reduce the risk of transboundary harm and thus contribute to defining the content of the substantive obligation to prevent such harm in a particular situation.[426] On the other hand, the affected state might face difficulties proving the existence of harm or its causation when the responsible state has breached its procedural obligations and, for instance, not given the affected state proper access to the necessary information.[427] Hence, there is a certain 'disconnect' between the Court's repeated recognition of the anticipatory nature of prevention and its treatment of the obligation in the context of state responsibility.[428]

It appears more convincing to view the procedural duties not (only) as independent customary obligations, but (also) as expressions of the substantive obligation to prevent harm.[429] This would recognize that the substantive content of the due diligence obligations can be informed through the application of the procedural elements of due diligence, such as the obligation to conduct an EIA, and to notify and consult with affected states.[430] At the same time, states may use their compliance with procedural rules – including from soft law instruments – as evidence that they have acted with due diligence when responding to potential claims that they have breached their preventive obligations.[431]

More fundamentally, international jurisprudence should also take account of the evidentiary challenges an injured state may face in proving a breach of due diligence. In disputes concerning alleged transboundary harm caused by LMOs, the defendant state should be required to provide all relevant information about the LMO it obtained in the course of regulatory procedures. Although the precautionary principle alone may not

425 ICJ, Pulp Mills (n. 18), Joint Dissenting Opinion of Judges Al-Khasawneh and Simma, para. 26; also see *Bratspies* (n. 20), 194.
426 Cf. ICJ, Pulp Mills (n. 18), Joint Dissenting Opinion of Judges Al-Khasawneh and Simma, para. 26.
427 *Duvic-Paoli* (n. 4), 338.
428 *Ibid.*
429 *Bendel/Harrison* (n. 250), 18–19; *Duvic-Paoli* (n. 4), 336–339; *Brunnée* (n. 252), 161.
430 ICJ, Certain Activities/Construction of a Road (Merits) (n. 19), Separate Opinion of Judge Donoghue, para. 9.
431 *Bendel/Harrison* (n. 250), 19.

result in a shift of the burden of proof,[432] the broad information-sharing obligations under the CBD[433] and the Cartagena Protocol[434] as well as under national law[435] indicate that withholding information about a harmful LMO is not a legitimate litigation strategy to defend against potential claims for compensation.

F. Summary

This chapter shows that the general customary obligation of states to prevent significant transboundary harm from being caused by activities under their jurisdiction or control applies to adverse transboundary effects caused by LMOs in the same manner as it applies to other forms of transboundary environmental interference. It has also confirmed that the obligation to prevent unintentional transboundary movements contained in Article 16(3) of the Cartagena Protocol is based on a universally recognized rule of customary international law, at least when the LMO in question causes significant adverse effects to the receiving environment, persons, or property.

Yet, there are a number of important caveats. At first, the obligation does not apply to harm caused following an intentional transboundary movement. A general obligation to obtain the prior consent of the receiving state before exporting an LMO, as set out in the Cartagena Protocol, is currently not part of customary international law.

Moreover, while international responsibility for transboundary harm requires such harm to be 'significant', the mere presence of an LMO in the territory of another state is unlikely to reach this threshold. Therefore, the affected state will have to show that a foreign LMO which occurs in its territory causes some form of 'real detriment'. However, a large-scale introduction of LMOs into the environment of another state, such as that caused by an invasive gene drive uncontrolledly spreading across borders, arguably reaches the threshold of 'significant' transboundary harm.[436] In

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432 See *supra* section B.VI.3.

433 Article 19(4) CBD (n. 12); see chapter 3, section B.IV.

434 Article 20 Cartagena Protocol (n. 91); see chapter 3, section A.II.3.

435 See Gentechnikgesetz (Genetic Engineering Act) (16 December 1993), last amended by Article 8 of the law of 27 September 2021 (Bundesgesetzblatt, Pt. I, p. 4530), Section 35, which provides an (enforceable) right of the injured party against both the operator and the responsible authorities to be provided with all relevant information about the GMO presumed to have caused damage.

436 *Förster* (n. 86), 177; see supra section B.VII.2.

any event, such an uncontrolled spread is also likely to cause significant damage to ecosystems.[437]

Nevertheless, the mere occurrence of such harm does not *per se* indicate a violation of international law. Instead, the obligation only requires the exercise of due diligence, which means that a state must make reasonable efforts to inform itself about the factual and legal circumstances that relate to a proposed activity and take appropriate preventive measures in due time.[438] Hence, in order to establish a violation, a claimant would need to demonstrate that the responsible state has failed to employ due diligence and that this failure caused the occurrence of transboundary harm. Ultimately, this will require an *ex post* determination of what measures would have been appropriate in the individual case from an *ex ante* perspective. International jurisprudence should take account of the unavoidable evidentiary challenges any injured state will face in such a situation by requiring the responsible state to submit any relevant information it possesses about the cause of harm, such as any scientific or regulatory knowledge about the characteristics of a harmful LMO. It should also correct the view that the obligation to prevent harm can only be breached when harm has already occurred. Instead, a breach should be assumed whenever a state fails to employ due diligence to prevent such harm, regardless of whether this failure has already led to actual harm.

While the substantive content of due diligence remains rather 'amorphous',[439] the corollary procedural obligations are more specific. In particular, the obligation to carry out an environmental impact assessment prior to commencing a hazardous activity has become widely accepted as a requirement under customary international law. After all, the documentation prepared during the EIA procedure can be regarded as written evidence of the exercise of due diligence, as it commonly includes a description of the potential impacts of the proposed activity as well as of the required prevention and mitigation measures. Against this background, it comes as no surprise that the adequacy of EIAs carried out in individual cases is increasingly subject to legal review by international courts and arbitral tribunals.[440] At the same time, the greater level of detail in the procedural manifestations of prevention has often led international jurisprudence to focus on procedural aspects while applying less scrutiny to

437 See chapter 1, section C.IV.
438 ILC, Articles on Prevention (n. 22), Commentary to Article 10, para. 10.
439 Cf. *Bratspies* (n. 20), 194.
440 See *supra* section D.II.

the question whether the substantive obligation to prevent harm has been observed. Ultimately, the relationship between procedural and substantive aspects of prevention is still an unsettled question. When knowledge about the environmental risks of a certain activity is insufficient, the precautionary approach lowers the evidentiary threshold for invoking preventive measures, but does not operate as a reversal of the burden of proof.

To date, no state has ever claimed a breach of international law for adverse transboundary effects caused by LMOs uncontrolledly entering its territory. In light of recent advances in developing self-spreading biotechnology like engineered gene drives, such claims are likely to arise in the future. As noted earlier, the potential of these techniques to create organisms that traverse political borders it widely recognized.[441] But doubts remain whether customary international law is capable of preventing unilateral releases when the potential for a transboundary spread of the organism is controversial. The following chapter shows that the international regulation of engineered gene drives is currently subject to vivid and controversial debates. While these discussions have resulted in a first substantive decision carried by near-universal consensus, it remains to be seen whether it effectively guardrails safe deployments of this emerging technique.

441 See chapter 1, section C.IV.4.

Chapter 5: The International Governance of Engineered Gene Drives

As set out in the first chapter, recent advances in molecular biology include the development of *synthetic gene drives*, which make it possible to quickly disseminate genetic modifications to populations of wild species.[1] Research into these techniques is justified, *inter alia*, by the potential to obtain a long sought-after tool to control infectious diseases.[2] However, others have warned that releases of engineered gene drives could be irreversible and could have major effects on ecosystems or human health on a transboundary or even global level.[3]

The present chapter[4] assesses the current debate on the regulation of gene drive techniques in international law. The most relevant treaties in this context are the *Convention on Biological Diversity* (CBD)[5] and its *Cartagena Protocol on Biosafety*.[6] In 2018, the parties to the CBD adopted a first substantive decision on the issue of engineered gene drives (A.). While the decision is not legally binding in a formal sense, it still has a normative effect as 'soft law' (B.). This is also because the decision does not stipulate new obligations but rather confirms the applicability of already-existing

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1 See chapter 1, section C.

2 Cf. *Stephanie James* et al., Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group, 98 (2018) Am. J. Trop. Med. Hyg. 1; *Austin Burt* et al., Gene Drive to Reduce Malaria Transmission in Sub-Saharan Africa, 5 (2018) Journal of Responsible Innovation S80.

3 Cf. *John M. Marshall*, The Cartagena Protocol and Genetically Modified Mosquitoes, 28 (2010) Nature Biotech. 896, 896; *Kenneth A. Oye* et al., Regulating Gene Drives, 345 (2014) Science 626; *Kevin M. Esvelt/Neil J. Gemmell*, Conservation Demands Safe Gene Drive, 15 (2017) PLOS Biology e2003850; *Virginie Courtier-Orgogozo* et al., Agricultural Pest Control with CRISPR-based Gene Drive, 18 (2017) EMBO Reports 878.

4 Parts of earlier versions of this chapter were contributed to an unpublished study on gene drives by *R. Guy Reeves* et al. (2020), which was commissioned by the German *Bundestag.* The chapter was substantially revised thereafter.

5 Convention on Biological Diversity (05 June 1992; effective 29 December 1993), 1760 UNTS 79.

6 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 January 2000; effective 11 September 2003), 2226 UNTS 208; see chapter 3, section A.

rules and principles on gene drives (C.). However, the decision does not address potential transboundary spreads (D.).

A. The Development of COP Decision 14/19

Due to its near-universal membership,[7] the *Conference of Parties* (COP) to the CBD has emerged as the principal forum for discussing the regulation of gene drives at the global level.[8] However, parties to the CBD have been deeply divided over whether engineered gene drives should be developed at all, and if so, whether their release into the environment should be allowed.[9]

In the context of the CBD, the issue of engineered gene drives has been part of a broader discussion about the international regulation of *synthetic biology*.[10] In 2014, COP 12 established an *Ad Hoc Technical Expert Group* (AHTEG) on this issue,[11] which defined the term 'synthetic biology' as

> *'a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems.'*[12]

7 See chapter 3, section B.

8 See *Natalie Kofler* et al., Editing Nature: Local Roots of Global Governance, 362 (2018) Science 527, 527; *Hung-En Lai* et al., Synthetic Biology and the United Nations, 37 (2019) Trends in Biotechnology 1146; *Heidi J. Mitchell/Detlef Bartsch*, Regulation of GM Organisms for Invasive Species Control, 7 (2020) Front. Bioeng. & Biotechnol. 927, 4.

9 See *Jesse L. Reynolds*, Governing New Biotechnologies for Biodiversity Conservation: Gene Drives, International Law, and Emerging Politics, 20 (2020) Global Environmental Politics 28; *Florian Rabitz*, Gene Drives and the International Biodiversity Regime, 28 (2019) RECIEL 339.

10 For an overview, see *Felicity Keiper/Ana Atanassova*, Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols, 8 (2020) Front. Bioeng. & Biotechnol. 310.

11 CBD COP, Decision XII/24. New and Emerging Issues: Synthetic Biology, UN Doc. UNEP/CBD/COP/DEC/XII/24 (2014), para. 4.

12 AHTEG on Synthetic Biology, Report of the Ad Hoc Technical Expert Group on Synthetic Biology: Montreal, Canada, 21–25 September 2015, UN Doc. UNEP/CBD/SYNBIO/AHTEG/2015/1/3 (2015), para. 24. The definition was formally acknowledged by the states parties in CBD COP, Decision XIII/17. Synthetic Biology, UN Doc. CBD/COP/DEC/XIII/17 (2016), para. 4.

In its decision of 2014, the COP also adopted a first set of principles on the use of synthetic biology.[13] Parties were urged to take a precautionary approach and to

> *'establish, or have in place, effective risk assessment and management procedures and/or regulatory systems to regulate environmental release [sic!] of any organisms, components or products resulting from synthetic biology techniques'.*[14]

In this regard, the decision explicitly referred to Article 3 CBD, which enshrines the obligation of states to ensure that activities within their jurisdiction or control do not cause transboundary harm.[15] Moreover, the decision called upon governments to approve field trials of organisms resulting from synthetic biology only after appropriate risk assessments have been carried out in accordance with national, regional and/or international frameworks.[16]

Two years later, at COP 13 in 2016, the parties to the CBD reiterated these principles and noted that they 'can also apply to some living modified organisms containing gene drives'.[17] At the same time, they rejected language that would have urged parties to 'obtain consent from other governments whose biodiversity could be affected by any proposed gene drive before approval of its release'.[18] The meeting also rejected a moratorium on the further development of gene drives,[19] which was called for by some parties and non-governmental organizations (NGOs).[20]

In the lead-up to COP 14 in 2018, the members of the CBD's *Subsidiary Body on Scientific, Technical and Technological Advice* (SBSTTA) disagreed

13 CBD COP, Decision XII/24 (n. 11).
14 *Ibid.*, para. 3(a).
15 *Ibid.*
16 *Ibid.*, paras. 3(b) and (c).
17 CBD COP, Decision XIII/17 (2016) (n. 12), para. 2.
18 Cf. CBD COP, Synthetic Biology: Draft Decision Submitted by the Chair of Working Group II, UN Doc. UNEP/CBD/COP/13/WG.2/CRP.22 (2016), para. 2.
19 IISD, Summary of the UN Biodioversity Conference: 2–17 December 2016, ENB Vol. 9 No. 678 (2016), 17; *Ewen Callaway*, 'Gene Drive' Moratorium Shot Down at UN Biodiversity Meeting, Nature News (21 December 2016), available at: http://www.nature.com/news/gene-drive-moratorium-shot-down-at-un-biodiversity-meeting-1.21216 (last accessed 28 May 2022).
20 See SynBioWatch, Common Call for a Global Moratorium on Genetically-Engineered Gene Drives (05 December 2016), available at: http://www.synbiowatch.org/gene-drives/gene-drives-moratorium/?lores (last accessed 28 May 2022).

on whether states should be called upon to apply a precautionary approach with regard to the release of gene drives or whether they should be called to refrain from such releases altogether.[21] At the COP meeting, some states parties and a number of NGO representatives again demanded a moratorium, although this time no longer on the development of gene drives but only on their release.[22] Other parties and NGOs opposed a moratorium, arguing that the technique should not be abandoned before its potential costs and benefits could be fully evaluated.[23] After controversial negotiations,[24] the parties adopted decision 14/19, which recognises that

> *'as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment'.*[25]

The decision also 'calls upon' upon parties and other governments[26] to apply a precautionary approach, and to

> *'only consider introducing organisms containing engineered gene drives into the environment, including for experimental releases and research and development purposes, when:*

21 CBD SBSTTA, Recommendation 22/3. Synthetic Biology, UN Doc. CBD/SBSTTA/REC/22/3 (2018), para. 10; see *Reynolds* (n. 9), 36–40.

22 Cf. SynBioWatch, A Call to Protect Food Systems from Genetic Extinction Technology: The Global Food and Agriculture Movement Says No to Release of Gene Drives (16 October 2018), available at: http://www.etcgroup.org/sites/www.etcgroup.org/files/files/etc_ftfsignonletter113018engweb_1.pdf (last accessed 28 May 2022); European Parliament, Resolution on the 15th Meeting of the Conference of Parties (COP15) To the Convention on Biological Diversity, P9_TA(2020)0015 (2020), para. 13; IISD, UN Biodiversity Conference Highlights: Sunday, 18 November 2018, ENB Vol. 9 No. 716 (2018), 2.

23 Cf. IISD (n. 22), 2; Outreach Network for Gene Drive Research, Open Letter: Research on Gene Drive Technology Can Benefit Conservation and Public Health (14 November 2018), available at: https://genedrivenetwork.org/open-letter (last accessed 28 May 2022); Royal Society, Gene Drive Research: Why It Matters (2018).

24 See IISD, Summary of the UN Biodiversity Conference: 13–29 November 2018, ENB Vol. 9 No. 725 (2018), 16–17; *Natalie Kofler*, Gene Drives: Yelling Match Drowns Out Marginalized Voices, 565 (2019) Nature 25.

25 CBD COP, Decision 14/19. Synthetic Biology, UN Doc. CBD/COP/DEC/14/19 (2018), para. 9.

26 This refers to governments of states not party to the CBD, namely the United States and the Holy See.

> *(a) Scientifically sound case-by-case risk assessments have been carried out,*
> *(b) Risk management measures are in place to avoid or minimise potential adverse effects, as appropriate;*
> *(c) Where appropriate, the "prior and informed consent", the "free, prior and informed consent" or "approval and involvement" of potentially affected indigenous peoples and local communities is sought or obtained, where applicable in accordance with national circumstances and legislation'.*[27]

Regarding the issue of contained use, the decision calls to develop and implement measures to prevent or minimise potential adverse effects from exposing the environment to organisms, components, and products of synthetic biology in contained use.[28]

B. Legal Status of COP Decision 14/19

COP decision 14/19 lays down specific principles for the research of gene drives techniques and spells out concrete preconditions that shall be met before engineered gene drives are released, even experimentally. Before further exploring the meaning and consequences of this decision, it ought first to be determined whether, and in which way, states are bound to it.

I. Functions of COP Decisions

The Conference of the Parties is an organ established by the CBD[29] in which all parties are represented and which is mandated to adopt decisions relating to the operation and further development of the treaty.[30] The COP is charged to 'keep under review the implementation' of the CBD and, to this end, may adopt and amend protocols and annexes.[31] It may also establish procedures and subsidiary bodies carrying out specific functions.[32]

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27 CBD COP, Decision 14/19 (n. 25), para. 11.
28 *Ibid.*, para. 12.
29 Article 23 CBD.
30 *Ibid.*; cf. *Jutta Brunnée*, COPing with Consent: Law-Making Under Multilateral Environmental Agreements, 15 (2002) Leiden J. Int'l L. 1, 16.
31 Articles 23(4)(c)-(f) CBD.
32 Articles 18(3), 20(2), 21(1), 23(2), 23(4)(a), 23(4)(b), 23(4)(g) CBD.

The COP usually meets biannually.[33] It also serves as the 'meeting of the Parties' (MOP)[34] to the protocols adopted under the auspices of the CBD, including the Cartagena Protocol[35] and its Supplementary Protocol on Redress and Liability.[36]

With regard to their legal nature, decisions adopted by the COP can be classified into three categories.[37] In some aspects, primarily concerning matters of internal governance, the COP is mandated by the CBD to adopt decisions that have direct legal effect.[38] The second category concerns the adoption of protocols and annexes to the CBD as well as amendments to these instruments and the CBD itself.[39] Such additions or amendments are first decided upon by the COP and must subsequently be ratified by the parties concerned to become legally binding upon them.[40]

The third category includes decisions on matters concerning the CBD and its implementation, which are not expressly assigned a legal status. Pursuant to Article 23(4)(j) CBD, the range of these decisions comprises 'any additional action that may be required for the achievement of the purposes of this Convention in the light of experience gained in its operation'. Hence, these decisions often address new or persisting challenges to the implementation of the CBD.[41]

Insofar as analysed here, decision 14/19 belongs to the third of the aforementioned categories, since it neither addresses matters of internal governance nor adopts changes to the treaty text.[42]

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33 CBD COP, Rules of Procedure for the Conference of the Parties, UN Doc. UNEP/CBD/COP/DEC/I/1 (1995), Rule 4(1).
34 The difference in name between COP and MOP does not indicate a substantive difference in function; see *Robin R. Churchill/Geir Ulfstein*, Autonomous Institutional Arrangements in Multilateral Environmental Agreements: A Little-Noticed Phenomenon in International Law, 94 (2000) AJIL 623, 629–630.
35 Cf. Article 29 Cartagena Protocol.
36 Cf. Article 14 Supplementary Protocol, which provides that the CBD COP, serving as the MOP to the Cartagena Protocol, shall serve as the meeting of the Parties to the Supplementary Protocol.
37 Similar typologies have been proposed by *Churchill/Ulfstein* (n. 34), 626; *Brunnée* (n. 30), 15–33.
38 See, e.g., Articles 23(3), 24(2), and 28(3) CBD.
39 See *supra* n. 32.
40 Cf. Articles 29(4), 30(3) CBD.
41 All decisions adopted by the CBD COP are available at https://www.cbd.int/cop/.
42 But see CBD COP, Decision 14/19 (n. 25), paras. 14–15, extending the mandate of subsidiary bodies, and *ibid.*, paras. 17–18, requesting the Executive Secretary and a subsidiary body to gather additional information. These parts of the decision concern self-governance and thus belong to the first category.

II. COP Decisions as 'Soft Law'

Unlike some other multilateral environmental agreements (MEAs), the CBD does not provide for the adoption of binding 'secondary law' by the COP that creates new obligations for the parties or extends existing ones.[43] Hence, except for the relatively rare cases of decisions in the first and second categories mentioned above – internal governance and the adoption or amendment of treaty provisions – decisions adopted by the COP are not legally binding upon the parties to the CBD. However, this does not mean that such decisions have no normative effect. Instead, it is widely acknowledged that decisions adopted by COPs of MEAs exert some form of normative influence concerning the obligations of their parties and can be seen, as argued here, as international 'soft law'.[44]

Two reasons justify this assumption. First, COP decisions are usually adopted by consensus.[45] The Rules of Procedure, which govern the conduct of meetings of the CBD COP,[46] provide that every effort shall be made to reach a consensus on all matters of substance.[47] Only if all efforts to reach consensus have been exhausted may decisions be taken by a two-thirds majority.[48] Thus, despite the lack of formal ratification, every COP decision is carried by the (at least implied[49]) consent of all parties. If a state agrees to a COP decision but later rejects or negates its content, it acts at least in a self-contradictory manner and may even face accusations of *bad faith*.[50]

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43 See, e.g., Montreal Protocol on Substances that Deplete the Ozone Layer (16 September 1987; effective 01 January 1989), 1522 UNTS 3, as last amended by the Meeting of Parties in 2018, Article 2(9); for further examples, see *Churchill/Ulfstein* (n. 34), 638–641.

44 See, e.g., *Churchill/Ulfstein* (n. 34); *Brunnée* (n. 30); *Annecoos Wiersema*, The New International Law-Makers? Conferences of the Parties to Multilateral Environmental Agreements, 31 (2008) Mich. J. Int'l L. 231; *Daniel Bodansky*, Thirty Years Later: Top Ten Developments in International Environmental Law (2020) Yearbook of International Environmental Law 1, 12–13.

45 *Churchill/Ulfstein* (n. 34), 642–643.

46 Cf. Article 23(3) CBD.

47 Cf. CBD COP Rules of Procedure (n. 33), Rule 40.

48 Cf. *ibid.*

49 In practice, many parties are not actively taking part in negotiations, but are represented through 'blocks' of states with mutual or (supposedly) congruent interests. In the negotiations on decision 14/19, relevant blocks were the European Union and an 'African Group', see IISD (n. 24), 16–17.

50 Cf. *Hartmut Hillgenberg*, A Fresh Look at Soft Law, 10 (1999) European Journal of International Law 499, 505–506; *Daniel Thürer*, Soft Law, in: Wolfrum/Peters

The second reason why COP decisions have normative force is closely related to the first. To reach a consensus, decisions are often negotiated in great detail and intensity.[51] Especially the 'operative clauses', which express the intent of the parties, are of fundamental importance for the normative effect of a decision: When a decision 'invites' or 'encourages' certain action, it implies a lower degree of expectation that parties will actually comply than when a decision 'urges' states to adhere to or refrain from a particular conduct.[52] As a result, the wording of decisions and resolutions is often negotiated with the same commitment and vigour as that of binding treaties or protocols.[53]

For these reasons, although decisions and declarations adopted by consensus are – except for the aforementioned first and second categories – not legally binding in a formal sense, they still have a 'de facto' normative power that influences the conduct of states and is therefore often characterized as 'soft law'.[54] In addition, decisions adopted by COPs to multilateral treaties stand in the specific context of the respective treaty and therefore closely relate to the 'hard law' provisions of that treaty. Consequently, it can be argued that COP decisions have the effect of 'thickening' the treaty obligations by adding to its text through interpretation and guidance.[55] Depending on the circumstances, COP decisions could even be regarded as subsequent practice by the parties to the treaty, which, pursuant to Article 31(3) of the *Vienna Convention on the Law of Treaties* (VCLT),[56] shall be taken into account when interpreting the treaty.[57] On

(ed.), MPEPIL, MN. 26–27; also see *Thomas Cottier/Jörg P. Müller*, Estoppel, in: Wolfrum/Peters (ed.), MPEPIL, MN. 12.

51 In the context of the UN climate change negotiations, see *Antto Vihma*, Climate of Consensus: Managing Decision Making in the UN Climate Change Negotiations, 24 (2015) RECIEL 58.

52 Cf. *Wiersema* (n. 44), 253–254; also see University of Joensuu et al., Multilateral Environmental Agreement Negotiator's Handbook (2nd ed. 2007), 3.67 – 3.71.

53 See *Brunnée* (n. 30), 7–15.

54 *Hillgenberg* (n. 50), 514–515; *Brunnée* (n. 30), 51; also see *Silja Vöneky*, Recht, Moral und Ethik (2012), 383 et seq.; but see *Wiersema* (n. 44), 261–264, arguing that the tripartite notion of hard law, soft law, and non-law was insufficient to capture the legal significance of COP decisions.

55 *Wiersema* (n. 44), 245.

56 Vienna Convention on the Law of Treaties (23 May 1969; effective 27 January 1980), 1155 UNTS 331.

57 Cf. *Churchill/Ulfstein* (n. 34), 641; *Wiersema* (n. 44), 278; see ILC, Draft Conclusions on Subsequent Agreements and Subsequent Practice in Relation to the Interpretation of Treaties, with Commentaries (2018), UN Doc. A/73/10, p. 12, Conclusion 11 and Commentary thereto.

the other hand, even a consensus decision may mask remaining substantive disagreements, which is why the circumstances of its adoption and the text of the decision must be carefully analysed.[58]

III. Soft Law Status of Decision 14/19 for Parties to the CBD

Coming back to decision 14/19, it can be concluded that it represents 'soft law' in the aforementioned sense. Not only was it adopted by the parties to the CBD by consensus.[59] The fact that parties were 'called upon'[60] – and not merely 'invited' or 'encouraged'[61] – to observe the stated principles indicates that there is indeed a mutual expectation that the parties will adhere to the decision. At the same time, parties were not 'urged', which would have indicated an even higher level of commitment.[62]

IV. Effect on Non-Parties

The provisions of decision 14/19 not only address the 'parties' to the CBD but also 'other Governments'.[63] This refers to the governments of non-parties to the CBD, namely the United States and the Holy See.[64] Although these governments attend the CBD COP as observers,[65] they do not formally participate in its decision-making. Therefore, the above conclusions about the decision's 'soft law' status do not apply with regard to the United States. Nevertheless, the decision is a clear political call of the international community to the United States, where a significant

58 *Brunnée* (n. 30), 41 and fn. 204.
59 See CBD COP, Report of the Conference of the Parties to the Convention on Biological Diversity on Its Fourteenth Meeting, UN Doc. CBD/COP/14/14 (2019), para. 399. While the report does not expressly state that the decision was carried by consensus, the exception of a majority vote would have been noted.
60 Cf. CBD COP, Decision 14/19 (n. 25), paras. 11–12.
61 See, e.g., CBD COP, Decision XIII/17 (2016) (n. 12), paras. 8–9.
62 See, e.g., CBD COP, Decision XII/24 (n. 11), para. 3; on this provision, see *infra* section C.I.
63 CBD COP, Decision 14/19 (n. 25), paras. 11–12.
64 See *supra* n. 7.
65 Cf. Article 23(5) CBD and Rule 6 of the CBD COP Rules of Procedure (n. 33). The United States regularly participate in the meetings of the CBD COP and its subsidiary bodies, and also make interventions from time to time.

share of the world's research on gene drives takes place,[66] to observe the adopted principles.

C. Substance, Context, and Consequences of COP Decision 14/19

The quasi-normative status of decision 14/19 is supported by the fact that it does not introduce new concepts and rules, but rather applies principles to gene drives that are already established in international (environmental) law.[67] First, states are called to apply a precautionary approach (I.). Then, the decision sets out three conditions that shall be met before any environmental release of engineered gene drives is 'considered' (II.). Finally, the decision calls for effective containment standards while engineered gene drives are still under development in the laboratory (III.).

I. Precautionary Approach (or Principle)

Decision 14/19 calls upon parties and other governments,

> *'taking into account the current uncertainties regarding engineered gene drives, to apply a precautionary approach, in accordance with the objectives of the Convention'.*[68]

According to its Article 1, the objectives of the CBD are the conservation of biological diversity, the sustainable use of its components, and fair benefit-sharing with regard to genetic resources. An iteration of the precautionary principle is laid down in the preamble to the CBD, which notes that

> *'where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimise such a threat'.*[69]

Although the preambles of international treaties do not have the function of laying down legal obligations, they often reiterate already-established

66 See *Kelsey L. Warmbrod* et al., Gene Drives: Pursuing Opportunities, Minimizing Risk (2020), 51; *Reynolds* (n. 9), 40–41.
67 CBD COP, Decision 14/19 (n. 25), paras. 11–12.
68 *Ibid.*, para. 11.
69 Cf. Preamble to the CBD, recital 9.

principles or rules of custom and also serve as 'context' that must be taken into account when interpreting the treaty pursuant to Article 31(2) VCLT.[70] In this way, preambles may become legally binding, especially when they are cast in clear and specific terms.[71]

1. References to Precaution in Earlier COP Decisions

A footnote to the term 'precautionary approach' in COP decision 14/19 refers to an earlier decision on synthetic biology adopted by COP 13 in 2016.[72] This decision, in turn, refers to two decisions adopted in 2012[73] and 2014[74], which had already urged parties and other governments to take a precautionary approach with regard to synthetic biology and gene drives. In this context, the decisions also referred to Article 3 of the CBD, which enshrines the obligation to prevent transboundary harm,[75] and to Article 14, which requires the parties to the CBD to minimize adverse impacts on biodiversity, including through environmental impact assessments of proposed projects that may have such impacts.[76]

Taken together, the decisions leave no doubt that the parties to the CBD view the precautionary approach as an essential guardrail in regulating engineered gene drives.

2. Early Deployment of Gene Drives as a Precautionary Measure?

According to some scholars, the precautionary approach may not unambiguously militate *against* the release of engineered gene drives in situations of scientific uncertainty. It has been argued that it could also be inter-

70 Cf. *Makane M. Mbengue*, Preamble, in: Wolfrum/Peters (ed.), MPEPIL.
71 *Ibid.*, MN. 11–13; see ICJ, Rights of Nationals of the United States of America in Morocco (France v. United States of America), Judgment of 17 August 1952, ICJ Rep. 176, 183–184.
72 CBD COP, Decision XIII/17 (2016) (n. 12).
73 CBD COP, Decision XI/11. New and Emerging Issues Relating to the Conservation and Sustainable Use of Biodiversity, UN Doc. UNEP/CBD/COP/DEC/XI/11 (2012), para. 4.
74 CBD COP, Decision XII/24 (n. 11), para. 3.
75 Cf. *ibid.*
76 Cf. CBD COP, Decision XI/11 (n. 73), para. 4. On the restrictive interpretation of this provision by the ICJ, see chapter 3, section B.VI.1.

preted as *permitting* such releases to mitigate biodiversity loss caused by other factors, such as invasive alien species.[77] According to this reading, the lack of scientific certainty about the environmental impacts of engineered gene drives should not be used as a reason to postpone their deployment for reducing harmful impacts on biological diversity from other sources.[78]

However, this interpretation is based on a misconception of the precautionary approach.[79] The principle refers to scientific uncertainty not in relation to the potential hazards of mitigation measures, but to the causes of biodiversity loss or other forms of environmental degradation that shall be mitigated.[80] The precautionary principle can, therefore, not be invoked to justify hazardous measures simply because they are motivated by the mitigation of harm resulting from other causes.

No different result follows from the wording of the precautionary approach in the *Rio Declaration*, which provides that scientific uncertainty shall not be used as a reason for postponing 'cost-effective measures to prevent environmental degradation'.[81] In particular, it cannot be inferred from this wording that the use of engineered gene drives may be acceptable despite scientific uncertainty but simply because they are potentially cheaper than conventional biocontrol measures.[82] The precautionary approach does not require using the *most cost-effective* measure to prevent environmental degradation. All the less can it be invoked to justify hazardous measures that are (allegedly) more cost-effective than others.

This reading is also supported by the aforementioned COP decisions, which show that the parties to the CBD understand the precautionary principle as calling for restraint in the use of gene drive techniques rather than their premature deployment.

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77 Cf. *Rabitz* (n. 9), 343; also see *Tina Rulli*, CRISPR and the Ethics of Gene Drive in Mosquitoes, in: David Boonin (ed.), The Palgrave Handbook of Philosophy and Public Policy (2018) 509, 511–513.

78 *Rabitz* (n. 9), 343–344.

79 On the misconceptions and (philosophical) dilemmas involved when the precautionary principle is used to choose among different policy options, see *Daniel Steel*, Philosophy and the Precautionary Principle (2015), 17–43.

80 See *Lyle Glowka* et al., A Guide to the Convention on Biological Diversity (1994), 11, who argue that the precautionary principle could place a burden on those who propose a new project to prove it will not significantly reduce or cause significant loss of biological diversity.

81 Cf. Rio Declaration on Environment and Development (14 June 1992), UN Doc. A/CONF.151/26/Rev.1 (Vol. I), Principle 15.

82 But see *Rabitz* (n. 9), 346.

3. Assessment

As noted above, decision 14/19 not only calls upon states to take a precautionary approach but, in the same paragraph, also sets out conditions for potential environmental releases.[83] These conditions can be construed as describing specific manifestations of precaution in the context of engineered gene drives.[84] At the same time, they show that there is a – at least theoretical – pathway to releases consistent with the precautionary approach. Consequently, it cannot be assumed that the precautionary principle does, by itself, result in a general prohibition of releasing engineered gene drives into the environment.

II. Preconditions for Environmental Releases of Engineered Gene Drives

After referring to the precautionary principle, decision 14/19 calls upon parties and other governments 'to only consider introducing organisms containing engineered gene drives into the environment' when three given criteria are met.[85] First, a scientifically sound case-by-case risk assessment must have been carried out (1.). Second, risk management measures must be in place to avoid or minimize potential adverse effects (2.). Third, the prior and informed consent of potentially affected indigenous peoples and local communities must have been sought and obtained, where required (3.). These criteria also apply to experimental releases as well as releases for research and development purposes.[86]

1. Scientifically Sound Case-by-Case Risk Assessment

The first condition for environmental releases of engineered gene drives is that 'scientifically sound case-by-case risk assessments have been carried

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83 Cf. CBD COP, Decision 14/19 (n. 25), para. 11; see the following section.
84 A similar approach has also been used in earlier COP decisions on genetic use restriction technologies in agriculture, see CBD COP, Decision V/5. Agricultural Biological Diversity: Review of Phase I of the Programme of Work and Adoption of a Multi-Year Work Programme, UN Doc. UNEP/CBD/COP/5/23, p. 74 (2000), para. 23.
85 CBD COP, Decision 14/19 (n. 25), para. 11.
86 *Ibid.*

out'.[87] This reiterates an obligation that is already established in international law (a)). In the context of the CBD, risk assessment was primarily addressed in the framework of the Cartagena Protocol (b)).

a) Status of the Obligation Under International Law

It was already shown above that states are obliged to carry out environmental impact or risk assessments of LMOs that may have adverse effects on biodiversity. Article 14(1)(a) CBD provides that parties shall 'introduce appropriate procedures requiring environmental impact assessment' of projects likely to have significant adverse effects on biodiversity.[88] According to Articles 10(1) and 15 of the Cartagena Protocol, a 'scientifically sound' risk assessment is a necessary part of the *Advance Informed Agreement* procedure that applies prior to intentional transboundary movements of LMOs.[89] Annex III to the Cartagena Protocol establishes methodological standards for carrying out such assessments.[90] In addition to these treaty law provisions, the duty to carry out an environmental impact assessment before authorizing hazardous activities that may have adverse transboundary effects is also part of universal customary international law.[91]

Consequently, by requiring risk assessments, the decision merely restates an obligation that is already binding upon states as 'hard law'. However, it also clarifies that this obligation applies to all releases of engineered gene drives, and thus regardless of whether there are specific indications of a risk to biodiversity in an individual case.

b) The Cartagena Protocol's AHTEG on Risk Assessment

Within the CBD framework, the issue of risk assessment was predominantly addressed by the meeting of the parties to the Cartagena Protocol (COP-MOP). In 2008, COP-MOP 4 established a dedicated *Ad Hoc Technical Experts Group (AHTEG) on Risk Assessment and Risk Management*,[92] which is

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87 *Ibid.*
88 See chapter 3, section B.VI.1.
89 See chapter 3, section A.II.1.c).
90 See *ibid.*
91 See chapter 4, section D.II.
92 Note that the AHTEG on Risk Assessment discussed here should not be confused with the AHTEG on Synthetic Biology discussed in *supra* section A.

composed of experts nominated by the parties.[93] The AHTEG developed a guidance document on risk assessment and monitoring of LMOs (aa)). Recently, it considered the need for additional guidance on risk assessments of LMOs containing engineered gene drives (bb)).

aa) Guidance on Risk Assessment and Monitoring of LMOs

By request of the parties to the Cartagena Protocol, the AHTEG on Risk Assessment developed a 'Guidance' on the risk assessment and monitoring of LMOs, which was completed in 2016.[94] The Guidance consists of three parts. The first part contains a general 'roadmap' for assessing the risks of LMOs, which elaborates, *inter alia*, individual steps of the assessment process set out in Annex III to the Cartagena Protocol.[95] The second part contains guidelines for assessing the risks of specific types of LMOs, including a chapter on living modified (LM) mosquitoes that act as disease vectors.[96] The third part contains guidelines for monitoring LMOs once released into the environment.[97]

The chapter on risk assessment of LM mosquitoes addresses various approaches of using biotechnology to reduce the transmission of vector-borne human pathogens.[98] It begins by introducing different techniques, including population suppression and population replacement strategies, such as engineered gene drives.[99] Subsequently, the chapter discusses a range of potential problems and concerns, including potential unintended effects of LM mosquitoes on biodiversity, vertical and horizontal gene transfer, and evolutionary responses in target species or pathogens.[100] With regard to unintentional transboundary movements, the chapter notes that mosquitoes have a very broad geographical distribution, and describes the risk of dispersal due to anthropogenic activities, such as transport and

93 CP COP-MOP, Decision BS-IV/11. Risk Assessment and Risk Management, UN Doc. UNEP/CBD/BS/COP-MOP/4/18, p. 80 (2008), para. 4.
94 AHTEG on Risk Assessment, Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment, UN Doc. UNEP/CBD/BS/COP-MOP/8/8/Add.1, Annex (2016).
95 *Ibid.*, 8–51.
96 *Ibid.*, 52–94.
97 *Ibid.*, 95–112.
98 *Ibid.*, 80–94.
99 *Ibid.*, 80–83; see chapter 1, section C.III.1.
100 *Ibid.*, 84–90.

trade of potential breeding sites.[101] Finally, the chapter discusses potential risk management and containment strategies.[102]

The value of the Guidance has been controversial, particularly regarding the 'roadmap' contained in the first chapter.[103] Criticism was also voiced about the composition of the AHTEG, which allegedly lacked experts with actual experience in conducting risk assessments of LMOs.[104] Moreover, the process was criticised for attempting to merge irreconcilable points of view, including on many non-technical issues, which allegedly resulted in political negotiations on the contents of a technical document.[105]

Consequently, the roadmap was criticized for not reflecting the process usually followed during risk assessments, therefore being neither practical nor useful.[106] Yet, in a survey on the utility of the Guidance, many governments with little or no experience in conducting risk assessments of LMOs stated that they actually found the roadmap to be useful and practical as well as consistent with the Cartagena Protocol.[107] Governments with more experience in conducting risk assessments were more hesitant to agree with these conclusions.[108] This could be explained by the quality of the Guidance, but also by the fact that these governments simply saw no need for further advice on their already-established procedures.

In a decision adopted by COP-MOP 8 in 2016, the parties to the Cartagena Protocol 'took note' of the Guidance.[109] They described it as a 'voluntary tool' while acknowledging that other guidance documents and national approaches could also assist in conducting risk assessments in accordance with the Protocol.[110] Notably, the decision did neither 'welcome'

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101 *Ibid.*, 91; see *Marshall* (n. 3), 896.

102 AHTEG on Risk Assessment, Guidance on Risk Assessment and Monitoring of LMOs (n. 94), 91–94.

103 See *Helmut Gaugitsch*, Under the Cartagena Protocol on Biosafety – Where Is the Roadmap for Risk Assessment Taking Us?, 3 (2015) Front. Bioeng. & Biotechnol. 212, 2; *Karen E. Hokanson*, When Policy Meets Practice: The Dilemma for Guidance on Risk Assessment Under the Cartagena Protocol on Biosafety, 7 (2019) Front. Bioeng. & Biotechnol. 82, 2.

104 *Hokanson* (n. 103), 5; also see *Keiper/Atanassova* (n. 10), 18.

105 *Hokanson* (n. 103), 10.

106 *Ibid.*, 16.

107 *Ibid.*, 11–15; cf. CBD Secretariat, Analysis of the Results of the Testing of the "Guidance on Risk Assessment of Living Modified Organisms", UN Doc. UNEP/CBD/BS/COP-MOP/7/INF/3 (2014).

108 Cf. *Hokanson* (n. 103), 11–15.

109 CP COP-MOP, Decision VIII/12. Risk Assessment and Risk Management, UN Doc. CBD/CP/MOP/DEC/VIII/12 (2016), para. 2.

110 *Ibid.*, para. 3.

nor ‘endorse’ the Guidance, which are terms commonly used in COP decisions approving reports.[111] Consequently, in light of the aforementioned criteria,[112] the Guidance is neither legally binding nor constitutes quasi-normative ‘soft law’. It is even doubtful whether the document provides a real added value to states seeking to improve their risk assessment procedures. A better approach would be to encourage bilateral partnerships where experienced governments assist others in need of support.[113]

bb) Additional Guidance on Risk Assessment of Engineered Gene Drives

In 2015, even before concluding its work on the general guidance document, the AHTEG recommended developing additional guidance on the risk assessment of LMOs developed through synthetic biology.[114] An outline of potential issues to be covered by such a document notes that gene drives could pose serious threats to human health and ecosystems.[115] It argues that existing risk assessment methodologies may need to be adapted to fully reflect these potential adverse effects.[116]

At COP-MOP 9 in 2018, parties had diverging views about the need to develop additional guidance on specific questions of risk assessment, including gene drives.[117] As a compromise, it was decided to launch a process to identify and prioritise specific issues on which further guidance should be developed.[118] The CBD Secretariat[119] was requested to commis-

111 Cf. University of Joensuu et al. (n. 52), p. 3–71; see CBD COP, Decision 14/19 (n. 25), para. 1, which ‘welcomes’ the outcomes of the AHTEG on Synthetic Biology.

112 See *supra* section B.II.

113 *Hokanson* (n. 103), 17.

114 AHTEG on Risk Assessment, Report of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management, Brasilia, 16–20 November 2015, UN Doc. UNEP/CBD/BS/RARM/AHTEG/2015/1/4 (2015), para. 37.

115 AHTEG on Risk Assessment, Outline of Guidance on Risk Assessment of Living Modified Organisms Developed Through Synthetic Biology, UN Doc. UNEP/CBD/BS/COP-MOP/8/8/Add.3, Annex (2016), 4.

116 *Ibid.*

117 Cf. CP COP-MOP, Decision 9/13. Risk Assessment and Risk Management (Articles 15 and 16), UN Doc. CBD/CP/MOP/DEC/9/13 (2018), para. 2.

118 *Ibid.*, para. 6.

119 According to Article 31(1) of the Cartagena Protocol, the Secretariat established by Article 24 CBD shall also serve as the secretariat to the Protocol.

sion a study informing this process,[120] which was subsequently prepared by a private contractor.[121]

The study noted that various aspects essentially distinguish engineered gene drive-bearing organisms from other LMOs.[122] It held that these differences involve methodological challenges that will likely render the risk assessment of such organisms more detailed and more complex than assessments of conventional LMOs.[123] Traditional risk assessment techniques, such as 'stepwise' releases, could not be applied since the smallest scale introduction of an LMO with a low-threshold gene drive could result in a spread and thus permanently impact the environment.[124] The study also noted the potential of cross-border dissemination. While this was assumed to be a characteristic of the host organism rather than the gene drive technique itself, the fact that most applications currently under development target non-domesticated species meant that there would be little to no possibility of preventing transboundary movements.[125]

Based on the study, the AHTEG concluded in April 2020 that additional guidance for the risk assessment of LMOs containing engineered gene drives should be developed.[126] This was endorsed in March 2022 by the Subsidiary Body on Scientific, Technical and Technological Advice,[127] which unlike the AHTEGs is a standing body under the CBD.[128] The draft COP decision envisages renewing the mandate of the AHTEG on Risk Assessment and asking it to develop 'additional voluntary guidance materials for conducting case-by-case risk assessments of living modified organisms containing engineered gene drives in accordance with annex III of the [Cartagena] Protocol', with a special focus to be placed on

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120 CP COP-MOP Decision 9/13 (2018) (n. 117), para. 11.

121 *Greet Smets/Patrick Rüdelsheim*, Study on Risk Assessment: Application of Annex I of Decision CP 9/13 to Living Modified Organisms Containing Engineered Gene Drives, UN Doc. CBD/CP/RA/AHTEG/2020/1/4, Annex (2020).

122 *Ibid.*, 31.

123 *Ibid.*, 31–32.

124 *Ibid.*, 32; also see *Keiper/Atanassova* (n. 10), 15.

125 *Smets/Rüdelsheim* (n. 121), 33.

126 AHTEG on Risk Assessment, Report of the Ad Hoc Technical Expert Group on Risk Assessment, UN Doc. CBD/CP/RA/AHTEG/2020/1/5 (2020), Annex I, para. 42.

127 CBD SBSTTA, Recommendation 24/5. Risk Assessment and Risk Management, UN Doc. CBD/SBSTTA/REC/24/5 (2022), para. 5.

128 Cf. Article 25 CBD.

engineered gene drive mosquitoes and existing national and regional risk management experiences.[129]

It appears likely that the COP will follow this recommendation at its next face-to-face meeting.[130] However, the experience of developing the 'general' guidance document on risk assessment discussed above shows that the usual format and composition of the AHTEGs may hinder a clear separation between scientific advice and political negotiations. Parties should keep in mind the mandate of the Cartagena Protocol, which is primarily to regulate transboundary movements of LMOs. The potential of engineered gene drives to spread across borders is undisputed.[131] Therefore, any additional guidance should focus on how this potential can be adequately considered in pre-release risk assessments.

c) Assessment

Insofar as decision 14/19 makes releases of engineered gene drive contingent upon scientifically sound risk assessments, it only restates an obligation firmly anchored in international environmental law. However, as shown above,[132] the scope and methodologies of such assessments are much less regulated. Therefore, the efforts of the AHTEG on risk assessment to develop further guidance on how to conduct risk assessments of LMOs are laudable. At the same time, it seems that this standard-setting effort is welcomed only half-heartedly by those states that already have well-established procedures for assessing the risks of biotechnology products. Future work on risk assessment of gene drives should, therefore, focus on the challenges to which all frameworks must be adapted, especially potential transboundary spreads.

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129 CBD SBSTTA (n. 127), Annex, para. 1(d).

130 CBD COP 15 was was originally scheduled to take place in October 2020 in Kunming, China, but its face-to-face segment was postponed several times due to the COVID-19 pandemic. As of May 2022, the conference is scheduled for the third quarter of 2022; see CBD Secretariat, Calendar of SCBD Meetings (25 May 2022), available at: https://www.cbd.int/meetings/ (last accessed 28 May 2022).

131 See *infra* section D.

132 See chapter 4, section D.II.

2. Appropriate Risk Management Measures

The second condition for releases of organisms containing engineered gene drives set out in COP decision 14/19 is that 'appropriate risk management measures are in place to avoid or minimise potential adverse effects, as appropriate'.[133]

Again, this restates an already-existing obligation of states under international law (a)). A number of risk management strategies for gene drives have already been proposed, which could be relevant because states must use the 'best available techniques' to prevent damage (b)).

a) Status of the Obligation Under International Law

Like the obligation to carry out risk assessments, the obligation to apply appropriate risk management measures is already established in international law. Article 8(g) CBD provides that states must regulate, manage or control the risks associated with the release of LMOs.[134] Article 16 of the Cartagena Protocol further specifies this obligation by providing, *inter alia*, that states shall prevent unintentional transboundary movements.[135] In customary international law, risk management is inherent in the general obligation to act with due diligence to prevent transboundary harm. This entails a duty to use the 'best available technologies' to prevent such damage.[136]

b) Proposed Risk Management Strategies for Gene Drives as 'Best Available Techniques'?

The risk management measures required in a particular case will largely depend on the result of the risk assessment in that case. However, a number of general risk management strategies for gene drives have already been proposed, which could arguably contribute to an emerging 'best available technology' (BAT) standard. These include a 'stepwise' approach

133 CBD COP, Decision 14/19 (n. 25), para. 11(b).
134 See chapter 3, section B.III.
135 See chapter 3, section A.II.2.a)cc).
136 See chapter 4, section D.III.

to the deployment of gene drives (aa)) and the use of self-limiting gene drives (bb)).

aa) Phased Pathway to the Deployment of Gene Drives

Several authors and governmental as well as non-governmental organizations have proposed a 'phased pathway' or 'stepwise approach' to releasing engineered gene drives into the environment. According to these concepts, a gene drive would first be tested in cage trials and confined releases before being deployed on a larger scale.[137] It has been argued that the generation of release-relevant data requires a gradual reduction of the containment in order to expose the gene drive to increasingly realistic conditions.[138] The experience and data gained during the preceding steps would be used as a basis for risk assessment of the following, less confined step.[139] Moreover, the development of approaches that fail to fulfil pre-defined criteria on efficacy and safety could be terminated.[140]

These proposals have, however, faced strong opposition. The main contention against 'phased' testing pathways is that even confined releases could be irreversible and lead to an uncontrolled spread of the gene drives, especially when low-threshold, invasive drive systems are released.[141] Consequently, it has been argued that 'semi-field testing' in outdoor cages or under environmental confinement should not be considered as contained use but as an environmental release.[142]

The stepwise approach was also controversial within the AHTEG on Synthetic Biology. While some experts noted that a stepwise approach could be appropriate to gather the information needed to fill knowledge gaps, others warned that any environmental release could be irre-

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137 NASEM, Gene Drives on the Horizon (2016), 86–111; *James* et al. (n. 2), 22–25; *Keith R. Hayes* et al., Identifying and Detecting Potentially Adverse Ecological Outcomes Associated with the Release of Gene-Drive Modified Organisms, 5 (2018) Journal of Responsible Innovation S139-S158; WHO-TDR/FNIH, Guidance Framework for Testing of Genetically Modified Mosquitoes (2nd ed. 2021), 13–17.

138 *Hayes* et al. (n. 137), S141.

139 *Smets/Rüdelsheim* (n. 121), 25.

140 *Hayes* et al. (n. 137), S141.

141 *Samson Simon* et al., Synthetic Gene Drive: Between Continuity and Novelty (2018) EMBO Reports e45760, 2–3; *Li C. Lim/Li L. Lim*, Gene Drives: Legal and Regulatory Issues (2019), 109–110; *Keiper/Atanassova* (n. 10), 15.

142 *Esvelt/Gemmell* (n. 3), 4; *Lim/Lim* (n. 141), 74.

versible.[143] Hence, strategies involving stepwise or phased releases currently do not constitute an internationally accepted standard.[144] At the same time, it seems that even opponents of the technique would agree that large-scale deployments should at least be preceded by confined trials and small-scale releases. Consequently, if gene drives were to be released into the environment, strategies of phased or stepwise releases should be seen as part of the best technologies currently available.

bb) Self-Limiting Gene Drives

It has been warned that developing a standard, self-propagating gene drive system could become highly invasive and cause severe ecological damage.[145] To mitigate this risk, scientists have proposed to develop drive systems that only have a limited capacity to spread.[146]

One approach is so-called 'daisy-chain' gene drives, which successively lose their capacity to spread and therefore stop after a certain number of generations.[147] A similar proposal uses non-invasive or high-threshold gene drives that do not become permanently established in the target population but require repeated subsequent releases of drive-bearing individuals.[148] Another approach is to develop 'prevision drives', which refers to drive systems programmed for specific genetic sequences that are unique to the target population but do not occur in other populations of the same species elsewhere in the world.[149]

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143 AHTEG on Synthetic Biology, Report of the Ad Hoc Technical Expert Group on Synthetic Biology: Montreal, Canada, 5–8 December 2017, UN Doc. CBD/SYNBIO/AHTEG/2017/1/3 (2017), para. 45.

144 See CP COP-MOP, Decision 9/12. Transit and Contained Use of Living Modified Organisms (Article 6), UN Doc. CBD/CP/MOP/DEC/9/12 (2018), para. 2(c), reminding parties that confined field trial were to be regarded as intentional introduction into the environment when the criteria for contained use under Article 3(b) were not met.

145 *Esvelt/Gemmell* (n. 3), 2; *Charleston Noble* et al., Current CRISPR Gene Drive Systems Are Likely to Be Highly Invasive in Wild Populations, 7 (2018) eLife e33423.

146 Cf. *James* et al. (n. 2), 5–6.

147 Cf. *Charleston Noble* et al., Daisy-Chain Gene Drives for the Alteration of Local Populations, 116 (2019) PNAS 8275.

148 Cf. *John Min* et al., Harnessing Gene Drive, 5 (2018) Journal of Responsible Innovation S40, S41.

149 Cf. *ibid.*, S48.

Critics of gene drive techniques argue that these confinement strategies still lack proof of concept and thus are not viable solutions to mitigate the risk of an uncontrolled spread.[150] Nevertheless, the obligation to use the best available technologies will require states to consider these strategies as alternatives to highly invasive, low-threshold drive systems. Deploying the latter when less hazardous alternatives are available would violate the obligation to act with due diligence. At the same time, the effectiveness of confinement strategies must still be established in risk assessment and, potentially, in phased testing.

c) Assessment

As a corollary to risk assessment, the obligation of states to employ appropriate risk management measures is also well-established in international law. However, since the required measures depend on the risks identified in the assessment, the content of this obligation is more difficult to define. This is also because there is no practical experience with releasing gene drives into the environment. However, if such releases were envisaged, proposals by researchers to limit the potential risks by stepwise testing and using self-limiting techniques should not be disregarded. They arguably constitute the 'best available technologies' that states are bound to use should they decide to move forward with environmental releases.

3. Free, Prior and Informed Consent

According to decision 14/19, the third prerequisite for releases of engineered gene drives is that

> *'[w]here appropriate, the "prior and informed consent", the "free, prior and informed consent" or "approval and involvement" of potentially affected indigenous peoples and local communities is sought or obtained, where applicable in accordance with national circumstances and legislation'.*[151]

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150 Cf. *Simon* et al. (n. 141), 3; *Lim/Lim* (n. 141), 3; see *Sumit Dhole* et al., Invasion and Migration of Spatially Self-Limiting Gene Drives, 11 (2018) Evolutionary Applications 794.

151 CBD COP, Decision 14/19 (n. 25), para. 11(c).

This provision refers to the consent of potentially affected *indigenous peoples and local communities* (a)). Besides, consent could also be required from potentially affected *individuals* (b)).

a) Status of the Obligation Under International Law

Neither the CBD nor the Cartagena Protocol expressly provides that states shall obtain the consent of indigenous peoples and local communities before releasing LMOs into the environment. However, a set of guidelines previously adopted by the CBD COP could potentially be applied to the present issues (aa)). An obligation to obtain the prior consent of indigenous peoples could also be derived from general human rights law (bb)).

aa) CBD Mo'otz Kuxtal Voluntary Guidelines

A footnote in COP decision 14/19 refers to the *Mo'otz Kuxtal Voluntary Guidelines* adopted by COP 13.[152] This soft law instrument establishes principles for obtaining the free, prior and informed consent (FPIC) of indigenous peoples and local communities when accessing their traditional knowledge. It serves the implementation of Article 8(j) CBD, which requires obtaining 'the approval and involvement of the holders of such knowledge' when promoting its wider application.

According to the Mo'otz Kuxtal Guidelines, *consent* or *approval* is understood as the agreement of the indigenous peoples and local communities concerned or their respective competent authorities, which presupposes that such consent may also be denied.[153] *Free* implies that the approval is obtained without coercing or unduly influencing the group concerned.[154] *Prior* means that the consent is obtained sufficiently in advance of any authorization and respecting the customary decision-making processes and time requirements of the indigenous peoples and local communities in

152 Cf. CBD COP, Decision XIII/18. Article 8(J) and Related Provisions: Mo'otz Kuxtal Voluntary Guidelines, UN Doc. CBD/COP/DEC/XIII/18 (2016). The Voluntary Guidelines as well as decision 14/19 refer to three different concepts, namely 'prior and informed consent', 'free, prior and informed consent' and 'approval and consent', which shall apply 'depending on national circumstances', although none of the instruments seem distinguish between them.

153 Cf. *ibid.*, para. 7(d).

154 Cf. *ibid.*, para. 7(a).

question.[155] Finally, *informed* consent presupposes that information is provided that covers all relevant aspects, including potential risks.[156]

By their terms, neither Article 8(j) nor the Mo'otz Kuxtal Guidelines apply to releases of LMOs in general or engineered gene drives in particular. However, the section on 'procedural considerations', which discusses the modalities of how FPIC should be obtained when it is required,[157] could also be applied to other areas. Consequently, the fact that the Guidelines are cited by decision 14/19 suggests that the parties to the CBD intended to endorse their application to releases of engineered gene drives.[158]

bb) United Nations Declaration on the Rights of Indigenous Peoples

An obligation to seek the consent of indigenous peoples could also be derived from general international law. An important role in this context is played by the *United Nations Declaration on the Rights of Indigenous Peoples* adopted by the UN General Assembly in 2007.[159] Although not legally binding in a formal sense, the Declaration is an important soft law document that has already been relied upon by several treaty bodies when interpreting pre-existing human rights treaties.[160]

The Declaration provides that states shall obtain the free and informed consent of indigenous peoples before relocating them from their lands or territories,[161] or before adopting legislative or administrative measures that may affect them.[162] Although the principle of FPIC originally concerned land use interventions,[163] it appears justifiable to also apply it to technological interventions such as engineered gene drives, at least where indigenous

155 Cf. *ibid.*, para. 7(b).
156 Cf. *ibid.*, para. 7(c).
157 *Ibid.*, paras. 17–21.
158 Cf. *Lim/Lim* (n. 141), 20.
159 UNGA, United Nations Declaration on the Rights of Indigenous Peoples, UN Doc. A/RES/61/295, Annex (2007). While only 144 states initially voted in favour of the Declaration, all states that had voted against it (Australia, Canada, New Zealand, and the United States, all having large indigenous populations) and some that had abstained endorsed it later, see *Benedict Kingsbury*, Indigenous Peoples, in: Wolfrum/Peters (ed.), MPEPIL, MN. 9.
160 See *ibid.*, MN. 15, with further references.
161 UN Declaration on the Rights of Indigenous Peoples (n. 159), Article 10.
162 *Ibid.*, Article 19.
163 Also cf. *ibid.*, Articles 28(1), 29(2), 32(2).

peoples are affected in their particular lifestyles or relationship with their environment.[164]

cc) Assessment

Although the concept of FPIC is widely recognized, it is still fraught with uncertainties and controversies, especially about the situations in which it applies and the modalities of how consent shall be obtained.[165] Consequently, the implementation and effectiveness of this right still largely depend on pertinent domestic laws.[166] This is also reflected in decision 14/19, which limits the application of FPIC to situations 'where appropriate' and 'where applicable in accordance with national circumstances and legislation'.[167]

Nevertheless, there appears to be broad support in favour of a requirement to obtain the FPIC of indigenous peoples and local communities potentially affected by releases of engineered gene drives.[168] The UN Declaration on the Rights of Indigenous Peoples makes clear that the particular lifestyles of indigenous peoples shall be protected as a human right.[169] If their lifestyles are likely to be affected by an engineered gene drive, their FPIC should be obtained prior to authorizing its release. But even beyond the scope of 'indigenous peoples and local communities',[170] the consent

164 *Dalton R. George* et al., Articulating 'Free, Prior and Informed Consent' (FPIC) For Engineered Gene Drives, 286 (2019) Proc. R. Soc. B 20191484; also see *Kofler* et al. (n. 8).

165 *George* et al. (n. 164), 3; see *David Szablowski*, Operationalizing Free, Prior, and Informed Consent in the Extractive Industry Sector? Examining the Challenges of a Negotiated Model of Justice, 30 (2010) Canadian Journal of Development Studies 111.

166 See *Szablowski* (n. 165).

167 CBD COP, Decision 14/19 (n. 25), para. 11(c).

168 Cf. Report of the AHTEG on Synthetic Biology 2017 (n. 143), para. 25; *Kofler* et al. (n. 8); AHTEG on Synthetic Biology, Report of the Ad Hoc Technical Expert Group on Synthetic Biology: Montreal, Canada, 4–7 June 2019, UN Doc. CBD/SYNBIO/AHTEG/2019/1/3 (2019), Annex, para. 1; *George* et al. (n. 164).

169 UN Declaration on the Rights of Indigenous Peoples (n. 159), Article 5.

170 Note that Article 8(j) CBD refers 'indigenous and local communities embodying traditional lifestyles'. On request by the UN Permanent Forum on Indigenous Issues, the COP decided in 2014 to instead refer to 'indigenous peoples and local communities' in the future, see CBD COP, Decision XII/12 F. Terminology "Indigenous Peoples and Local Communities", UN Doc. UNEP/CBD/COP/DEC/XII/12 (2014), paras. 1–2. This shows that in the present

of potentially affected populations should become a standard precondition for any gene drive release.[171]

b) Excursus: Consent of Individuals as a Human Rights Requirement?

The aforementioned requirement to obtain 'free, prior and informed consent' refers to the consent of entire communities rather than potentially affected individuals.[172] Thus, the concept must be distinguished from the 'informed consent' commonly required from individuals participating in medical trials.[173] The latter is derived from Article 7 of the *International Covenant on Civil and Political Rights*,[174] which provides that

> *'no one shall be subjected without his free consent to medical or scientific experimentation'.*

In the context of engineered gene drives in mosquitoes, there appears to be a scientific consensus that the drive components should be assessed for their toxicity and allergenicity potential.[175] It also seems undisputed that potential alterations in the disease transmission of modified mosquitoes should be considered.[176] However, it is controversial whether this entails a requirement to obtain the consent of all potentially affected individuals.

According to one view, '[t]here are, strictly speaking, no human subjects of field trials' and, consequently, regulations requiring the informed consent of every participant do not apply.[177] According to a more differentiat-

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context, 'local communities' means such that embody traditional lifestyles in the sense of Article 8(j) CBD.

171 Cf. *Silja Vöneky*, International Standard Setting in Biomedicine – Foundations and New Challenges, 61 (2019) German YBIL 131, 141; see *Joanna Buchthal* et al., Mice Against Ticks: An Experimental Community-Guided Effort to Prevent Tick-Borne Disease by Altering the Shared Environment, 374 (2019) Philos. Trans. R. Soc. B 20180105.

172 *George* et al. (n. 164), 3–4.

173 See *Onora O'Neill*, Informed Consent and Public Health, 359 (2004) Philos. Trans. R. Soc. B 1133.

174 International Covenant on Civil and Political Rights (16 December 1966; effective 23 March 1976), 999 UNTS 171.

175 *Andrew Roberts* et al., Results from the Workshop "Problem Formulation for the Use of Gene Drive in Mosquitoes", 96 (2017) Am. J. Trop. Med. Hyg. 530, 531.

176 *Ibid.*

177 *Carolyn P. Neuhaus/Arthur L. Caplan*, Ethical Lessons from a Tale of Two Genetically Modified Insects, 35 (2017) Nature Biotech. 713, 716.

ed view, informed consent must be obtained from individuals when blood or other clinical data are collected from them, when they participate in behavioural or social science research involving the completion of surveys or questionnaires, or when their home or property is accessed or the location recorded as a spatial variable for the release or collection of organisms.[178]

If Article 7 ICCPR was held to be applicable, the free consent of every potentially affected individual would be required. This seems impossible to achieve, especially considering that many mosquito species have a wide geographical range. To solve this impasse, it has been proposed to apply 'opt-out' models of consent to large-scale field trials.[179] However, this approach is questionable because there is no real possibility for individual residents to opt out from the potential effects of a gene drive on their environment or even health.[180]

According to another proposal, individual consent should be replaced by a form of community consent given by a representative of the potentially affected population. This could especially be applied to experiments that may affect individuals but do not constitute medical research *strico sensu*.[181] In effect, this would extend the FPIC requirement for indigenous peoples[182] beyond this specific target group to all potentially affected communities. In any case, the validity of such community consent should be contingent upon a scientifically sound risk assessment and a transparent consultation process.[183]

This appears to be in line with the – soft law – *Universal Declaration on Bioethics and Human Rights* adopted in 2005 by the General Conference of

178 *Pamela A. Kolopack/James V. Lavery*, Informed Consent in Field Trials of Gene-Drive Mosquitoes, 1 (2017) Gates Open Research 14, 4; WHO-TDR/FNIH, Guidance Framework for Testing GM Mosquitoes (n. 137), 94; see *Andrew D. McRae* et al., Who Is the Research Subject in Cluster Randomized Trials in Health Research?, 12 (2011) Trials 183.

179 Cf. *James* et al. (n. 2), 32.

180 Cf. *O'Neill* (n. 173).

181 *Vöneky* (n. 171), 141; *Delphine Thizy* et al., Providing a Policy Framework for Responsible Gene Drive Research: An Analysis of the Existing Governance Landscape and Priority Areas for Further Research, 5 (2020) Wellcome Open Research 173, 5; WHO-TDR/FNIH, Guidance Framework for Testing GM Mosquitoes (n. 137), 94.

182 See *supra* n. 170 and accompanying text.

183 *Vöneky* (n. 171), 141.

the UN Educational, Scientific and Cultural Organization (UNESCO).[184] It provides that, in principle, scientific research should only be carried out with the FPIC of the person concerned, but that exceptions may be made in accordance with ethical and legal standards adopted by states.[185] Moreover, the Declaration provides that in appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought.[186] However, it also makes clear that such a collective agreement should in no case substitute an informed consent of an individual where required.[187]

Whether the consent of individuals is required primarily involves scientific questions. When a modified mosquito exhibits no tangible changes in biting patterns, disease transmission, and the salvia transferred to the host during the bite, it makes no difference for individuals whether they are bitten by a drive-bearing mosquito or a wild type. However, when there are such changes, it seems difficult to argue that a human bit by such a mosquito is not subjected to (medical or) scientific experimentation[188] in the sense of Article 7 ICCPR. At least when such experiments may be detrimental to their health, the free consent of all potentially affected persons must be obtained.[189] Community consent can only complement but not substitute the individual consent that may, depending on the circumstances, be required under Article 7 ICCPR.[190] This is even more true when modified insects are used to disperse vaccines.[191]

184 UNESCO General Conference, Universal Declaration on Bioethics and Human Rights (19 October 2005), Records of the General Conference, 33rd session, Vol. 1: Resolutions, p. 74.
185 *Ibid.*, Article 6(2).
186 *Ibid.*, Article 6(3).
187 *Ibid.*
188 The Human Rights Committee did not consider it necessary to draw up a list of prohibited acts or to establish sharp distinctions between the different treatments prohibited by Article 7 ICCPR, cf. Human Rights Committee, CCPR General Comment No. 20 (Article 7), UN Doc. HRI/GEN/1/Rev.1, p. 30 (1992), para. 4.
189 Cf. *ibid.*, para. 7.
190 Also see *ibid.*, pointing out that Article 7 ICCPR requires the 'free consent *of the person concerned*' (emphasis added).
191 *Vöneky* (n. 171), fn. 38 on p. 140; see *D. S. Yamamoto* et al., Flying Vaccinator; a Transgenic Mosquito Delivers a Leishmania Vaccine via Blood Feeding, 19 (2010) Insect Molecular Biology 391.

4. Conclusions

The three criteria for environmental releases of engineered gene drives set out in CBD COP decision 14/19 seem to be ordered by decreasing clarity. First, the obligation to carry out risk assessments is well established in international law.[192] Despite remaining national differences, whether an assessment is 'scientifically sound' can be determined through peer review.[193]

Second, the obligation to apply risk management measures is derived from the obligation of states to act with due diligence and to employ the best available technologies. While there are specific proposals to reduce the risks inherent in gene drive techniques, the measures actually required will largely depend on the result of the risk assessment and can, therefore, not be defined abstractly.[194]

Third, the requirement to obtain the FPIC of affected indigenous peoples and local communities is the least concise of the conditions. It is clearly made subject to 'national circumstances and legislation',[195] which gives states many grounds for not applying the requirement. The consent of individuals, which may be required under international human rights law, is not addressed by the decision. Probably it will be upon human rights jurisprudence to determine whether the FPIC requirement applies to engineered gene drives under human rights law.

After the decision was adopted, views diverged on whether these criteria resulted in a *de facto* moratorium or rather showed a clear path toward responsible releases.[196] In any event, it should be noted that the fulfilment of these criteria does not automatically make releases permissible. Decision 14/19 calls upon states 'to only consider' releases when the criteria are met. This clearly indicates that they are meant as preconditions and that releases should not even be considered as long as they are not met. Moreover, other

192 See *supra* section C.II.1.
193 See *R. Guy Reeves* et al., Scientific Standards and the Regulation of Genetically Modified Insects, 6 (2012) PLOS Neglected Tropical Diseases e1502.
194 See *supra* section C.II.2.
195 CBD COP, Decision 14/19 (n. 25), para. 11(c).
196 See *Ewen Callaway*, UN Treaty Agrees to Limit Gene Drives but Rejects a Moratorium, Nature News, 29 November 2018, available at: https://www.nature.com/articles/d41586-018-07600-w (last accessed 28 May 2022).

rules of international law must also be observed,[197] including with regard to potential transboundary spreads.[198]

III. Safety of Synthetic Biology in Contained Use

As far as is known, no engineered gene drive has so far been released into the environment. Instead, research is currently carried out in containment, particularly in laboratories and insect cages.[199] However, due to the inherent properties of gene drives, any accidental release could have unpredictable ecological consequences.[200]

Against this background, decision 14/19 addresses the prevention of harm from 'organisms, components and products of synthetic biology in contained use', which, in CBD COP parlance, includes engineered gene drives.[201] The decision calls upon parties, other governments[202] and relevant organizations to develop or implement

> *'measures to prevent or minimize potential adverse effects arising from exposing the environment to organisms, components and products of synthetic biology in contained use, including measures for detection, identification and monitoring, in accordance with domestic circumstances or internationally agreed guidelines, as appropriate, with special consideration to the centres of origin and genetic diversity'.*[203]

There are no binding international rules on the contained use of LMOs (1.). The notion 'internationally agreed guidelines' apparently refers to a non-binding manual on laboratory biosafety developed by the World Health Organization (2.). A coherent framework is also missing in the European Union, and some of its member states have begun to adopt uni-

197 See chapter 3.

198 Also see *infra* section D.

199 See chapter 1, section C.III.1.c). For a systematic overview of the research currently performed, see *Smets/Rüdelsheim* (n. 121), 19–20; *Ethan Bier*, Gene Drives Gaining Speed, 23 (2022) Nature Rev. Genet. 5.

200 *Omar S. Akbari* et al., Safeguarding Gene Drive Experiments in the Laboratory, 349 (2015) Science 927.

201 Gene drives are considered to be one particular application of synthetic biology since CBD COP, Decision XIII/17 (2016) (n. 12), para. 2.

202 See *supra* section B.IV.

203 CBD COP, Decision 14/19 (n. 25), para. 12.

lateral approaches (3.). Besides, scientists have made proposals to improve the safety of laboratory research on gene drives (4.).

1. No Binding International Rules on LMOs in Contained Use

The CBD does not expressly address LMOs in contained use. In this respect, only the general obligation to control the risks associated with LMOs applies.[204] The Cartagena Protocol applies to contained use since it covers all handling and use of LMOs.[205] According to its Article 3(b), 'contained use' is defined as

> *'any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact, and their impact on, the external environment.'*

Article 6(2) provides that LMOs destined for contained use are not subject to the *Advance Informed Agreement* mechanism under the Cartagena Protocol. In any case, the Cartagena Protocol does not contain any specific provisions regulating the contained use of LMOs.

Binding international rules on the contained use of LMOs or other hazardous biological materials are not laid down in other instruments either. Although there exist various international standards and guidelines on laboratory biosafety,[206] including the ISO Standard for Laboratory Biorisk Management,[207] the OIE Manual for Diagnostic Tests and Vaccines for Terrestic Animals,[208] and the WHO's Laboratory Biosafety Manual discussed below,[209] none of these documents create binding rules of international law.

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204 Cf. Article 8(g) CBD.

205 Article 4 Cartagena Protocol.

206 For a collection of relevant documents, see *Michael P. Owen*, Lab Rat's Web Portal for Laboratory Biorisk Management (04 January 2020), available at: https://www.seanet.com/~owenmp/biosafety/lab-biorisk-mgmt.html (last accessed 28 May 2022).

207 ISO, Biorisk Management for Laboratories and Other Related Organisations, ISO 35001:2019 (2019).

208 OIE, Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (8th ed. 2018), ch. 1.1.4.

209 See *infra* section C.III.2.

Consequently, there are currently no dedicated binding rules on risk assessment and minimal control measures applicable to LMOs in contained use.[210] This is particularly striking in the context of engineered gene drives and modified viruses, since even small releases could result in extensive dissemination.[211] An accidental laboratory release has also been discussed as a possible origin of the SARS-CoV-2 coronavirus that caused the COVID-19 pandemic in 2020.[212]

2. The WHO Laboratory Biosafety Manual

Decision 14/19 calls upon states to act 'in accordance with […] internationally agreed guidelines'. This appears to refer to the *Laboratory Biosafety Manual*, which was developed under the auspices of the World Health Organization (WHO).[213] Although not adopted by governments, the Manual is widely regarded as 'a de facto standard that represents best practices' for laboratory biosafety.[214]

Earlier editions of the Manual have introduced four different risk groups, ranging from organisms unlikely to cause harm to pathogens that cause serious disease and can be readily transmitted.[215] These risk groups corresponded to four biosafety levels (BSL), ranging from BSL-1 as the lowest to BSL-4 as the highest level.[216] Most domestic frameworks on the contained use of microorganisms or LMOs have adopted this sys-

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210 *Cécile J. B. van der Vlugt* et al., A Framework for the Risk Assessment and Management of Gene Drive Technology in Contained Use, 23 (2018) Appl. Biosaf. 25, 25.

211 *Marshall* (n. 3), 897; *Lim/Lim* (n. 141), 76; see Report of the AHTEG on Synthetic Biology 2017 (n. 143), para. 51(c).

212 Cf. *Kristian G. Andersen* et al., The Proximal Origin of SARS-CoV-2, 26 (2020) Nature Medicine 450; *Matt Field*, Experts Know the New Coronavirus Is Not a Bioweapon. They Disagree on Whether It Could Have Leaked from a Research Lab, Bulletin of the Atomic Scientists, 30 March 2020, available at: https://thebulletin.org/2020/03/experts-know-the-new-coronavirus-is-not-a-bioweapon-they-disagree-on-whether-it-could-have-leaked-from-a-research-lab/ (last accessed 28 May 2022); *Paul Rincon*, Coronavirus: Is There Any Evidence for Lab Release Theory?, BBC News, 01 May 2020, available at: https://www.bbc.com/news/science-environment-52318539 (last accessed 28 May 2022).

213 WHO, Laboratory Biosafety Manual (4th ed. 2020).

214 *Kazunobu Kojima* et al., Risk-Based Reboot for Global Lab Biosafety, 360 (2018) Science 260.

215 WHO, Laboratory Biosafety Manual (3rd ed. 2004), 1.

216 *Ibid.*, 2.

tem.[217] However, the requirements applicable for each level vary significantly under different national or regional biosafety regulations.[218] In addition, the classification of works varies significantly, as shown by the fact that basic research involving SARS-like coronaviruses was routinely carried out in medium-safety BSL-2 laboratories,[219] despite reports about such viruses escaping even from BSL-3 facilities and infecting laboratory workers.[220] It has also been argued that most regimes currently do not address the specific risks involved with the use of self-propagating biological agents such as gene drives.[221]

In the latest edition of the Manual published in 2020, the system of biosafety levels was waived in favour of a more differentiated approach.[222] The Manual now proposes to determine the actual risk of working with biological agents on a case-by-case basis.[223] Nevertheless, it still differentiates between 'core requirements',[224] 'heightened control measures'[225] and 'maximum control measures',[226] which shall be applied depending on the previously-established degree of risk.

Gene editing and gene drives are identified as 'emerging biological risks' in a chapter on laboratory biosecurity, which refers to the potential for

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217 See, e.g., Directive 2000/54/EC on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work (18 September 2000), OJ L 262, p. 21; Directive 2009/41/EC on the Contained Use of Genetically Modified Micro-Organisms (06 May 2009), OJ L 125, p. 75; U.S. Centers for Disease Control and Prevention, Biosafety in Microbiological and Biomedical Laboratories (6th ed. 2020); Government of Canada, Canadian Biosafety Standard: For Facilities Handling or Storing Human and Terrestrial Animal Pathogens and Toxins (2nd ed. 2015); Gentechnikgesetz (Genetic Engineering Act) (16 December 1993), last amended by Article 8 of the law of 27 September 2021 (Bundesgesetzblatt, Pt. I, p. 4530), Section 7(1).

218 *Barbara Johnson/Rocco Casagrande*, Comparison of International Guidance for Biosafety Regarding Work Conducted at Biosafety Level 3 (BSL-3) and Gain-of-Function (GOF) Experiments, 21 (2016) Appl. Biosaf. 128; *Rincon* (n. 212).

219 *Andersen* et al. (n. 212), 451–452.

220 Cf. *Poh L. Lim* et al., Laboratory-Acquired Severe Acute Respiratory Syndrome, 350 (2004) N. Engl. J. Med. 1740; see *Field* (n. 212).

221 Cf. *Jeantine E. Lunshof/Angela Birnbaum*, Adaptive Risk Management of Gene Drive Experiments, 22 (2017) Appl. Biosaf. 97, 99; *van der Vlugt* et al. (n. 210), 26–27.

222 WHO (n. 213), xvii.

223 *Ibid.*, 5–27.

224 *Ibid.*, 27–47.

225 *Ibid.*, 49–57.

226 *Ibid.*, 59–64.

deliberate misuses.[227] In this regard, the Manual recommends not to focus on any particular issue or technology, but rather to use a single framework to assess and manage risks regardless of the technology involved.[228] Consequently, the Manual does not specifically address gene drives or other types of LMOs.

In sum, the Manual's recognition as a 'de facto standard' mainly roots in its legacy of introducing the four biosafety levels with corresponding minimum requirements for laboratory hardware and the performance of works. However, its value for ensuring laboratory biosafety (and biosecurity) for engineered gene drives appears to be rather limited.

3. Excursus: Regulation of Gene Drives in Contained Use in the European Union

Uniform rules for the contained use of engineered gene drives are not only missing on the global level but also in the European Union.[229] While there is an EU-wide authorization system for the release of GMOs into the environment,[230] the EU Directive on contained use only applies to genetically modified microorganisms[231] and therefore does not cover gene drives in other organisms, such as in plants, arthropods, or mammals. Consequently, the responsibility for regulating the contained use of most gene drive techniques lies with the EU member states.[232]

In the absence of a coherent international framework, a number of EU member states have already begun to adopt unilateral approaches. For example, in the Netherlands, the *GMO Regulation* was amended in July

227 As opposed to biosafety, laboratory biosecurity refers to measures that are not aimed at preventing accidental escapes but rather the loss, theft, misuse, diversion or intentional release of biological agents, cf. *ibid.*, 83.

228 *Ibid.*, 88.

229 See *Marion Dolezel* et al., Beyond Limits – The Pitfalls of Global Gene Drives for Environmental Risk Assessment in the European Union, 15 (2020) BioRisk 1.

230 See Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms (12 March 2001), OJ L 106, p. 1; see chapter 3, section A.IV.

231 Directive 2009/41/EC on the Contained Use of Genetically Modified Micro-Organisms (n. 217), Article 1.

232 *Mitchell/Bartsch* (n. 8), 5.

2016.[233] It now provides that activities involving gene drives are classified in *containment category IV*, which is the strictest containment level.[234] Consequently, laboratory works with gene drives require prior authorization, which involves an assessment of the proposed activity and specification of the required containment level on a case-by-case basis.[235]

In Germany, the *Ordinance on Safety Levels and Measures for Genetic Engineering Works* was revised in August 2019.[236] The ordinance now provides that laboratory works aimed at producing genetic elements that promote their own dispersal in populations of sexually reproducing organisms[237] shall, in principle, be subject to biosafety level 3.[238] This means that, as in the Netherlands, these works require prior authorization by the competent authority.[239] During the authorization process, the competent authority may, based on the risk assessment to be submitted by the operator, also assign the works to a different biosafety level.[240]Moreover, the competent authority shall obtain an opinion on the specific safety measures required for the proposed works from the *Central Biosafety Committee* (ZKBS), an expert commission established under the German *Gene Technology Act*.[241] Notably, the revised ordinance overturns an earlier opinion by the ZKBS, which had concluded that the production and handling of gene drive

233 Cf. Dutch State Secretary for Infrastructure and the Environment, Regeling Genetisch Gemodificeerde Organismen Milieubeheer 2013 (GMO Regulation) (01 January 2018).

234 *C. van der Vlugt* et al., Risk Assessment Method for Activities Involving Organisms with a Gene Drive Under Contained Use, RIVM Letter report 2018–0090 (2018), 11–12.

235 *Ibid.*

236 Verordnung über die Sicherheitsstufen und Sicherheitsmaßnahmen bei gentechnischen Arbeiten in gentechnischen Anlagen (Ordinance on the security levels and safety measures for genetic engineering operations in genetic engineering facilities) (12 August 2019; effective 01 March 2021), Bundesgesetzblatt Pt. I, p. 1235 (hereinafter 'Genetic Engineering Safety Ordinance 2021').

237 It remains unclear whether this also applies to other self-propagating genetic elements that do not rely on the sexual reproduction of their host organism, such as genetically modified viruses.

238 Genetic Engineering Safety Ordinance 2021 (n. 236), Section 10(5) (for microorganisms) and Section 11(6) (for animals and plants).

239 Gentechnikgesetz (Genetic Engineering Act) (n. 217), Sections 8(1) and 9(3). According to Section 31, the *Länder* (the federated states in Germany) shall be responsible for designating the respective competent authorities responsible for implementing the Act.

240 Genetic Engineering Safety Ordinance 2021 (n. 236), Sections 10(5)(2) and 11(6)(2).

241 *Ibid.*, Sections 10(5)(3) and 11(6)(3).

systems should only be subject to biosafety level 2.[242] This level applies to works that merely involve a ‘low risk’ to human health or the environment and requires that the works must be notified to, but not authorized by, the competent authority.[243]

In 2018, members of the competent authorities in Belgium, Germany, the Netherlands and the United Kingdom proposed a framework for risk assessment and risk management of gene drive technology in contained use.[244] The paper identifies three risk classes of gene drives organisms, which depend on the likelihood of occurrence and the level of severity of potential adverse effects in case of an unintentional release.[245] The paper argues that these classes largely correspond to the biosafety levels identified in the WHO’s Laboratory Biosafety Manual, but should be complemented by additional control measures to take account of the particular risks involved with gene drives.[246]

The paper, as well as the aforementioned national regimes, demonstrate the low level of harmonization concerning biosafety for laboratory research on gene drives. Domestic regulators even disagree on whether such research should be subject to a general requirement of prior authorization or whether a case-by-case determination is sufficient. Moreover, although the system of biosafety levels is broadly recognized and applied, the lack of coherent standards for laboratory hardware and the performance of works under these levels show that it would be insufficient to simply agree on harmonized biosafety or risk levels for different types of gene drives.

4. Containment Standards for Gene Drives Formulated by Researchers

In the absence of international standards on contained use agreed by governments, guidelines developed by scientists may become more relevant in defining minimum requirements. In a paper published in 2015, leading researchers in the area of engineered gene drives recommended that laboratory studies of gene drives use a combination of multiple confine-

242 ZKBS, Position Statement of the ZKBS on the Classification of Genetic Engineering Operations for the Production and Use of Higher Organisms Using Recombinant Gene Drive Systems, Az. 45310.0111 (2016), 4.
243 Gentechnikgesetz (Genetic Engineering Act) (n. 217), Section 7(1), subpara. 2.
244 *Van der Vlugt* et al. (n. 210).
245 *Ibid.*, 29; see *supra* section C.III.2.
246 *Ibid.*, 29–30.

ment strategies.[247] Potential strategies identified by the authors include the molecular level (e.g. targeting synthetic DNA sequences not present in wild organisms), the ecological level (e.g. performing experiments in an area lacking wild populations), the reproductive level (i.e. using a laboratory strain that cannot reproduce with wild organisms), and physical barriers that should only be removed when the organisms are inactive.[248] Because these strategies operate independently from each other, the authors assume that using a combination could result in 'multiplicative' safety improvements.[249]

The paper is still widely regarded as describing the current state of knowledge and 'best practice' in preventing unintentional releases of engineered gene drives.[250] It could even be seen as a description of the 'best available technologies' in this context. As shown earlier, international law obliges states to ensure that the best available techniques are used to prevent damage,[251] and decision 14/19 even refers to 'internationally agreed guidelines'. Until states develop and adopt such guidelines themselves,[252] there appears to be a certain leeway for the scientific community to define by itself what the 'best available technologies' are.[253]

IV. Conclusions

Since it articulates a first set of concise principles on the use of engineered gene drives, decision 14/19 represents a leap forward in international standard-setting on this matter. At the same time, the decision does not create any new obligations, but rather clarifies the application of already-established rules of international law to gene drives. This is not only true for the precautionary approach, but also for the obligation to ensure that appropriate risk assessment and risk management measures are in place.

247 *Akbari* et al. (n. 200).
248 *Ibid.*, 927–928.
249 *Ibid.*, 928.
250 See, e.g., NASEM, Gene Drives on the Horizon (n. 137), 160; *Lunshof/Birnbaum* (n. 221), 100; *van der Vlugt* et al. (n. 210), 29; *Simon* et al. (n. 141), 1; *Noble* et al. (n. 147), 8276; *Warmbrod* et al. (n. 66), 33.
251 See chapter 4, section D.III.
252 See *supra* section C.II.1.b)bb).
253 Cf. NASEM, Gene Drives on the Horizon (n. 137), 166–169; *Warmbrod* et al. (n. 66), 31.

By mentioning the principle of 'free, prior and informed consent' of indigenous peoples and local communities, the decision takes account of an emerging collective human right that is increasingly accepted. However, one should not underestimate the role of human rights of individuals, especially when drive-bearing organisms interact with humans (e.g., through biting). Lastly, the call to ensure the biosafety of contained use applications of synthetic biology appears to be rather uncontroversial. However, international harmonization in this regard is far less advanced than one might think.

D. Governance of (Potential) Transboundary Spreads

An issue left unaddressed by decision 14/19 is potential transboundary spreads of engineered gene drives. This is surprising, especially considering that the potential of drive-bearing organisms to spread across political borders once released is generally recognized.[254]

It has been suggested that that before releasing any gene drive system that may spread across borders, potentially affected states should be consulted or even asked to approve the release.[255] An obligation to do so could result from the Cartagena Protocol (I.) as well as from the general obligation to prevent significant transboundary harm (II.).

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254 See, e.g., *Marshall* (n. 3), 896; *Oye* et al. (n. 3), 628; NASEM, Gene Drives on the Horizon (n. 137), 149; AHTEG on Risk Assessment, Guidance on Risk Assessment and Monitoring of LMOs (n. 94), 91; *Esvelt/Gemmell* (n. 3), 4; *James* et al. (n. 2), 41; *Warmbrod* et al. (n. 66), 33; *John B. Connolly* et al., Systematic Identification of Plausible Pathways to Potential Harm via Problem Formulation for Investigational Releases of a Population Suppression Gene Drive to Control the Human Malaria Vector Anopheles Gambiae in West Africa, 20 (2021) Malaria Journal 170, 61; WHO-TDR/FNIH, Guidance Framework for Testing GM Mosquitoes (n. 137), 125; also see *Elena Angulo/Ben Gilna*, When Biotech Crosses Borders, 26 (2008) Nature Biotech. 277.

255 *John M. Marshall*, Commentary: The Cartagena Protocol in the Context of Recent Releases of Transgenic and Wolbachia-Infected Mosquitoes, 19 (2011) Asia-Pacific Journal of Molecular Biology and Biotechnology 91, 97; NASEM, Gene Drives on the Horizon (n. 137), 157; *Esvelt/Gemmell* (n. 3), 4; *Kent H. Redford* et al., Genetic Frontiers for Conservation (2019), 41; *Robyn R. Raban* et al., Progress Towards Engineering Gene Drives for Population Control, 223 (2020) Journal of Experimental Biology, 1–4; WHO-TDR/FNIH, Guidance Framework for Testing GM Mosquitoes (n. 137), 125.

I. Regulation of Transboundary Movements Under the Cartagena Protocol

1. 'Likely' Transboundary Movements as 'Intentional' Transboundary Movements?

As shown above, organisms containing engineered gene drive systems constitute living modified organisms (LMOs) in the sense of the Cartagena Protocol.[256] The Protocol provides that *intentional* transboundary movements require the 'advance informed agreement' (AIA) of the receiving state,[257] whereas *unintentional* transboundary movements shall be prevented.[258]

Against this background, it has been argued that the release of an engineered gene drive that is known to be highly invasive and likely to spread across national borders should be considered to constitute an *intentional* transboundary movement, even when the initial release is only carried out domestically.[259] This would result in an obligation to obtain the AIA of all potentially affected states before authorizing the release.[260] Such an interpretation finds support in the Protocol's two-coined objective, which is to protect not only biological diversity but also the sovereign decision-making of each party whether to admit a particular LMO into its territory.[261]

However, it seems questionable whether an interpretation that equates *potential* or even *likely* transboundary movements with *intentional* transboundary movements is permissible. According to Article 31(1) VCLT, the primary reference for interpreting the terms of a treaty is their 'ordinary meaning'. In its ordinary meaning, the term 'intentional' means 'done on purpose'[262] or 'done with the aim of carrying out the act'.[263] Thus,

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256 See chapter 3, section A.I.1.e)bb).

257 Article 7(1) Cartagena Protocol; see chapter 3, section A.II.1.

258 Article 16(3) Cartagena Protocol, see chapter 3, section A.II.2.a)cc).

259 Cf. *Marshall* (n. 255), 97; *Rabitz* (n. 9), 346; *Lim/Lim* (n. 141), 99–103.

260 Cf. *Marshall* (n. 3), 896; *Rabitz* (n. 9), 346; *Redford* et al. (n. 255), 41; *Florian Rabitz*, The International Governance of Gene Drive Organisms (2021) Environmental Politics 1, 13.

261 See chapter 3, section A.III.

262 Cf. 'intentional, adj.', in: *James Murray* et al., Oxford English Dictionary, Online Edition, available at: http://www.oed.com/ (last accessed 28 May 2022).

263 Cf. 'intentional, adj.', in: *Bryan A. Garner* (ed.), Black's Law Dictionary (11th ed. 2019), 965.

the notion of 'intentional transboundary movement' implies that such a movement is carried out deliberately. Consequently, movements that occur unintentionally or accidentally do not constitute intentional but *unintentional* transboundary movements. This is in line with a decision adopted by the parties to the Cartagena Protocol, which provides that unintentional transboundary movements are such where an LMO 'inadvertently crosses the national borders of a Party where the living modified organism was released'.[264]

In the alternative, it could be assumed that the obligation to prevent *unintentional* transboundary movements, which requires states to take 'all appropriate measures' to that end, results in a prohibition to release gene drives whenever their transboundary spread is difficult or even impossible to prevent.[265] Ultimately, this would have the same effect of requiring the prior consent of potentially affected states into such releases.

While this interpretation appears to accord with the terms and spirit of the Cartagena Protocol, its practical effectiveness is questionable. As shown earlier, the obligation to take 'all appropriate measures' is one of due diligence and does therefore not require to guarantee that unintended transboundary movements do not occur under any circumstances.[266] This is in line with general international law, which does not generally prohibit ultra-hazardous activities but only requires that adequate safeguards are put in place to prevent adverse transboundary effects.[267] On a factual basis, however, there will often be differing perceptions about the risk of a transboundary spread as well as the potential resulting damage.[268]

As a result, there is a considerable likelihood that transboundary spreads of gene drives are neither regarded as *intentional* transboundary movements – which would trigger the AIA mechanism – nor constitute a violation of the due diligence standard that applies to *unintentional* transboundary movements.

264 CP COP-MOP, Decision VIII/16. Unintentional Transboundary Movements and Emergency Measures (Article 17), UN Doc. CBD/CP/MOP/DEC/VIII/16 (2016), Annex.
265 *Marshall* (n. 3), 896.
266 See chapter 3, section A.II.2.a.cc)(2).
267 See chapter 4, section C.
268 *Marshall* (n. 255), 97.

2. Proposal for a Clarification

To close the gaps currently left by the Cartagena Protocol, it has been proposed to develop a new multilateral instrument that expressly acknowledges that any release of organisms containing self-propagating genetic elements, including gene drives, requires the consent of all affected states.[269] However, given that the first environmental releases are expected to take place already in the next few years, the process of negotiating and ratifying a new instrument – if it were successful at all – would likely take too long.[270] For this reason, it appears more sensible to make use of the existing frameworks.

A fairly straightforward approach to strengthen the effectiveness of the Cartagena Protocol could be to clarify that any release of an engineered gene drive *likely* to spread across borders is considered to constitute an *intentional* transboundary movement, thus requiring the AIA of all potentially affected states prior to the release.[271] This could be accomplished through a decision adopted by the meeting of the parties to the Cartagena Protocol (COP-MOP). As shown above, such a decision would not be formally binding, but could clarify the obligations under the Protocol as quasi-normative soft law.[272]

Such a step would not be unprecedented. In a decision adopted at COP-MOP 9 in 2018, the parties to the Cartagena Protocol addressed the issue of confined field trials. As noted earlier, such confined trials have been proposed as part of 'stepwise' approaches to releasing gene drives.[273] However, the decision 'reminds parties' that

> *'[a] field trial, confined field trial or experimental introduction is to be regarded as intentional introduction into the environment when the conditions specified in Article 3, paragraph b, of the Protocol are not met'.*[274]

Admittedly, when making this decision, the parties could rely on the definition of 'contained use' in Article 3(b) of the Cartagena Protocol, while

269 *Graciela R. Ostera/Lawrence O. Gostin*, Biosafety Concerns Involving Genetically Modified Mosquitoes to Combat Malaria and Dengue in Developing Countries, 305 (2011) Journal of the American Medical Association 930, 931; *Marshall* (n. 3), 896.
270 Cf. *Marshall* (n. 255), 97; also see *Angulo/Gilna* (n. 254), 281.
271 *Marshall* (n. 255), 97–98; *Rabitz* (n. 9), 347; *Rabitz* (n. 260), 13–14.
272 See *supra* section B.II.
273 Cf. *James* et al. (n. 2), 22–25; *Hayes* et al. (n. 137); see *supra* section C.II.2.b)aa).
274 CP COP-MOP Decision 9/12 (2018) (n. 144), para. 2(c).

there is no such definition of what constitutes an 'intentional' transboundary movement. Nevertheless, a potential decision could, for instance, call upon parties to

> *'consider the intentional release of any living modified organism that is likely to traverse political borders after its release to constitute an intentional transboundary movement of that organism to the potentially affected Parties, thus requiring their advance informed agreement in accordance with Article 7, paragraph 1, of the Protocol'.*

If the consensus usually required for such a decision could not be achieved, an alternative approach would be to 'call upon parties to voluntarily obtain the AIA of the potentially affected states', or at least to 'notify, consult and cooperate with potentially affected states'. This would merely institutionalize an already-existing obligation, namely to notify and consult with potentially affected states about hazardous activities that may have transboundary effects.[275]

II. Transboundary Spreads and the Obligation to Prevent Significant Transboundary Harm

Ambiguities also exist with regard to the obligation to prevent significant transboundary harm. As shown earlier, states are obliged to ensure that activities within their jurisdiction do not cause damage to the environment of other states or areas beyond national jurisdiction.[276] However, this obligation only applies to harm that is 'significant', which requires that it must lead to a 'real detriment' to matters such as human health, property, or the environment.[277] This poses no problems when a gene drive causes such detriment through unintended side-effects on untargeted species, ecosystems, or human health. It also seems to be undisputed that the deliberate eradication of a species in its native habitat range contravenes the CBD and therefore constitutes significant harm.[278]

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275 Article 5 CBD; Article 17(4) Cartagena Protocol; see chapter 4, section D.IV.
276 Article 3 CBD, see chapter 3, section B.II., and chapter 4.
277 Cf. ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148, Commentary to Article 2, para. 4; also see chapter 4, section B.IV.
278 Cf. *Axel Hochkirch* et al., License to Kill?, 11 (2018) Conservation Letters e12370, 2–3; *Reynolds* (n. 9), 34.

Establishing a 'real detriment' could be more difficult when a gene drive exceeds its intended target range but, apart from this, functions as intended and does not cause any injury.[279] For instance, consider a (hypothetical) case where a modification drive designed to reduce the potential of a mosquito species to transmit a human pathogen spreads to a neighbouring state and replaces the local population there, resulting in a substantial reduction of transmission rates in that state.[280] In such a case, it could be argued that there is no case of significant transboundary harm because the neighbouring state does not suffer any 'real detriment' but rather benefits from an improvement of its public health.

However, such an understanding would ignore that the modification or replacement of an entire species severely interferes with the territorial integrity of the affected state. It also disregards the concept of 'biological diversity', which is not limited to individual species but also encompasses ecosystems and the greater ecological complexes of which they are part.[281] Arguably, this even includes the pathogen addressed by the gene drive and its interactions with vector and host organisms.[282] Moreover, it is recognized that damage to biological diversity can take many forms and is not limited to cases of 'biodiversity loss'.[283] Finally, the notion of 'significant harm' is not meant to exclude certain types of harm but rather cases of tolerable nuisance.[284] However, when a gene drive has a lasting effect on an entire species, it can hardly be said to be insignificant.

Consequently, the transboundary spread of an engineered gene drive will most probably constitute 'significant transboundary harm'.[285] When such a spread is known to be likely, a release is therefore only permissible with the consent of all affected states. However, there will often be differing perceptions of the risks related to the release of a particular gene drive

279 See chapter 4, section B.VII.2.
280 See chapter 1, section C.III.1.a).
281 Cf. Article 2 CBD; see chapter 6, section B.II.1.
282 *Hochkirch* et al. (n. 278), 3–4.
283 CBD COP, Synthesis Report on Technical Information Relating to Damage to Biological Diversity and Approaches to Valuation and Restoration of Damage to Biological Diversity, as Well as Information on National/Domestic Measures and Experiences: Note by the Executive Secretary, UN Doc. UNEP/CBD/COP/9/20/Add.1 (2008), paras. 8–19.
284 Cf. *K. Sachariew*, The Definition of Thresholds of Tolerance for Transboundary Environmental Injury Under International Law: Development and Present Status, 37 (1990) Netherlands International Law Review 193.
285 See chapter 4, section B.VII.2.

and the probability that it will have transboundary effects.[286] This became evident in 2016 when the parties to the CBD rejected language that would have urged states to obtain the consent of potentially affected states before approving any proposed release of a gene drive.[287]

Moreover, as shown earlier, the jurisprudence of the International Court of Justice indicates that a violation of the obligation to prevent significant transboundary harm cannot be assumed unless such harm has actually occurred, which limits the options of a potentially affected state to object to a particular release.[288] *Vice versa*, a breach is not assumed solely because damage has occurred, but there must be proof that the releasing state has breached its obligation to employ due diligence.[289] Therefore, it remains questionable whether the obligation to prevent significant transboundary harm under general international law effectively prevents unilateral releases of gene drives that may disseminate into the territory of other states.

E. Summary and Outlook

Although no engineered gene drive systems have been released into the environment so far, it is assumed that the first field trials could commence as early as 2023.[290] Therefore, it is no surprise that the debate on the international regulation of this emerging technology has rapidly gained momentum in recent years. In 2018, this culminated in the adoption of the first substantive decision on gene drives by the parties to the CBD. The fact that virtually all countries except for the United States carried this decision by consensus awards it a high degree of normative authority. This is also because the decision does not attempt to establish new principles, but rather endorses the application of certain already-established rules of international law to the issue of gene drives. However, the present chapter has shown that this is still prone to various uncertainties and grey areas.

For instance, the decision recalls ‘the current uncertainties regarding engineered gene drives’ and calls upon states to apply a precautionary approach. Contrary to what a few authors have contended, this cannot be used to justify premature releases in order to address other environmental

286 *Marshall* (n. 255), 97.
287 Cf. CBD COP, UN Doc. UNEP/CBD/COP/13/WG.2/CRP.22 (n. 18), para. 2.
288 See chapter 4, section E.II.
289 See chapter 4, section E.I.
290 *Mitchell/Bartsch* (n. 8), 8.

threats that require rapid action. Instead, the precautionary principle calls for restraint in using gene drive techniques as long as their risks and benefits cannot be fully evaluated.

The decision calls on states 'to only consider' releasing engineered gene drives when three conditions are met, namely when a scientifically sound risk assessment has been carried out, appropriate risk management measures are in place, and, where applicable, the free, prior and informed consent of indigenous peoples and local communities has been obtained.[291] The analysis in this chapter shows that these criteria have been previously recognized by the parties to the CBD, although their consequences in the context of gene drives may be less clear than it seems at first sight. In this regard, the benchmarks for what constitutes the 'best available technologies' are currently not defined by the states but rather by the researchers involved in the development of gene drives. The same is true for the call to ensure the safety of gene drive in contained use, where the decision even suggests a level of international harmonization that actually does not exist.

Unsurprisingly, the consequences of the conditions articulated by decision 14/19 are already controversial among states and various stakeholders. While opponents of the gene drive technique argue that the decision's language comes close to a moratorium, scientists involved in the development of gene drives claimed that it did not necessitate changes in their ongoing activities.[292] However, it seems that neither assessment is correct. The criteria are not impossible to fulfil, but they also do not constitute a comprehensive 'checklist' for future releases. Therefore, the decision should be seen as a carefully balanced compromise between both ends of the spectrum, which does not answer the question as to whether responsible gene drive releases are possible under the current rules of international law.

An issue left unaddressed by decision 14/19 is the potential for engineered gene drives to spread across borders. Considering that this problem is so broadly recognized, one might wonder why the states chose to ignore the proverbial 'elephant in the room'. However, the likeliness of such spreads will often be controversial between the state planning a release and potentially affected neighbouring states, which makes it difficult to agree on general rules.

A way forward could be to clarify that releases that are likely to result in a transboundary spread constitute 'intentional transboundary movements'

291 CBD COP, Decision 14/19 (n. 25), paras. 11–12.
292 Cf. *Callaway* (n. 196).

under the Cartagena Protocol. This could be done through a decision adopted by the parties to the Cartagena Protocol, which would not be unprecedented. Although the Cartagena Protocol lacks the participation of several key actors in the area of gene drives, such a decision would still constitute an important step in clarifying that the pertinent obligation of universal customary law, namely not to cause undue environmental interference to other states, applies no less to proposed releases of engineered gene drives.

Part Three:
Operator Liability

Chapter 6: The Nagoya – Kuala Lumpur Supplementary Protocol on Redress and Liability

The *Nagoya – Kuala Lumpur Supplementary Protocol on Redress and Liability* of 2010[1] is an international treaty that provides rules on liability[2] for damage resulting from living modified organisms (LMOs) obtained through modern biotechnology. It complements the *Cartagena Protocol on Biosafety*,[3] which addresses the safe handling and transboundary movement of LMOs but does not contain substantive provisions on liability for damage resulting from these organisms.[4] Before the Supplementary Protocol was adopted, a number of authors discussed the need for, and potential contents of, an additional instrument on liability for damage resulting from LMOs.[5] However, after the Supplementary Protocol was adopted in 2010, comparatively few publications have assessed its final provisions in depth.[6]

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1 Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64 (hereinafter 'Supplementary Protocol' or 'SP').

2 On the meaning of this term, see chapter 2, section C.

3 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 January 2000; effective 11 September 2003), 2226 UNTS 208 (hereinafter 'Cartagena Protocol' or 'CP').

4 See chapter 3, section A.II.6.

5 See *Alfonso Ascencio*, The Transboundary Movement of Living Modified Organisms: Issues Relating to Liability and Compensation, 6 (1997) RECIEL 293; *Philippe Cullet*, Liability and Redress for Modern Biotechnology, 15 (2006) YB Int'l Env. L. 165; *Susanne Förster*, Internationale Haftungsregeln für schädliche Folgewirkungen gentechnisch veränderter Organismen (2007); *Elizabeth Duall*, Liability and Redress Regime for Genetically Modified Organisms Under the Cartegena Protocol, 36 (2007) Geo. Wash. Int'l L. Rev. 173; *Katherine E. Kohm*, Shortcomings of the Cartagena Protocol: Resolving the Liability Loophole at an International Level, 27 (2009) UCLA Journal of Environmental Law and Policy 145; *Dire Tladi*, Civil Liability in the Context of the Cartagena Protocol: To Be or Not to Be (Binding)?, 10 (2010) Int. Environ. Agreements 15.

6 See the contributions in *Akiho Shibata* (ed.), International Liability Regime for Biodiversity Damage (2014); also see *Stefan Jungcurt/Nicole Schabus*, Liability and Redress in the Context of the Cartagena Protocol on Biosafety, 19 (2010) RECIEL 197; *Sufian Jusoh*, Harmonisation of Liability Rules in Transboundary Move-

The following section briefly reviews the Supplementary Protocol's negotiating history (A.), followed by a thorough analysis of the obligations and responsibilities it creates. The scope of the Supplementary Protocol covers damage to biodiversity resulting from LMOs which have been subject to a transboundary movement (B.). Liability for such damage is addressed by the Supplementary Protocol in two ways. The first approach and main focus of the Supplementary Protocol is *administrative liability*, which seeks to require the responsible operator to take practical measures in response to damage to biological diversity caused by an LMO (C.).[7] The second approach is a provision on *civil liability*, which addresses material and personal damage that is 'associated with' damage to biodiversity (D.). Several provisions concern general and cross-cutting issues, such as exemptions from liability, financial security and the Supplementary Protocol's relationship to the law of state responsibility (E.). However, a number of crucial issues are not addressed by the Supplementary Protocol (F.). Nor can these gaps be filled by an *Implementation Guide* published by an association of biotechnology companies (G.).

A. *Negotiating History*

During the negotiations of the Cartagena Protocol, it was highly controversial whether the Protocol should contain substantive provisions on liability for damage resulting from LMOs and whether such rules should be legally binding.[8] Because no agreement could be reached, the negotiating parties decided to postpone the matter and only adopted an 'enabling provision' in Article 27 of the Cartagena Protocol, whereby they undertook

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ment of Biotechnology Crops (2012), 189–203; *Odile J. Lim Tung*, Genetically Modified Organisms and Transboundary Damage, 38 (2013) SAYIL 67; *Gurdial S. Nijar*, The Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges, 13 (2013) Int. Environ. Agreements 271; *Aarti Gupta/Amandine Orsini*, Liability, Redress and the Cartagena Protocol, in: Elisa Morgera/Jona Razzaque/Michael G. Faure (eds.), Biodiversity and Nature Protection Law, Elgar Encyclopedia of Environmental Law, Volume III (2017) 445.

7 For terminological clarifications, see chapter 2, section G.

8 *Kate Cook*, Liability: 'No Liability, No Protocol', in: Christoph Bail/Robert Falkner/Helen Marquard (eds.), The Cartagena Protocol on Biosafety (2002) 371; *Akiho Shibata*, A New Dimension in International Environmental Liability Regimes: A Prelude to the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 17, 19–24.

to elaborate 'international rules and procedures' on liability and redress after the Cartagena Protocol had entered into force.[9] After the Protocol had entered into force in 2003, the negotiation process was launched by the first meeting of the parties to the Protocol (COP-MOP) in 2004.[10] A *Technical Group of Experts* compiled views and laid out the potential aspects that would need to be considered when developing a comprehensive set of rules.[11] On this basis, a *Working Group* established by the COP-MOP commenced negotiations.[12] However, while parties pushing for binding rules began to provide concrete text proposals on the various elements, some developed countries still challenged the overall need to adopt a legally binding instrument.[13]

9 Cf. *Nijar* (n. 6), 279; *Alejandro Lago Candeira*, Administrative Approach to Liability: Its Origin, Negotiation and Outcome, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 92, 96; *Worku D. Yifru/Kathryn Garforth*, The Supplementary Protocol: A Treaty Subject to Domestic Law?, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 150, 154.

10 Cf. CP COP-MOP, Terms of Reference for the Open-Ended Ad Hoc Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety: Synthesis Report of Submissions Received from Parties, Other Governments and Organizations, UN Doc. UNEP/CBD/BS/COP-MOP/1/9 (2003); CP COP-MOP, Decision BS-I/8. Establishment of an Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Protocol, UN Doc. UNEP/CBD/BS/COP-MOP/1/15, p. 102 (2004).

11 Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, Report of the Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, UN Doc. UNEP/CBD/BS/TEG-L&R/1/3 (2004).

12 For detailed accounts of the negotiating process, see *Gurdial S. Nijar* et al., Liability & Redress Under the Cartagena Protocol on Biosafety (2008); *Tladi* (n. 5); *Jungcurt/Schabus* (n. 6); Third World Network, Liability and Redress for Damage Resulting from GMOs: The Negotiations Under the Cartagena Protocol on Biosafety (2012); *Wen Xiang*, International Liability and Redress for Genetically Modified Organisms and Challenge for China's Biosafety Regulation, in: Vasilka Sancin/Maša Kovič Dine (eds.), International Environmental Law (2012), 581; *Nijar* (n. 6), 280–282; *René Lefeber/Jimena Nieto Carrasco*, Negotiating the Supplementary Protocol: The Co-Chairs' Perspective, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 52. Detailed reports of the negotiating meetings were published in IISD, Earth Negotiations Bulletin, Volume 09: Biological Diversity and Plant Genetic Resources (19 December 2017), available at: http://enb.iisd.org/vol09/ (last accessed 28 May 2022).

13 *Nijar* (n. 6), 281; also see Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Proto-

At the third session of the Working Group in 2007, the group's co-chairs presented a streamlined document which contained two parallel approaches to operator liability.[14] Besides the conventional civil liability approach, which refers to the harmonization of domestic laws on civil liability, the co-chairs' proposal also featured a so-called *administrative approach*, which provides for the implementation of response measures to remedy environmental damage (rather than the mere payment of financial compensation).[15] The administrative approach is premised on the existence of *competent national authorities* which evaluate the damage and determine the response measures that have to be taken by the responsible operator.[16] The approach originates from environmental legislation in the United States, particularly the *Comprehensive Environmental Responsibility, Compensation and Liability Act* of 1980 (CERCLA),[17] and was adopted in 2004 by the European Union in its *Environmental Liability Directive*.[18] In 2005, the administrative approach was employed in an international treaty for the first time in the *Liability Annex* to the Environmental Protocol to the Antarctic Treaty.[19] After an initial period of scepticism, parties soon

col on Biosafety, Liability and Redress (Article 27): Compilation of Submissions on Experiences and Views on Criteria for the Assessment of the Effectiveness of Any Rules and Procedures Referred to in Article 27 of the Protocol, UN Doc. UNEP/CBD/BS/WG-L&R/2/INF/2 (2006).

14 See Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, Report of the […] Third Meeting, UN Doc. UNEP/CBD/BS/WG-LR/3/3 (2007), Annexes I and II.

15 *Gurdial S. Nijar*, Civil Liability in the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 111, 121.

16 See *Jungcurt/Schabus* (n. 6), 202; for a detailed account, see *infra* section C.

17 Cf. United States, Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund), as Amended Through P.L. 109–591, Enacted August 10, 2005, 42 U.S.C. §§ 9601–9675 (hereinafter 'CERCLA').

18 Directive 2004/35/CE on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage (21 April 2004), OJ L 143, p. 56 (hereinafter 'EU Environmental Liability Directive'); see *G. Winter* et al., Weighing up the EC Environmental Liability Directive, 20 (2008) J. Envt'l L. 163, 164–165.

19 Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty: Liability Arising from Environmental Emergencies (14 June 2005; not yet in force), ATCM Measure 1 (2005) (hereinafter 'Antarctic Liability Annex'); see *Michael Johnson*, Liability for Environmental Damage in Antarctica, 19 (2006) Geo. Int'l Envtl. L. Rev. 33; *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 85–86.

accepted that the administrative approach could be a viable option for liability in the context of biodiversity damage resulting from LMOs.[20]

While the administrative approach increasingly found support, it was still highly controversial whether the instrument should also include legally binding provisions on civil liability.[21] Developing countries insisted on including such provisions, arguing that their civil liability regimes were not yet equipped to deal with damage resulting from LMOs.[22] In addition, developing countries saw strict liability[23] rules as a possible remedy for their hitherto underdeveloped biosafety regimes.[24] On the other hand, many developed countries opposed the inclusion of civil liability provisions, arguing that they would open the gates for claims for traditional damage, which in their view was not covered by the mandate provided by the Cartagena Protocol.[25] Moreover, a number of developed country parties, including the European Union,[26] expressly wanted to avoid having to amend their existing domestic regimes on biosafety and liability for LMO-related damage.[27] This seems to reflect a general reluctance of states to commit to international civil liability regimes, as the implementation of such regimes often requires substantive changes to domestic rules and procedures.[28] Some parties were also concerned that the adoption of civil

20 *Nijar* (n. 6), 281–282.
21 See *Tladi* (n. 5), 17–18.
22 *Jungcurt/Schabus* (n. 6), 203; see *Elmo Thomas/Mahlet Teshome Kebede*, One Legally Binding Provision on Civil Liability: Why It Was so Important from the African Negotiator's Perspective, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 125.
23 See chapter 2, section E.
24 Cf. *Nijar* (n. 15), 118.
25 *Jungcurt/Schabus* (n. 6), 201; cf. IISD, Summary of the Second Meeting of the Group of Friends of the Co-Chairs on Liability and Redress in the Context of the Cartagena Protocol on Biosafety: 8–12 February 2010, ENB Vol. 9 No. 495 (2010), 7.
26 On the EU's position, see *Edward H. P. Brans/Dorith H. Dongelmans*, The Supplementary Protocol and the EU Environmental Liability Directive, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 180, 197–198.
27 *Nijar* (n. 6), 282.
28 See CBD Secretariat, Status of Third-Party Liability Treaties and Analysis of Difficulties Facing Their Entry into Force: Note by the Executive Secretary, UN Doc. UNEP/CBD/BS/WG-L&R/1/INF/3 (2005); *Jungcurt/Schabus* (n. 6), 201–202; more generally, see *Anne Daniel*, Civil Liability Regimes as a Complement to Multilateral Environmental Agreements, 12 (2003) RECIEL 225.

liability rules would imply an acknowledgement of the inherent danger of biotechnology products.[29]

At COP-MOP 4 in 2008, the negotiating parties agreed in principle to develop a legally binding instrument that followed the administrative approach but also included one article on civil liability.[30] This compromise resulted in the provisions now contained in paragraphs 2 and 3 of Article 12.[31] Originally, this article was meant to be complemented by a non-binding set of guidelines on civil liability and redress.[32] However, although parties had begun to negotiate on a draft for these guidelines,[33] their completion was no longer pursued when the adoption of the Supplementary Protocol came into reach.[34]

The Supplementary Protocol was adopted on 15 October 2010 during COP-MOP 5 in Nagoya, Japan.[35] After being ratified by 40 states,[36] the Supplementary Protocol entered into force on 5 March 2018, as provided

29 *Nijar* (n. 6), 282.

30 Cf. CP COP-MOP, Decision BS-IV/12. Liability and Redress Under the Cartagena Protocol on Biosafety, UN Doc. UNEP/CBD/BS/COP-MOP/4/18, p. 84 (2008); see IISD, Summary of the Fourth Meeting of the Parties to the Cartagena Protocol on Biosafety: 12–16 May 2008, ENB Vol. 9 No. 441 (2008), 7; *Tladi* (n. 5), 18–22.

31 While the first paragraph of Article 12 also refers to civil liability, it rather seems to relate to the implementation of the administrative approach, cf. *infra* section C.V.1. For a detailed discussion of paras. 2 and 3, which relate to civil liability in a stricter sense, see *infra* section D.II.

32 Cf. CP COP-MOP Decision BS-IV/12 (2008) (n. 30), Annex, section 2.

33 Cf. Group of Friends on L&R, Draft Guidelines on Civil Liability and Redress in the Field of Damage Resulting from Transboundary Movements of Living Modified Organisms: Proposal by the Co-Chairs, UN Doc. UNEP/CBD/BS/GF-L&R/3/3 (2010).

34 Cf. CP COP-MOP, Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, UN Doc. UNEP/CBD/BS/COP-MOP/5/17 (2010), para. 129; *Jungcurt/Schabus* (n. 6), 203.

35 Cf. CP COP-MOP, Decision BS-V/11. International Rules and Procedures in the Field of Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms, UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 62 (2010).

36 Pursuant to Article 18(3) SP, the ratification by a regional economic integration organization (such as the European Union) shall not be counted towards the number of 40 ratifications in addition to the ratifications of the Member States of such an organization.

by Article 18(1).[37] As of May 2022, it has 49 parties, including the European Union and all of its Member States except Greece and Malta.[38]

B. Scope

According to Article 3(1), the Supplementary Protocol applies to 'damage resulting from living modified organisms which find their origin in a transboundary movement'. This provision consists of three elements. Firstly, the Supplementary Protocol applies to living modified organisms (I.). Secondly, the notion of damage is defined as an 'adverse effect on the conservation and sustainable use of biological diversity' (II.). The third criterion is that damage must result from LMOs 'which find their origin in a transboundary movement' (III.). In addition, the Protocol contains provisions governing its temporal and geographical scope (IV.).

I. Subject Matter: Living Modified Organisms

Like the Cartagena Protocol, the Supplementary Protocol applies to *Living Modified Organisms* (LMOs). The definition of this term,[39] as well as all other definitions contained in the Cartagena Protocol, are expressly incorporated into the Supplementary Protocol.[40]

Besides LMOs intended for intentional introduction into the environment, the scope of the Supplementary Protocol expressly extends to LMOs destined for contained use and to LMOs intended for direct use for food,

37 Cf. UN OLA, Status of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, United Nations Treaty Collection, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-c&chapter=27&clang=_en (last accessed 28 May 2022).

38 Cf. *ibid.*, see Council of the European Union, Council Decision on the Conclusion on Behalf of the European Union of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (12 February 2013), OJ L 46, p. 1.

39 A living modified organism is defined in Article 3(g) CP as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. On the meaning and scope of this phrase, see chapter 3, section A.I.1.

40 Article 2(1) SP.

feed or processing.[41] Unlike the Cartagena Protocol,[42] the Supplementary Protocol does not provide for a differentiated treatment of these types of uses of LMOs.[43]

1. LMOs That Are Pharmaceuticals for Humans

However, it could be questioned whether the Supplementary Protocol applies to LMOs used for pharmaceutical purposes. The Supplementary Protocol does not contain any reference to pharmaceuticals, and their coverage was apparently not discussed during its negotiations.[44] As shown above, the Cartagena Protocol contains an express provision ruling out from its scope the transboundary movement of LMOs 'which are pharmaceuticals for humans', provided they are addressed by 'other relevant international agreements or organisations'.[45] Pursuant to Article 16(3) SP, the provisions of the Cartagena Protocol shall apply, *mutatis mutandis*,[46]

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41 Article 3(1) SP.

42 The Cartagena Protocol's Advance Informed Agreement (AIA) mechanism does not apply to LMOs destined for contained use, see Article 6(2) CP, and provides for a simplified AIA mechanism for LMO-FFPs, see Articles 7(3) and 11 CP. For details, see chapter 3, sections A.II.1.a) and A.II.1.f).

43 *Nijar* (n. 6), 273. Whether LMO-FFPs should be covered by the Supplementary Protocol was highly controversial during the negotiations, see *Lim Tung* (n. 6), 70–71.

44 This finding is derived from a full-text search of the Supplementary Protocol's *travaux préparatoires*, including publicly available draft texts and reports from the negotiations between 2002 and 2010, the topically structured documentation of proposed rules and government positions in *Nijar* et al. (n. 12), and the *Earth Negotiations Bulletin* reports of those meetings that were covered, see IISD (n. 12). In their responses to a questionnaire submitted before the actual negotiations commenced, *Uganda* and *Cameroon* identified the import and consumption of LMO pharmaceuticals as belonging to the 'types of activities or situations perceived most likely to cause damage', and one NGO suggested the inclusion of pharmaceuticals into the scope of the instrument to be developed; see Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, Compilation of Views Submitted in Response to Questionnaire on Liability and Redress for Damage Resulting from Transboundary Movement of LMOs, UN Doc. UNEP/CBD/BS/TEG-L&R/1/INF/1 (2004), on pages 7, 60 and 77. However, the issue of pharmaceuticals was apparently never raised in the actual negotiations.

45 Article 5 CP; see chapter 3, section A.I.4.

46 With the necessary changes, see 'mutatis mutandis', in: *Aaron X. Fellmeth/Maurice Horwitz*, Guide to Latin in International Law (2011), 189.

to the Supplementary Protocol. This means that the general exemption for LMO pharmaceuticals in the Cartagena Protocol also applies to the Supplementary Protocol.[47] Consequently, LMOs that are pharmaceuticals for humans would not be covered by the Supplementary Protocol's scope if they were addressed by other relevant international agreements or organisations,[48] which, as noted earlier, seems not (yet) to be the case.[49]

This result is of particular importance for LMOs employed for disease control purposes (such as genetically modified insects or organisms equipped with engineered gene drives[50]). If these types of LMOs were regarded as pharmaceuticals (as suggested by one author[51]), damage caused by these organisms would fall outside the scope of the Supplementary Protocol.[52] This would be a significant limitation, especially since it is widely acknowledged that engineered gene drives involve a substantial risk of causing (potentially transboundary) damage to biodiversity.[53] However, as argued above, classifying LMOs used for disease control as 'pharmaceuticals for humans' would overstretch the ordinary meaning of this term in its context. Consequently, the exemption only applies to LMOs directly used as medicinal drugs but not to LMOs used for other public health purposes, such as disease vector control.

2. Products Derived From LMOs

During the negotiations of the Supplementary Protocol, it was highly contentious whether it should apply to products which have been derived

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47 This does not affect the above-mentioned equal treatment by the Supplementary Protocol of different categories of LMOs (contained use/LMO-FFPs/intended for introduction into the environment) that are subject to differential treatment in the Cartagena Protocol, since Article 16(3) incorporates the provisions of the Cartagena Protocol only 'except as otherwise provided'. The list of LMOs covered by Supplementary Protocol contained in Article 3 can be regarded as such a derogating provision.

48 This conclusion is shared, even though without reasoning, by *Lim Tung* (n. 6), 71; and *Nijar* (n. 6), 273.

49 See chapter 3, section A.I.4.

50 See chapter 1, sections C.III.1 and E.III.

51 *Lim Tung* (n. 6), 71; *Odile J. Lim Tung*, Transboundary Movements of Genetically Modified Organisms and the Cartagena Protocol: Key Issues and Concerns, 17 (2014) Potchefstroom Electronic Law Journal 1739, 1744–1745.

52 Cf. *Lim Tung* (n. 6), 71.

53 See chapter 1, section C.IV.4, and chapter 5, section D.

from LMOs (so-called 'products thereof').[54] In the final text, all references to *products thereof* were removed. In the report of COP-MOP 5, at which the Supplementary Protocol was adopted, it was noted that there were different understandings of whether 'processed materials that are of living modified organism-origin' were covered by Article 27 of the Cartagena Protocol, which mandated the development of the Supplementary Protocol.[55] The report noted that one such understanding was that parties '*may apply* the Supplementary Protocol to damage caused by such processed materials, provided that a causal link is established between the damage and the living modified organism in question'.[56] But this has no bearing on the interpretation of the Supplementary Protocol, as it merely restates a general principle of international law. By virtue of their sovereignty, states are free to unilaterally apply norms of international law even outside of their defined scope of application, provided that this does not collide with other obligations of that state.[57] Such conflicting obligations may, in particular, arise from international trade law, where the extension of liability rules to products of LMOs might be considered as an unjustified trade restriction.[58] In any event, there was consensus among negotiators that the Supplementary Protocol should only apply when the original LMO, and not just the processed material, had been subject to a transboundary movement.[59]

54 Cf. *Reynaldo A. Alvarez-Morales*, A Scientific Perspective on the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 105, 107–109; *Shibata* (n. 8), 22–24; *Lefeber/Nieto Carrasco* (n. 12), 66–67.

55 Report of COP-MOP 5 (n. 34), para. 133.

56 *Ibid.* (emphasis added).

57 This follows from the sovereign independence of states, cf. *Malcolm N. Shaw*, International Law (8th ed. 2017), 167, noting that '[t]he starting points for the consideration of the rights and obligations of states within the international legal system remains that international law permits freedom of action for states, unless there is a rule constraining this'. Also see PCIJ, Case of the S.S. "Lotus" (France v. Turkey), Judgment of 07 September 1927, PCIJ Rep. Ser. A, No. 10, 18; *James Crawford*, Brownlie's Principles of Public International Law (9th ed. 2019), 431–432.

58 Cf. *Rodigro C. A. Lima*, Trade and the Supplementary Protocol: How to Achieve Mutual Supportiveness, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 131, 135; *Jusoh* (n. 6), 217–232; see chapter 3, section C.

59 *Shibata* (n. 8), 24; *Lefeber/Nieto Carrasco* (n. 12), 67; *Lima* (n. 58), note 5 at p. 135.

II. Damage to Biological Diversity

Pursuant to Article 3(1), the Supplementary Protocol applies to 'damage' resulting from LMOs. The term 'damage' is defined by Article 2(2)(b) as

> *'an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.*

Unlike virtually all other international instruments on environmental liability,[60] the Supplementary Protocol's scope does not cover all forms of

60 See, e.g., the Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment (21 June 1993; not yet in force), 32 ILM 1228, Article II(10); Vienna Convention on Civil Liability for Nuclear Damage (25 May 1963; effective 12 September 1997), 1063 UNTS 358, as amended by the Protocol of 12 September 1997 (effective 4 October 2003), IAEA Doc. INFCIRC/566 (hereinafter '1997 Vienna Convention on Civil Liability for Nuclear Damage'), Article 1(1)(k); International Convention on Civil Liability for Oil Pollution Damage (29 November 1969; effective 19 June 1975), 973 UNTS 3, as amended by the Protocol of 27 November 1992 (effective 30 May 1996), 1956 UNTS 255 (hereinafter '1992 Oil Pollution Convention'), Article 1(6); International Convention on Civil Liability for Bunker Oil Pollution Damage (23 March 2001; effective 21 November 2008), IMO Doc. LEG/CONF.12/19 (hereinafter 'Bunker Oil Convention'), Article 1(9); Convention on Civil Liability for Oil Pollution Damage Resulting from Exploration for and Exploitation of Seabed Mineral Resources (01 May 1977; not yet in force), 16 ILM 1451, Article 1(6); International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea (03 May 1996; not yet in force), 25 ILM 1406, as amended by the Protocol of 30 April 2010, IMO Doc. LEG/CONF.17/DC/1 (hereinafter 'HNS Convention'), Article 1(6)(c); Convention on Civil Liability for Damage Caused During Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels (10 October 1989; not yet in force), UN Doc. ECE/TRANS/79, Article 1(10); Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal (10 December 1999; not yet in force), UNEP/CHW.5/29, p. 88 (hereinafter 'Basel Protocol on Liability for Hazardous Wastes'), Article II(2)(c)(iv); Kiev Protocol on Civil Liability and Compensation for Damage Caused by the Transboundary Effects of Industrial Accidents on Transboundary Waters (21 May 2003; not yet in force), UN Doc. ECE/MP.WAT/11-ECE/CP.TEIA/9 (hereinafter 'Kiev Liability Protocol'), Article II(2)(d)(iv); Antarctic Liability Annex (n. 19), Article 2(b). However, note that while all of these instruments provide for reimbursement of expenses made for reasonable measures of prevention or reinstatement actually undertaken, many expressly exclude monetary compensation for damage to the environment *per se*, see chapter 11, section B.I.1. Also see Convention on International Liability for Damage Caused by Space Objects (29 March 1972; effective 01 September 1972), 961 UNTS 187, Article 1(a); Convention on Third Party Liability in the Field of Nuclear Energy (29 July

environmental damage but is strictly limited to adverse effects on the conservation and sustainable use of biodiversity. Material and personal damage are only addressed insofar as it is 'associated with' biodiversity damage,[61] while economic loss is not mentioned in the Supplementary Protocol at all. Hence, any injury suffered from an incident not resulting in biodiversity damage is excluded from the Protocol's scope. The reason for this lies in the object and purpose of the biosafety regime, which is the 'conservation and sustainable use of biological diversity, taking also into account risks to human health'.[62]

The Supplementary Protocol's definition of 'damage' involves a number of terms that require closer inspection. First, the meaning of 'biological diversity' must be clarified (1.). Second, damage is defined by the Protocol as an 'adverse effect on the conservation and sustainable use' of biodiversity (2.). Such effects need to be 'measurable or otherwise observable' and 'significant' (3.). In addition, 'risks to human health' shall also be taken into account (4.).

1. Biological Diversity

The term 'biological diversity' is defined by Article 2 of the CBD as

> *'the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems'.*

The term 'variability' implies that the concept of biological diversity does not address individual species, habitats and ecosystems or the environment as such. For this reason, it has been suggested that injury to 'variability among living organisms' may be difficult to quantify in order to establish

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1960; effective 01 April 1968), 956 UNTS 251, as amended by the Additional Protocol of 28 January 1964 and the Protocol of 16 November 1982 (effective 7 October 1988), 1519 UNTS 329, Article III(a), which does not include damage to the environment. A further Protocol to the Paris Convention adopted in 2004 includes damage to the environment into the scope of compensable damage, but this Protocol has not yet entered into force. For a useful collection of documents, see *Hannes Descamps/Robin Slabbinck* et al. (eds.), International Documents on Environmental Liability (2008).

61 Article 12(2) SP; see *infra* section D.I.

62 Article 1 CP.

the occurrence of damage.[63] However, such an understanding is based on an excessively narrow interpretation of the term 'variability'. The term refers to the variability of life in all forms, levels and combinations, including the variety and frequency of different ecosystems, species and genetic information.[64] At the same time, efforts to preserve this variability will inevitably be focused on 'tangible manifestations of biological diversity' such as particular ecosystems or populations of species.[65] Consequently, injury to the variability among living organisms can arise from damage to individual components of biological diversity, such as individual species or ecosystems,[66] but whether such injury amounts to 'damage' in terms of the Supplementary Protocol has to be assessed in light of the other given criteria.

2. Adverse Effects on the Conservation and Sustainable Use of Biological Diversity

The term 'damage' is defined in Article 2(2)(b) as an 'adverse effect on the conservation and sustainable use' of biological diversity. The reference to *conservation* and *sustainable use* originates from the Cartagena Protocol,

63 *Duall* (n. 5), 195, citing ICCP, Liability and Redress for Damage Resulting from the Transboundary Movements of Living Modified Organisms: Review of Existing Relevant Instruments and Identification of Elements: Note by the Executive Secretary, UN Doc. UNEP/CBD/ICCP/2/3 (2001), para. 77.

64 *Lyle Glowka* et al., A Guide to the Convention on Biological Diversity (1994), 16.

65 CBD COP, Synthesis Report on Technical Information Relating to Damage to Biological Diversity and Approaches to Valuation and Restoration of Damage to Biological Diversity, as Well as Information on National/Domestic Measures and Experiences: Note by the Executive Secretary, UN Doc. UNEP/CBD/COP/9/20/Add.1 (2008), para. 9; also see *Glowka* et al., IUCN Guide to the CBD (n. 64), 16.

66 Synthesis Report on Article 14(2) CBD (n. 65), para. 19; This understanding is confirmed by the *Biodiversity Compact* (see chapter 7), which refers to adverse changes to species or ecosystems and 'natural resource services essential to sustain any Species', see The Compact: A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a Living Modified Organism, Second Amended Text (18 September 2012), available at: http://www.biodiversitycompact.org/wp-content/uploads/Compact-Second-Amended-Text-with-translation-reference-January-2014-2.pdf (last accessed 28 May 2022), Article 6.2.

which applies to LMOs that 'may have' said adverse effects.[67] Against this background, it has been questioned whether the phrase 'conservation and sustainable use of biological diversity' signifies a concept distinct from that of 'damage to biological diversity', which is used (but not defined) in the CBD.[68]

a) Adverse Effects on Conservation

While the CBD does not define the term 'conservation of' biological diversity, the term's ordinary meaning[69] implies that it primarily refers to preventing the loss of biological diversity. This is confirmed by the CBD's preamble, which recognizes that 'biological diversity is being significantly reduced by certain human activities'.[70] Moreover, the term 'biodiversity loss' was defined in a decision adopted by the Conference of Parties (COP) to the CBD in 2004 as

> *'the long-term or permanent qualitative or quantitative reduction in components of biodiversity and their potential to provide goods and services, to be measured at global, regional and national levels'.*[71]

As shown above, decisions adopted by the CBD COP are usually carried by a consensus of all states parties, which arguably awards them a quasi-normative 'soft law' status that also takes influence on the interpretation

67 Cf. Article 4 CP. This wording, in turn, originates from Article 8(g) CBD. On the question of whether the Cartagena Protocol is limited to hazardous LMOs, see chapter 3, section A.I.2.

68 See Articles 14(1)(d), 14(2), 22(1) CBD; cf. ICCP (n. 63), para. 77; *Duall* (n. 5); *Juan-Francisco E. Espinosa*, The Definition of Damage Resulting from Transboundary Movements of Living Modified Organisms in Light of the Cartagena Protocol, 47 (2009) Canadian YBIL 319, 326–327; *Worku D. Yifru* et al., Review of Issues, Instruments and Practices Relevant to Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms (2012), 22; *Armelle Gouritin*, EU Environmental Law, International Environmental Law, and Human Rights Law (2016), 161–162.

69 Cf. 'conservation, n.', in: *James Murray* et al., Oxford English Dictionary, Online Edition, available at: http://www.oed.com/ (last accessed 28 May 2022).

70 See Preamble to the CBD, Recital 6.

71 CBD COP, Decision VII/30. Strategic Plan: Future Evaluation of Progress, UN Doc. UNEP/CBD/COP/DEC/VII/30 (2004), para. 2. In this context, also see Synthesis Report on Article 14(2) CBD (n. 65), paras. 8–15.

of the terms of the CBD.[72] Hence, it can be assumed that any 'loss' of biodiversity, i.e. a reduction or loss of a certain species either in a certain habitat or globally, will also be an adverse effect on the 'conservation of' biological diversity.[73] Even beyond the threshold of actual loss, conservation of biodiversity could be adversely affected, for instance, when human efforts to prevent biodiversity loss are undermined.[74] Moreover, it can be drawn from the definition that damage not only encompasses the physical loss of components of biodiversity *per se*, but also the loss of their ability to provide goods and services.[75]

However, not every change to biological diversity necessarily constitutes an 'adverse effect' on its conservation. For instance, it could be questioned whether the mere undesired presence of an LMO in an ecosystem or changes to the genome of natural species due to cross-over (or hybridization) events necessarily constitute 'adverse effects'. For instance, the *Biodiversity Compact*, a private civil liability instrument developed by multinational biotechnology corporations,[76] expressly provides that these types of changes do not per se constitute 'significant and adverse changes' that give rise to liability under the Compact.[77] However, such a restrictive interpretation appears not to be warranted for the Supplementary Protocol, since there is no indication that an 'adverse effect on the conservation' is only given when there is a 'loss' of biodiversity in the sense of the aforementioned definition.

b) Adverse Effects on Sustainable Use

'Sustainable use' is defined in Article 2 CBD as the 'use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity'. Sustainable use could be adversely affected when such use is no longer possible or must be restricted in order to prevent the loss of biodiversity, for instance when the continuation of previously sustainable use practices would risk the extinction of certain species or the destruction of components of biological diversity (e.g.

72 See chapter 5, section B.
73 Cf. *Espinosa* (n. 68), 336–337.
74 In the context of engineered gene drives, see *Axel Hochkirch* et al., License to Kill?, 11 (2018) Conservation Letters e12370.
75 Synthesis Report on Article 14(2) CBD (n. 65), para. 14.
76 See chapter 7.
77 Cf. Biodiversity Compact (n. 66), Article 8.3.

habitats or ecosystems). In this understanding, the concept of 'sustainable use' has a clear anthropocentric focus[78] while, in contrast, 'conservation' aims at preserving biodiversity as such and follows a more ecocentric approach.[79]

c) Conclusions

The foregoing analysis has shown that there are no apparent differences between the concepts of 'adverse effects on the conservation and sustainable use of biological diversity' used in the Supplementary Protocol and 'damage to biological diversity' used in the CBD.[80] Any event that endangers or reduces the 'variability of living organisms' will affect either the conservation of biological diversity, its sustainable use, or both. This is clearly the case when a species is endangered or extinct. On the other hand, not every change to the composition of biological diversity necessarily constitutes an 'adverse effect', and not every adverse effect is caused by a 'loss' of biodiversity.[81] Whether particular changes result in adverse effects on its *conservation* or *sustainable use* will have to be assessed on a case-by-case basis, having regard to the threshold that adverse effects must be both 'measurable or otherwise detectable' and 'significant'.[82]

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78 *Espinosa* (n. 68), 337 even assumes that 'it is necessary to verify that there has been a loss of income or that there has been a consequential loss to a state, including loss of income'.

79 On the difference and interplay between anthropocentric and ecocentric approaches, see *Alan E. Boyle*, The Role of International Human Rights Law in the Protection of the Environment, in: Alan E. Boyle/Michael Anderson (eds.), Human Rights Approaches to Environmental Protection (1996) 43, 51–53; *Silja Vöneky/Felix Beck*, Umweltschutz und Menschenrechte, in: Alexander Proelß (ed.), Internationales Umweltrecht (2nd ed. 20202) 191, MN. 150–152.

80 Cf. *Espinosa* (n. 68), 335; *Shibata* (n. 8), 23; but see *Daniela M. Schmitt*, Staatenverantwortlichkeit für Schäden an der biologischen Vielfalt (2018), 81 who assumes that there is a difference between damage to biological diversity *per se* and damage to its conservation and sustainable use.

81 Cf. Synthesis Report on Article 14(2) CBD (n. 65), para. 16.

82 Cf. Article 2(2)(b)(i) and (ii) SP; see next section.

3. Threshold of Damage: 'Measurable' and 'Significant'

To qualify as recoverable damage under the Supplementary Protocol, adverse effects on biological diversity need to fulfil two requirements stipulated in Article 2(2)(b): First, the damage must be *measurable or otherwise observable*. Wherever available, this shall be determined according to scientifically established baselines that have been recognized by a competent authority and that take into account any other human-induced or natural variation.[83] The notion 'baseline' refers to information about the state of the affected environment before the incident occurred.[84]

Generally, determining a baseline condition requires data on the condition of the affected ecosystem just before the incident occurred.[85] In principle, this would require periodic, nationwide biodiversity surveys.[86] As the Supplementary Protocol remains silent on the matter of baseline data collection prior to the occurrence of damage,[87] the availability of such data will largely depend on the existence of biodiversity inventories and studies performed by individual states parties.[88] However, baselines can also be estimated *ex post*, for instance by using *temporal trend analysis,* which builds upon historical data from impacted areas (where available), *reference area comparison*, which evaluates trends in similar areas that remained unaffected, or mathematical modelling techniques.[89]

The second threshold for damage to be recoverable is that it must be *significant*, which shall be established on the basis of a non-exhaustive list of factors provided in Article 3(3) of the Supplementary Protocol. These factors include the long-term or permanent change (i.e. change that will not be redressed through natural recovery within a reasonable time), the

83 Article 2(2)(b)(i) SP.

84 Cf. EU Environmental Liability Directive (n. 18), Article 2(14).

85 *Brans/Dongelmans* (n. 26), 187.

86 On this problem in the context of globally spreading gene drives, see *Marion Dolezel* et al., Beyond Limits – The Pitfalls of Global Gene Drives for Environmental Risk Assessment in the European Union, 15 (2020) BioRisk 1, 12–13.

87 *Brans/Dongelmans* (n. 26), 187–188.

88 In this context, see *Ted Gullison* et al., Good Practices for the Collection of Biodiversity Baseline Data (2015); for the EU, see EEA, EU 2010 Biodiversity Baseline – Adapted to the MAES Typology, EEA Technical report No 9/2015.

89 Cf. Synthesis Report on Article 14(2) CBD (n. 65), para. 40. See *Joshua Lipton/Kate LeJeune*, Determining and Quantifying Environmental Damage, in: Joshua Lipton/Ece Özdemiroğlu et al. (eds.), Equivalency Methods for Environmental Liability (2018) 57, 74–79.

extent of the qualitative or quantitative changes, the reduction of ecosystem services, and the extent of any adverse effects on human health.[90]

It is questionable whether these criteria are sufficiently precise. While some authors assume that the definition of damage contained in the Supplementary Protocol established 'hard criteria' for determining damage to the environment,[91] others argue that it may be difficult in practice for experts to agree on the 'significance' of adverse effects, especially when there is scientific uncertainty on the (potentially long-term) negative impacts.[92] Some even challenge the 'remarkably vague' wording used in this part of the Supplementary Protocol and doubt whether there is any harmonized understanding of when unwanted side-effects of releasing an LMO amount to 'damage to biological diversity'.[93] In any event, a critical limitation for measuring adverse effects on biodiversity damage could be that there is a lack of knowledge about the situation of biodiversity before the rise of harmful anthropogenic activities.[94] Hence, there might be situations in which establishing a baseline will not be possible due to a lack of pre-incident information on the state of biodiversity. It is unclear whether other methods are available in these situations to measure change where baselines do not exist.[95] At the same time, this shows that establishing damage to biodiversity is more a scientific issue than a legal one.[96]

4. Risks to Human Health

As an additional element in its definition of *damage*, the Supplementary Protocol refers to 'taking also into account risks to human health'.[97] This wording originates from Article 8(g) of the CBD and Article 1 of the Cartagena Protocol, where it is used in addition to the risks that LMOs might pose to biodiversity. However, the meaning of the phrase 'taking

90 Article 2(3) SP.
91 Cf. *Jungcurt/Schabus* (n. 6), 200.
92 *Lim Tung* (n. 6), 72.
93 *Yifru/Garforth* (n. 9), 156; also see *Gouritin* (n. 68), 163.
94 *Jean-Baptiste Mihoub* et al., Setting Temporal Baselines for Biodiversity: The Limits of Available Monitoring Data for Capturing the Full Impact of Anthropogenic Pressures, (2017) 7 Sci. Rep. 41591, 1–2.
95 Cf. Synthesis Report on Article 14(2) CBD (n. 65), paras. 42–43.
96 *Ibid.*, para. 6.
97 Article 2(2)(b).

also into account' is ambiguous.[98] On the one hand, it could refer to only those health risks that occur as a consequence of the adverse effects that an LMO may have on biological diversity.[99] On the other hand, the reference to human health could also be interpreted more broadly as including risks to human health that *directly* result from an LMO (e.g. increased allergenicity) without the LMO necessarily having adverse effects on biodiversity.[100] According to a third view, health impacts are not recognized as a compensable category of damage but merely need to be taken into account 'as one of the factors to determine the significance of adverse effects' to biological diversity.[101]

The Supplementary Protocol's *travaux préparatoires* offer no guidance as to the correct interpretation of the phrase in question. The inclusion of risks or damage to human health in the definition of 'damage to biological diversity' was controversial throughout the negotiations of both protocols.[102] In the context of the Supplementary Protocol, some parties advocated for including damage to human health as a compensable type of damage, while others argued that the reference to 'risks to human health' was merely an aspect when evaluating possible damage to biodiversity.[103]

98 Cf. *Aarti Gupta*, Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety, 42 (2000) Environment: Science and Policy for Sustainable Development 22; *Ruth Mackenzie* et al., An Explanatory Guide to the Cartagena Protocol on Biosafety (2003), MN. 45–51; *Shibata* (n. 8), 22; *Tladi* (n. 5), n. 12 on p. 6; *Espinosa* (n. 68), 326–327; *Jusoh* (n. 6), 191; *Gupta/Orsini* (n. 6), 448.

99 *Mackenzie* et al., IUCN Guide (n. 98), MN. 49; cf. *Eriko Futami/Tadashi Otsuka*, A Japanese Approach to the Domestic Implementation of the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 201, 203.

100 *Mackenzie* et al., IUCN Guide (n. 98), MN. 50; the same view is apparently taken regarding the CBD by *Glowka* et al., IUCN Guide to the CBD (n. 64), 45–46.

101 *Lim Tung* (n. 6), 73.

102 For the Cartagena Protocol, see *Mackenzie* et al., IUCN Guide (n. 98), MN. 48. For the Supplementary Protocol, see *Shibata* (n. 8), 22, who contends that the reference to human health 'was deliberately left open for the Parties to interpret'.

103 Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, Synthesis of Proposed Texts and Views on Approaches, Options and Issues Identified Pertaining to Liability and Redress in the Context of Article 27 of the Biosafety Protocol: Note by the Co-Chairs, UN Doc. UNEP/CBD/BS/WG-L&R/2/2 (2006), 20–22; also see *Espinosa* (n. 68), 337–338; *Dire Tladi*, Challenges and Opportunities in the Implementation of the Supplementary Protocol: Re-Inter-

Other parties argued that damage to human health fell into the category of 'traditional damage' and thus was to be addressed by rules on civil liability.[104] Indeed, the substantive provisions of the Supplementary Protocol do not provide a remedy for personal injury but remain strictly focused on biodiversity damage.[105] It thus seems reasonable to conclude that damage to human health, as a type of personal injury, is outside the scope of 'damage to biological diversity'.[106] Instead, the obligation to 'take into account' risks to human health requires considering health risks when determining whether adverse effects of LMOs amount to 'damage to biodiversity' as defined in the preceding parts of the definition.

5. Domestic Criteria to Address Damage

Article 3(6) of the Supplementary Protocol provides that 'Parties may use criteria set out in their domestic law to address damage that occurs within the limits of their national jurisdiction'. Again, the meaning of this provision is far from obvious, because the Protocol does not specify what is meant by 'addressing damage'.[107] However, the drafting history shows that this rule was inserted to provide parties with significant discretion to define for themselves what constitutes *biological diversity* and what constitutes *damage* to the so-defined biological diversity.[108] Thus, parties are allowed to continue using their existing definitions of 'damage' or even to derogate from the concept of *damage to biological diversity* altogether.[109] Consequently, the respective Japanese legislation on liability for damage caused by GMOs only covers adverse effects to native and wild species, which excludes cultivated crops and non-native species.[110] Similarly, the European Union's *Environmental Liability Directive* merely covers damage to certain enlisted protected species and natural habitats, but not to bio-

pretation and Re-Imagination, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014), 175.

104 Synthesis of Proposed Texts (2006) (n. 103), 21; on civil liability in the Supplementary Protocol see *infra* section D.

105 See *infra* section C.I.

106 On personal injury, see *infra* section D.I.

107 Cf. *Yifru/Garforth* (n. 9), 156.

108 See *Shibata* (n. 8), 37; IISD, Friends of the Co-Chairs Highlights: Monday, 8 February 2010, ENB Vol. 9 No. 491 (2010), 1.

109 *Yifru/Garforth* (n. 9), 156.

110 *Shibata* (n. 8), 37–38; see *Futami/Otsuka* (n. 99), 213–214.

diversity *per se*.[111] Nevertheless, in light of Article 3(6), these implementations appear to be consistent with the Supplementary Protocol.[112]

6. Types of Damage Not Addressed by the Supplementary Protocol

The preceding sections have shown that the scope of the Supplementary Protocol is clearly restricted to damage to biological diversity, i.e. a particular type of damage to the environment *per se*.[113] Individual damage such as bodily harm, or property damage, is only addressed by the truncated provisions on civil liability in Article 12 and only as long as such damage is 'associated with' biodiversity damage.[114] Personal and material damage which does not result from biodiversity damage is ruled out from the Supplementary Protocol.[115]

Various other types of damage that LMOs might cause are also not covered by the Supplementary Protocol. Most strikingly, it does not address economic loss caused, for instance, by contamination of organic or conventionally grown crops with LMOs or their pollen, which often affects the market value of these crops or even renders them unsaleable.[116] Furthermore, the Supplementary Protocol does not address adverse socio-economic effects in terms of Article 26 of the Cartagena Protocol,[117] which

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111 Cf. Article 2(1)(a) of the EU Environmental Liability Directive (n. 18), which defines the term 'environmental damage' as, *inter alia*, 'damage to protected species and natural habitats, which is any damage that has significant adverse effects on reaching or maintaining the favourable conservation status of such habitats or species'. Also see *Brans/Dongelmans* (n. 26), 198–199.

112 But see *ibid.*, 198–200, arguing that there are important differences between the Supplementary Protocol and the EU-ELD concerning the scope of both regimes and their measure of damages, and that implementing the Supplementary Protocol into EU law by extending the scope of the EU-ELD required substantive changes to the latter.

113 On the difficulties in defining 'damage to biological diversity', see *Espinosa* (n. 68). On the compensability of damage to the environment *per se* under international law, see chapter 11, section B.I.

114 See *infra* section D.I.

115 *Lefeber* (n. 19), 90.

116 Cf. *Lim Tung* (n. 6), 72–74, referring to a number of cases concerning contamination of conventional or organic crops; *Cullet* (n. 5), 177; *Lim Tung* (n. 6), 72–74; also see *Förster* (n. 5), 336; *Jusoh* (n. 6), 100–103.

117 The inclusion of 'damage to socio-economic considerations' (or 'conditions') was proposed during the negotiations of the Supplementary Protocol, but eventually not adopted in the final text. See CP COP-MOP, Final Report of

may concern issues such as food security, public health, spiritual and cultural values, traditional practices and market access.[118] This is in line with the object and purpose of the Supplementary Protocol, which is neither meant to establish nor does it actually establish a comprehensive liability regime for any damage other than to biodiversity.[119]

7. Conclusions

The preceding discussion of the types of damage addressed by the Supplementary Protocol has shown that it falls far short of addressing all potential adverse effects of LMOs. Its rigorous focus on damage to biological diversity stands in line with the objective of the CBD but stops short of the Cartagena Protocol. As shown earlier, the Cartagena Protocol's main purpose is less to protect biodiversity as a 'global common' but rather to protect the sovereign decision-making of each party on whether to admit LMOs into its territory.[120] While a transboundary movement, as will be shown in the next section, is a precondition for the Supplementary Protocol to apply, it is far from covering all relevant types of adverse effects that may result from such movements.

The most significant shortcoming is Article 3(6), which expressly allows the member states to determine the occurrence of damage according to any criteria of their own. The European Union has vehemently promoted its *Environmental Liability Directive* as a role model in the negotiations.[121] Hence, the other delegations cannot have overlooked the fact that this very Directive fails to address damage to biological diversity in the sense

the Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, UN Doc. UNEP/CBD/BS/COP-MOP/4/11 (2008), 9; *Gouritin* (n. 68), 158–159; *Lim Tung* (n. 6), 73; *Espinosa* (n. 68), 338.

118 Article 26 of the Cartagena Protocol expressly allows parties to take socio-economic considerations 'into account' in their decision-making on the import of LMOs. For details, including a closer analysis of the meaning of the term 'socio-economic considerations', see chapter 3, section A.II.1.e). *Förster* (n. 5), 338, argues that due to the vagueness of the concept of socio-economics, liability for adverse socio-economic effects would be unpredictable.

119 *Yifru/Garforth* (n. 9), 160; *Nijar* (n. 15), 113–114; *Lim Tung* (n. 6), 72–74; *Gouritin* (n. 68), 158–159.

120 See chapter 3, section A.III.

121 See *Gouritin* (n. 68), 164–166.

defined in the CBD but merely covers damage to some of its components that enjoy special legal protection.[122]

III. Damage Resulting from LMOs 'Which Find Their Origin in a Transboundary Movement' (Article 3(1))

Pursuant to Article 3(1), the Supplementary Protocol applies to damage resulting from living modified organisms 'which find their origin in a transboundary movement'. This requirement is semantically confusing. Since 'transboundary movement' is defined as 'the movement of a living modified organism from one Party to another Party',[123] an LMO can hardly 'originate' from a transboundary movement. What is meant is that damage (in the defined sense) must result from an LMO that has previously been subject to a transboundary movement.[124]

Both the Cartagena Protocol and the Supplementary Protocol distinguish between different kinds of transboundary movements, namely *intentional and lawful* transboundary movements (1.), *unintentional* transboundary movements (2.), *intentional but illegal* transboundary movements (3.), and transboundary movements from non-parties (4.). Moreover, damage may also occur from LMOs in transit (5.) and from purely domestic activities involving LMOs (6.).

1. Damage Resulting From Authorized Uses Following Intentional Transboundary Movement (Article 3(2))

With regard to LMOs that have been subject to an *intentional* (and *lawful*[125]) transboundary movement, Article 3(2) provides that the Supplementary Protocol applies 'to damage resulting from any authorized use' of such LMOs. This constitutes a significant restriction of the Supplementary

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122 See *Brans/Dongelmans* (n. 26), 198–200.

123 Article 3(k) CP.

124 *Nijar* (n. 6), 273.

125 As shown earlier, any intentional transboundary movement carried out in contravention of a party's domestic measures to implement the Cartagena Protocol is referred to as an 'illegal transboundary movement' (see Article 25(1) CP and chapter 3, section A.II.2.c). Thus, *e contrario*, any transboundary movement carried out *in compliance* with the pertinent implementing measures is a 'lawful' transboundary movement.

Protocol's scope since it excludes damage resulting from LMOs that were lawfully *imported* but afterwards *used* without appropriate authorization. Such a situation could arise, for instance, when an LMO is (truthfully) declared to be intended for contained use at the time of import (and thus not subject to the AIA mechanism) but later released without authorization.[126]

Since the exclusion of LMOs unlawfully released into the environment seemingly contradicts the overall objective of the Supplementary Protocol, it could be questioned whether such a restriction was indeed intended by the negotiating parties or whether it constitutes an unintended *lacuna* that would justify an extensive interpretation of the Supplementary Protocol or even an analogous application to these cases.[127] However, the *travaux préparatoires* show that a distinction between authorized and unauthorized uses of LMOs was discussed during the drafting process, but the references to unlawful uses were removed later in the course of the negotiations.[128] Furthermore, the list of 'operators' who can be held liable under the Supplementary Protocol includes, among others, the developer, importer, and permit-holder, but not the person who actually released an LMO into the environment.[129] Hence, damage resulting from any *unauthorized use* of an LMO after it has been *lawfully imported* appears to be excluded from the Supplementary Protocol's scope.

126 See chapter 3, section A.II.1.g).

127 See *Silja Vöneky*, Analogy in International Law, in: Wolfrum/Peters (ed.), MPEPIL, MN. 2.

128 See Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, Synthesis of Proposed Operational Texts on Approaches and Options Identified Pertaining to Liability and Redress in the Context of Article 27 of the Biosafety Protocol: Fourth Meeting of the Working Group, Montreal, 22–26 October 2007, UN Doc. UNEP/CBD/BS/WG-L&R/4/2 (2007), 5–6, where several proposals referred to 'damage resulting from any authorized use of the LMO, as well as any use in violation of such authorization'. A separate question was whether the Supplementary Protocol should extend to damage resulting from uses of the LMO for purposes different to that specified at the time of the transboundary movement of the LMO, see Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety (n. 128), 11.

129 Cf. Article 2(2)(c) SP; see *infra* section C.II.

2. Damage Resulting From Unintentional Movements (Article 3(3))

Article 3(3) clarifies that the Supplementary Protocol also covers damage resulting from *unintentional* transboundary movements. Hence, the Protocol applies to situations where an LMO uncontrolledly spreads into another state[130] and causes biodiversity damage there. These situations are already addressed in Article 17 of the Cartagena Protocol, which provides that when a state 'knows' of a release of an LMO which may lead to an unintentional transboundary movement, it is required to notify and consult the potentially affected states, provided that the LMO in question is likely to have significant adverse effects on biodiversity.[131] After the affected state has been notified, it is that state's sole responsibility to take the necessary action.[132] The Supplementary Protocol obliges neither the state of origin nor the responsible foreign operator to take response measures, nor does it require them to bear the costs of such measures taken by the affected states.[133]

Moreover, the Supplementary Protocol also does not cover 'transboundary damage' *stricto sensu*,[134] that is damage caused by activities under the jurisdiction of one state which also affects the territory of another state.[135] This means that the Protocol does not apply to transboundary harm caused by an LMO which has *not* been subject to a transboundary movement, for instance when an LMO facilitates the spread of a non-altered invasive species into another state's territory. Furthermore, the mere unsolicited presence of an LMO in the territory of another state (if this was

130 An unintended transboundary movement could occur, for instance, by natural migration, carried by animals, pollen or seed, or inadvertently transported by humans, e.g. along with other goods or in clothing.
131 See chapter 3, section A.II.2.b).
132 This is also evidenced by Article 17(4) CP, which provides that the state of origin shall consult the affected states 'to enable them to determine appropriate responses and initiate necessary action, including emergency measures'.
133 Note that the affected state(s) may invoke the international responsibility of the state of origin, provided that there has been a breach of an international obligation which can be attributed to that state, see chapter 9.
134 *Yifru/Garforth* (n. 9), 157–158.
135 Cf. ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148, Article 2(c) and commentary, para. 9; *Hanqin Xue*, Transboundary Damage in International Law (2003), 316; see chapter 4, section B.

to be considered *transboundary damage* at all[136]) does not give rise to liability under the Supplementary Protocol unless the LMO causes biodiversity damage or threatens to do so.

3. Damage Resulting From Illegal Transboundary Movements (Article 3(3))

Article 3(3) provides that the Supplementary Protocol also applies to damage resulting from illegal transboundary movements. This refers to Article 25 of the Cartagena Protocol, which provides that any movements carried out in contravention of any party's domestic measures to implement the Protocol shall be deemed 'illegal transboundary movements' and shall be prevented by the parties to the Protocol.[137] Since this includes domestic measures to implement the *Advance Informed Agreement* (AIA) mechanism, any damage resulting from an LMO imported without the AIA of the party of import is covered by the Supplementary Protocol. This may be relevant, for instance, when private actors import and release gene drive-equipped organisms without the necessary approvals and authorizations.[138] Against this background, it is even less understandable that LMOs that were lawfully imported but subsequently released illegally are excluded from the scope.[139]

4. Damage Resulting From Transboundary Movements From Non-Parties (Article 3(7))

According to Article 3(7), domestic law implementing the Supplementary Protocol shall also apply to damage resulting from transboundary movements of LMOs from non-parties. This means that LMOs imported from abroad will always be subject to domestic liability provisions established by states parties to the Supplementary Protocol, regardless of whether the state of origin also is a party to the Supplementary Protocol or not. Consequently, operators (such as exporters) situated in a non-party state may still

136 This is assumed by *Yifru/Garforth* (n. 9), p. 158, note 31, but see chapter 4, section B.VII.
137 See chapter 3, section A.II.2.c).
138 In this context, see chapter 3, section A.II.1.g).
139 See *supra* section B.III.1.

have to comply with the requirements imposed by the importing party in implementing the Supplementary Protocol.[140] The main problem in this context will be that liability may not be enforceable in such situations, as the states are not generally required to recognize foreign judgments establishing the liability of operators situated in their jurisdiction (unless there are international agreements expressly providing for mutual recognition and enforcement of judgments, such as in the EU[141]). However, this problem is not limited to operators from non-party states since, as shown below, the Supplementary Protocol does not even provide for mutual recognition and enforcement of judgments among its parties.[142]

5. Damage Resulting From LMOs in Transit

The Supplementary Protocol does not expressly stipulate whether it applies to damage arising from LMOs in transit. But Article 4 of the Cartagena Protocol expressly provides that the latter shall also apply to the transit of LMOs[143] and, as shown above, the provisions of the Cartagena Protocol apply *mutatis mutandis* to the Supplementary Protocol.[144] Consequently, the Supplementary Protocol also applies to damage resulting from LMOs that are merely in transit through the territory of a state party, for instance when the LMO unintentionally escapes into the environment of the transit state.

6. Damaged Caused by Domestic Activities With LMOs

The Supplementary Protocol does not cover damage caused by LMOs that have not been subject to a transboundary movement. The reason for this lies in the Supplementary Protocol's parent instrument, the Cartagena Protocol, which primarily serves to regulate the transboundary movement

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140 *Lima* (n. 58), 134.
141 See chapter 2, section F.
142 See *infra* section F.II.
143 Note that the transit of LMOs is not subject to the AIA procedure provided for by the Cartagena Protocol, nevertheless this is without prejudice to any right of a party of transit to regulate the transport of LMOs through its territory domestically, see Article 6(1) Cartagena Protocol.
144 Article 16(3) SP, see *supra* note 46 and accompanying text.

of LMOs.[145] However, there is no apparent reason barring states from extending their measures implementing the Supplementary Protocol also to damage caused by LMOs of domestic origin. This could even be required in order to ensure that implementation measures comply with the principle of *domestic treatment* under international trade law,[146] an issue expressly left open by both protocols.[147]

7. Conclusions

The Supplementary Protocol applies when damage to biological diversity results from an LMO that has previously been subject to a transboundary movement, regardless of whether this movement was intentional and authorized, intentional but illegal, unintentional, or occurred due to an accidental release during transit. Against this background, the exclusion of damage resulting from illegal uses following a lawful import is a striking omission. Although it could be questioned whether environmental liability law is an appropriate tool to address criminal behaviour at all, the fact that damage following an illegal transboundary movement is expressly encompassed shows that the parties did not intend to exonerate illegal conduct from liability generally. However, the *travaux préparatoires* unambiguously show that unauthorized uses following a lawful import were meant to be excluded from the Supplementary Protocol's scope.

IV. Temporal Scope (Article 3(4))

According to Article 3(4), the Supplementary Protocol applies to damage resulting from a transboundary movement of LMOs that 'started' after the Supplementary Protocol entered into force for the party of import concerned. In contrast, the Cartagena Protocol's AIA procedure applies to the 'first intentional transboundary movement' of certain LMOs. However,

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145 See chapter 3, section A.III.

146 Cf. General Agreement on Tariffs and Trade 1994 (15 April 1994; effective 01 January 1995), 1867 UNTS 187, Annex 1A, Article III(4); see CropLife International/Global Industry Coalition, Implementation Guide to the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (2013), 5; also see chapter 3, section C.I.

147 For the Cartagena Protocol, see chapter 3, section C.III. For the Supplementary Protocol, see *infra* section E.V.

the two provisions seem not to have a substantial difference in meaning, as both refer to the point in time when the LMO in question has reached the territory of the importing party for the first time, regardless of whether the movement was intentional, unintentional or illegal.

V. Spatial Scope (Article 3(5))

According to Article 3(5), the Supplementary Protocol applies to 'damage that occurred in areas within the limits of the national jurisdiction of Parties'. Hence, the Supplementary Protocol does not focus on where damage *originates* but on where it *occurs*, i.e. where the adverse effects on biodiversity materialize.

Besides its land territory, the territorial jurisdiction[148] of a state extends to its internal waters and the territorial sea adjacent to its coast.[149] Hence, the present provision clearly rules out damage that occurs in areas *beyond* the limits of national jurisdiction.[150] The inclusion of such damage was discussed during the negotiations of the Supplementary Protocol[151] but ultimately rejected in favour of a 'narrow' geographical scope.[152] This

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148 In public international law, the term 'jurisdiction' generally refers to the lawful power of a state to make and enforce rules. While jurisdiction can be based on a number of bases, its most common form is 'territorial jurisdiction' which is based on a state's sovereignty over its territory and certain adjacent maritime areas (see *Bernard H. Oxman*, Jurisdiction of States, in: Wolfrum/Peters (ed.), MPEPIL, MN. 9–42; *Shaw* (n. 57), 483–488; *Crawford* (n. 57), 192). By referring to '*areas* within the *limits* of national jurisdiction', Article 3(5) clearly indicates that it refers to territorial jurisdiction. The notion is related to the term 'areas beyond the limits of national jurisdiction' used in the international law of the sea, where it denotes the high seas beyond those maritime zones in which individual states may lawfully assert individual claims (see United Nations Convention on the Law of the Sea (10 December 1982; effective 16 November 1994), 1833 UNTS 3 (hereinafter 'UNCLOS'), Article 1(1)(1).

149 Cf. *Oxman* (n. 148), MN. 13–17.

150 *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 798; see chapter 4, section B.II.2.

151 Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, Report of the […] Fourth Meeting, UN Doc. UNEP/CBD/BS/WG-L&R/4/3 (2007), Operational text 6 on page 15.

152 IISD, Summary of the Fifth Meeting of the Open-Ended Ad Hoc Working Group on Liability and Redress in the Context of the Cartagena Protocol on Biosafety: 12–19 March 2008, ENB Vol. 9 No. 345 (2008), 4.

appears to be consistent with the Cartagena Protocol, which only governs the *transboundary* movement of LMOs, i.e. the movement 'from one Party to another Party',[153] but remains silent on the movement of LMOs to areas beyond national jurisdiction.[154]

Moreover, it is questionable whether the Supplementary Protocol applies to damage occurring in the *exclusive economic zone* (EEZ) of coastal states. In this area, which extends up to 200 nautical miles from the coastline,[155] the coastal state has 'sovereign rights' to explore, exploit, conserve, and manage the living and non-living resources.[156] In addition to these sovereign rights, the coastal state also enjoys 'jurisdiction' over a number of other matters, including the protection and preservation of the marine environment.[157] At the same time, all other states enjoy the so-called 'freedom of the high sea', which includes, *inter alia*, the freedom to sail ships flying their flag and the freedom of overflight.[158]

There is no express provision in the UNCLOS that confers jurisdiction to the coastal state with respect to liability for damage to the marine environment in the EEZ. However, Article 229 UNCLOS provides that the Convention shall not affect the right to institute civil proceedings for loss or damage caused by pollution of the marine environment.[159] Although it refers to 'civil liability', Article 229 UNCLOS could be interpreted extensively so as to allow not only for civil proceedings but also for the imposition of administrative liability as set out in the Supplementary Protocol. This is supported by Article 235(2) UNCLOS, which requires states to ensure that adequate remedies are available against pollution of the marine environment. Moreover, Article 235(3) UNCLOS requires states to further develop international law relating to liability for damage to the marine environment. Consequently, it can be assumed that the coastal state has jurisdiction for biodiversity damage in the EEZ resulting from LMOs and that the Supplementary Protocol is, therefore, applicable to such damage.

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153 Cf. Article 3(k) CP.

154 *Jusoh* (n. 6), 192.

155 See Articles 55 et seq. UNCLOS (n. 148). See generally *Dolliver Nelson*, Exclusive Economic Zone, in: Wolfrum/Peters (ed.), MPEPIL, MN. 1.

156 See Article 56(1)(a) UNCLOS (n. 148).

157 See Article 56(1)(b)(iii) UNCLOS.

158 See Articles 87(1)(a) and (b) UNCLOS.

159 Cf. *Vasco Becker-Weinberg*, Article 229 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017), MN. 1.

In any event, it might be challenging to effectively implement the provisions of the Supplementary Protocol in the EEZ with respect to foreign vessels.[160] This is particularly true considering that in most cases, the responsible vessel will have left the coastal state's EEZ long before the release of an LMO is detected or the detrimental effects on biodiversity become evident.

VI. Conclusions

The preceding analysis has shown that, in principle, the Supplementary Protocol has a broad scope of application. It applies to all possible types of damage to biological diversity resulting from an LMO regardless of its intended or actual use, provided that the LMO has been subject to a transboundary movement and damage is both measurable and significant. On closer inspection, however, there are several limitations that leave the parties considerable leeway for their national implementation. The Protocol does not provide conclusive guidance on the circumstances in which adverse effects on biological diversity constitute 'damage' that shall give rise to liability.[161] Parties may even apply their own definitions of 'damage' to biodiversity.[162] Whether damage is 'measurable' and 'significant' (which is a necessary condition for liability to arise at all) is also left up to the determination of the competent national authorities. In sum, it is therefore doubtful whether the Supplementary Protocol signifies a harmonized understanding of when unwanted side-effects of releasing an LMO shall give rise to liability.[163]

C. Administrative Liability: Response Measures to Redress Damage to Biological Diversity

As shown above, the term 'liability' is not always used consistently in international law.[164] Most treaties on operator liability for environmental damage refer to liability as *civil liability*, which denotes the obligation of

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160 See *ibid.*, MN. 10.
161 *Shibata* (n. 8), 37.
162 See supra, section B.II.5.
163 *Yifru/Garforth* (n. 9), 156.
164 See chapter 2, sections C.

the operator to pay monetary compensation for the damage caused by its activity. Besides, several more recent instruments follow a so-called *administrative approach*, which is characterized by the requirement for the operator to actively take response measures to mitigate and remediate the damage or to reimburse others for the expenses incurred in taking such measures, instead of simply paying monetary compensation.[165]

During the negotiations of the Supplementary Protocol, it was agreed to develop an instrument that follows the administrative approach but also includes a legally binding provision on civil liability.[166] Consequently, the Supplementary Protocol takes a 'two-pronged approach'[167] – with regard to damage to biological diversity, the instrument provides for the implementation of response measures, while material or personal damage that is 'associated with' damage to biodiversity is addressed by the provision on civil liability. Hence, each of the approaches serves to address different types of damage. The present section analyses the Supplementary Protocol's provisions on administrative liability, while the provision on civil liability is addressed in the subsequent section.[168]

The preamble to the Supplementary Protocol recognizes the need 'to provide for appropriate response measures where there is damage or sufficient likelihood of damage' to biological diversity.[169] Response measures are actions taken to restore the damage that has already occurred and to prevent further damage (I.). The responsibility to implement response measures is imposed on the 'responsible operator' (II.), provided that a causal link between the LMO in question and the damage can be established (III.). The implementation of liability is premised on the existence of a 'competent authority' that identifies the responsible operator and determines which measures shall be taken (IV.) To this end, parties are required to implement the Supplementary Protocol into their domestic law (V.).

165 See chapter 2, section G.
166 IISD (n. 30), 7.
167 *Lim Tung* (n. 6), 69.
168 See *infra* section D.
169 Cf. Recital 4 of the Supplementary Protocol.

I. Meaning and Scope of 'Response Measures'

Pursuant to Article 5(1)(c), states parties shall require the appropriate operator or operators to take 'appropriate response measures'. The term 'response measures' is defined in Article 2(2)(d) as

> *'reasonable actions to*
> *(i) Prevent, minimise, contain, mitigate, or otherwise avoid damage as appropriate;*
> *(ii) Restore biological diversity through actions to be undertaken in the following order of preference:*
> *a. Restoration of biological diversity to the condition that existed before the damage occurred, or its nearest equivalent; and where the competent authority determines this is not possible;*
> *b. Restoration by, inter alia, replacing the loss of biological diversity with other components of biological diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location'.*

As can be seen from the definition, the concept of response measures pursues a two-fold objective. In the first place, response measures shall prevent (further) loss of biodiversity, e.g. by containing or removing the noxious LMO from the affected environment. The nature and scope of measures necessary to achieve this aim will very much depend on the individual circumstances. Where damage to biological diversity cannot be prevented by remediation measures, the Supplementary Protocol provides that reasonable actions shall be taken to restore biological diversity to the condition that existed before the damage occurred or to its nearest possible equivalent.[170]

With regard to the envisaged use of engineered gene drives in mosquitoes,[171] researchers have suggested that a 'logical remediation strategy' for small-scale releases could be an intense application of standard pesticides followed by monitoring.[172] In the event of a larger-scale release, remediation would require additional vector control methods such as indoor residual spraying and larval source management.[173] Alternatively, re-

170 Article 2(2)(d)(i) SP.
171 See chapter 1, section C.III.1.
172 *Stephanie James* et al., Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group, 98 (2018) Am. J. Trop. Med. Hyg. 1, 13.
173 *Ibid.*

mediation could be achieved by releasing a variant of the target organism carrying a drive-resistant gene to halt the spread or by releasing another driving construct designed to ‘reverse’ the original gene drive.[174]

When the competent national authority determines that restoration of biological diversity to its *status quo ante* is not possible, the loss shall be replaced with other components of biodiversity for the same or another type of use at either the same or an alternative location.[175] By improving biodiversity with other components than those damaged or in other locations, the Supplementary Protocol provides for a form of *compensatory restoration*.[176] This approach is also known in other legal regimes.[177] Usually, compensatory restoration measures are implemented in areas proximate to the injured site or in other locations suitable to compensate for the injured species or ecosystem.[178] However, the Supplementary Protocol does neither determine the nature or scope of ‘compensatory’ response measures nor how to assess whether the measures taken are sufficient to compensate for the damage.[179]

The Supplementary Protocol also does not provide a mechanism to compensate for biodiversity damage that cannot be reasonably replaced by

174 *Ibid.*

175 Article 2(2)(d)(ii) SP.

176 *Förster* (n. 5), 391 refers to equivalent replacement measures as ‘alternative restitution’. This appears to confuse the terms ‘restitution’ and ‘compensation’ since, taxonomically, the term ‘restitution’ refers to reinstating the *status quo ante*. However, alternative measures are not capable of reinstating specific damage to the environment, but can merely compensate for the incurred loss by improving environmental quality elsewhere. They are thus not a form of restitution, but of compensation. This view appears to be shared by *Förster*, who in the main part of her study refers to ‘Ausgleich durch gleichwertige Ersatzmaßnahmen’, which translates to ‘compensation by equivalent replacement measures’, cf. *Förster* (n. 5), 345–346.

177 The EU-ELD follows a similar approach, but distinguishes between ‘compensatory remediation’, which shall compensate for the interim losses from the date of damage until the environment has been fully restored, and ‘complementary remediation’, which compensates for environmental losses that will not (fully) return to its baseline conditions, cf. EU Environmental Liability Directive (n. 18), Annex II. On compensatory restoration under international law generally, see chapter 11, section B.II.1.

178 *Michael T. Huguenin* et al., Assessment and Valuation of Damage to the Environment, in: Cymie R. Payne/Peter H. Sand (eds.), Gulf War Reparations and the UN Compensation Commission (2011) 67, 78.

179 Cf. *Förster* (n. 5), 350–351. Also see *Schmitt* (n. 80), 83, who criticizes that the Supplementary Protocol does not specify against which standard the equivalence of alternative measures shall be assessed.

compensatory restoration.[180] In this regard, it steps short of the *Antarctic Liability Annex*, which provides that in cases where no response action was taken, the responsible operator shall be liable to pay the 'costs of response action which should have been undertaken' to an international fund.[181] The fund shall then be used, *inter alia*, to reimburse costs for response measures when the responsible operator cannot be held liable.[182]

In sum, the response measures provided for by the Supplementary Protocol serve to pursue the following aims. Firstly, response measures shall avert damage wherever possible and as much as possible. Secondly, where damage cannot be avoided, biological diversity shall be restored to the condition that existed before the incident. Thirdly, where restitution is impossible, measures to compensate for the loss of biodiversity shall be taken by improving biological diversity in other components or at other locations. The priority of prevention over restoration, and of restoration over compensation, is clearly stipulated in the Supplementary Protocol and thus binding upon all of its parties. In this respect, the Supplementary Protocol sets out clear and specific objectives. Yet, the nature and extent of response measures remain to be determined by the parties' competent authorities according to their own priorities and the particular circumstances of every individual case.[183]

II. Identification of the Liable Operator

The obligations stipulated in Article 5(1) shall be imposed on the 'appropriate operator'. According to Article 5(2)(a), the competent authority shall 'identify the operator which has caused the damage' and which shall

180 *Förster* (n. 5), 358–360, points out the difficulties associated with the financial assessment of biodiversity damage. Possible components of such a valuation could include economic benefits derived from ecosystem services prior to the incident as well as an intrinsic, immaterial value of biodiversity, see *Unai Pascual* et al., The Economics of Valuing Ecosystem Services and Biodiversity, in: Pushpam Kumar (ed.), The Economics of Ecosystems and Biodiversity: Ecological and Economic Foundations (2010) 183, 196–211.

181 Antarctic Liability Annex (n. 19), Article VI(2); see *Silja Vöneky*, The Liability Annex to the Protocol on Environmental Protection to the Antarctic Treaty, in: Doris König/Peter-Tobias Stoll et al. (eds.), International Law Today: New Challenges and the Need for Reform? (2008) 165, 185–187.

182 Antarctic Liability Annex (n. 19), Article XII(1); see *Vöneky* (n. 181), 191.

183 Cf. *Tladi* (n. 103), 176.

consequently be held liable. The notion of 'operator' is defined in Article 2(2)(c) as

> *'any person in direct or indirect control of the living modified organism which could, as appropriate and as determined by domestic law, include, inter alia, the permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier'.*

This definition is remarkably broad and covers all persons involved with LMOs in the course of their occupational activities, including those who are only in 'indirect control' of the LMO.[184] Although not expressly mentioned, there is no doubt that the definition refers to natural and legal persons alike.[185] Furthermore, the list of possible operators is only illustrative and non-exhaustive, as indicated by the terms 'which could […] include, *inter alia* […]'.

It is questionable whether the operator held liable must have 'caused' the damage by its own conduct or whether it is sufficient that the damage resulted from the inherent characteristics of the LMO. Since Article 5(2)(a) refers to the 'operator *which has caused* the damage',[186] it could be argued that an operator can only be held liable when it has made a causal contribution to the damage.[187] This would almost always be the person who – whether intentionally or unintentionally – released the LMO into the environment, since the release is a *conditio sine qua non*, i.e. the last necessary link in any possible causal chain between the development of an LMO and the occurrence of damage. At the same time, Article 4 provides that a causal link 'shall be established between the damage and the living modi-

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184 Cf. *Shibata* (n. 8), 39; *Anastasia Telesetsky*, Introductory Note to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, 50 (2011) ILM 105, 106.

185 *Brans/Dongelmans* (n. 26), 186; see 'person', in: *Bryan A. Garner* (ed.), Black's Law Dictionary (11th ed. 2019), 1378–1379. Also see the definition of 'exporter' and 'importer' in Article 3(d) and (f) of the Cartagena Protocol, which refer to 'any legal or natural person'.

186 Emphasis added.

187 *Lim Tung* (n. 6), 75–76 contends that '[l]egal causation between the conduct of the suspected operator (or his or her agents) and the harm must be sufficiently compelling' (emphasis added). Similarly, *Jungcurt/Schabus* (n. 6), 202 assume that the competent authority must be able to establish the causal chain from damage to the 'operator's activities', but also admit that the Supplementary Protocol leaves 'unclear […] how the burden of proof and causation would be regulated', *Jungcurt/Schabus* (n. 6), 204–205.

fied organism in question',[188] which suggests that the operator's conduct is irrelevant when the damage results from the inherent characteristics of the LMO.

According to *Shibata*, 'it is the causal link between the damage and the LMO (and not the activity) that must be proved in order to establish liability'.[189] Consequently, he assumes that there is a presumption that the operator who had direct or indirect control of the LMO at the time of the incident has 'caused the damage' in the sense of Article 5(2)(a).[190] However, the operator in control of an activity involving LMOs might not necessarily be the actor best equipped to take the necessary response measures when damage occurs.[191]

According to a different approach, the Supplementary Protocol allows to distinguish between different causes of damage: If the damage results from a 'development risk', i.e. is caused by the 'intrinsic quality' of the LMO (such as certain noxious traits or behaviours), the developer or the producer would be the appropriate parties to hold liable.[192] On the other hand, when damage results from inappropriate handling of the LMO, such as when the LMO was used outside its intended environment or when necessary precautions were ignored, the person exercising control over the LMO at the time of the incident should be held liable.[193] This interpreta-

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188 On the requirement to establish a causal link, see *infra* section C.III.

189 *Shibata* (n. 8), 39.

190 *Ibid.*

191 *Ibid.*, 40. For instance, when the release of an engineered gene drive has unintended adverse effects, those actors who have performed the actual release might be best equipped to implement conventional strategies that involve the spraying of pesticides, while the developer of the gene drive could (hypothetically) provide a 'reversal drive' to undo the genetic modifications performed by the original drive; see *Kevin M. Esvelt* et al., Concerning RNA-Guided Gene Drives for the Alteration of Wild Populations, 3 (2014) eLife e03401, 10; *James* et al. (n. 172), 13.

192 *Förster* (n. 5), 390; *Nijar* (n. 6), 276; *Alvarez-Morales* (n. 54), 107; *Shibata* (n. 8), 39–40. For an economic perspective, see *Michael G. Faure/Andri Wibisana*, Liability in Cases of Damage Resulting from GMOs: An Economic Perspective, in: Bernhard A. Koch/Bjarte Askeland (eds.), Economic Loss Caused by Genetically Modified Organisms (2008) 531, 542–545, who argue that imposing liability for unforeseeable damage on the developer is reasonable since it will induce the developer to invest in research in order to 'acquire as much information about risk and about optimal technologies to prevent the risk'.

193 Cf. *Alvarez-Morales* (n. 54), 107; *Shibata* (n. 8), 39–40; *Förster* (n. 5), 390.

tion seems to better reflect the intention of the Supplementary Protocol to impose liability on the 'operator which has caused the damage'.[194]

Problems may also arise when the operator who has caused the damage is not available because it is not situated within the jurisdiction of the party where the damage occurred.[195] It was suggested that, in these cases, liability could be channelled to any other operator who was involved in the transboundary movement and is available to the authorities of the state concerned.[196] While this would substantially increase the likelihood that the competent authorities find a solvent actor who can be held liable, such an operator would not be held liable on the ground of its own contribution to the damage (if this was regarded to be a relevant factor), but only because the operator is situated in the jurisdiction of the state concerned. It could be questioned whether this approach is consistent with the aforementioned Article 5(2)(a), which stipulates that liability shall be placed on that 'operator *which has caused the damage*'. However, as shown below, the Supplementary Protocol does not provide any mechanism to enforce the liability of foreign operators.[197] Therefore, it would be consistent with the overall approach of the Supplementary Protocol to impose liability on the operators available to the authorities concerned. Any right of redress of these operators would be governed by the domestic laws of the states concerned or, ideally, by contractual arrangements between those actors involved in the LMO's value chain.

A related problem concerns the attribution of liability where multiple operators have had direct or indirect control of the LMO that has caused damage. While Article 5(1) provides that parties shall require 'the appropriate operator *or operators*' to take response measures, Article 5(2) and the following provisions only refer to 'the operator' in singular. However, for reasons of effectiveness, it makes sense to compel all available operators to take response measures, while it can be left to these operators to distribute their individual shares of responsibility among themselves. This resembles the concept of *joint and several liability* in civil liability regimes, where the injured party can assert claims against any of the liable parties, which can subsequently seek redress from the other liable parties according to their

194 Article 5(2)(a) SP.
195 See *infra* section F.II.
196 *Nijar* (n. 6), 276.
197 See *infra* section F.II.

individual share of responsibility for the damage.[198] Such an approach has already been implemented in the context of administrative liability, for example in CERCLA in the United States[199] and the Antarctic Liability Annex.[200] While the Supplementary Protocol does not expressly prescribe this approach, it does not seem to oppose it either. According to Article 9, the Supplementary Protocol shall not limit or restrict any right of recourse or indemnity that an operator may have against any other person.[201] Thus, parties could implement *joint and several liability* in their domestic law by allowing those operators who have implemented response measures to seek proportionate redress from other operators.

After all, the identification of the liable actor will be subject to the domestic law of each party.[202] This is expressly confirmed in the definition of the term 'operator' in Article 2(2)(c), which provides that the responsible operator shall be 'determined by domestic law'. Thus, the Supplementary Protocol neither establishes clear criteria of who should be liable nor does it give conclusive guidance on the process of identifying the responsible operator.[203] Instead, states parties enjoy a wide margin of discretion to establish respective criteria in their domestic law and to identify a liable operator through their competent national authorities in individual cases of damage.[204] In this regard, states parties seeking a narrow application of the Supplementary Protocol may require that an operator has had some

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198 But see *Faure/Wibisana* (n. 192), 556–559, who argue that 'channelling' liability to one single operator (e.g. the developer) who shall then seek redress from the responsible parties might discourage these other parties from preventing damage in the first place.

199 Cf. CERCLA (n. 17), 42 U.S.C.§ 9613(f)(1); see *LeRoy C. Paddock*, Funding Contaminated Site Cleanup in the United States, 3 (1994) RECIEL 133, 135.

200 Antarctic Liability Annex (n. 19), Article 6(4).

201 See *infra* section E.I. Similarly, Article 9 of the EU Environmental Liability Directive (n. 18) merely provides that the Directive is without prejudice to any national rules on cost allocation in cases of multiple party causation.

202 *Shibata* (n. 8), 39.

203 This is unusual compared to other international liability instruments, which usually channel liability to clearly identifiable actors (see *Xue* (n. 135), 80–86; *Yifru* et al. (n. 68), 17). For instance, the Basel Protocol provides that the person who notifies the transboundary movement of hazardous waste shall be liable until the disposer has taken possession of it, after which the disposer shall be liable, cf. Basel Protocol on Liability for Hazardous Wastes (n. 60), Article 4(1). Under the Antarctic Liability Annex, liability is channelled to the person which organizes the activity in the Antarctic from which an environmental emergency arises, cf. Antarctic Liability Annex (n. 19), Article 2(c).

204 Cf. *Yifru/Garforth* (n. 9), 157.

sort of control of the LMO at the time of the incident or even require proof of causation, while states opting for a broader application may extend liability to any operator who was involved with the LMO in the course of activities that ultimately lead to the occurrence of damage.[205]

III. Establishment of a Causal Link and Standard of Proof (Article 4)

Article 4 of the Supplementary Protocol provides:

> '*A causal link shall be established between the damage and the living modified organism in question in accordance with domestic law.*'

The term 'establish' refers to the proof of the said causal link.[206] Hence, the provision requires that a cause-effect relationship between the LMO in question and the damage can be demonstrated.[207] However, proving such a causal link may be difficult for several reasons.[208] Firstly, there will likely be a significant lapse of time between the importation, release or placing on the market of the LMO on the one hand, and the occurrence of harm or the attempt to prove the causal chain on the other hand.[209] Secondly, in many cases damage will not be caused directly by the LMO but will result from causal chains of effects that the LMO has on ecosystems, food chains or non-target organisms.[210] Thirdly, proof of causality could be hampered by the fact that the causal relationships between noxious traits of an LMO and the occurrence of certain damage patterns cannot be established with scientific certainty even when there is a considerable likelihood that some causal relationship exists.[211]

It has been noted that the Supplementary Protocol requires establishing a causal link but does not stipulate how this shall be done.[212] A similar provision can be found in the EU's Environmental Liability Directive,

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205 *Tladi* (n. 103), 175.
206 Cf. 'established', in: Black's Law Dictionary (n. 185), 688; 'establish', in: Hay (ed.) (n. 206), 827.
207 See *Faure/Wibisana* (n. 192), 552–553, who argue that the requirement of a causal link for liability is necessary in order not to discourage potentially beneficial activities in society.
208 See *Lim Tung* (n. 6), 81–82.
209 *Alvarez-Morales* (n. 54), 107.
210 *Förster* (n. 5), 271.
211 *Ibid.*, 272.
212 *Brans/Dongelmans* (n. 26), 186.

which requires that it must be ‘possible to establish a causal link between the damage and the activities of individual operators’.[213] In the view of the *Court of Justice of the European Union*, this provision ‘does not specify how such a causal link is to be established’ and that, consequently, EU Member States have a ‘broad discretion’ when developing respective criteria in their domestic law.[214] Consequently, Member States may provide that a causal link is presumed when the competent authority has plausible evidence justifying such a presumption *prima facie*.[215] Similarly, in the *Pulp Mills* case before the ICJ, Judge *Greenwood* argued that in environmental disputes, the claimant state should be required to establish the facts it asserts only ‘on the balance of probabilities’, because ‘the nature of environmental disputes is such that the application of [a] higher standard of proof would have the effect of making it all but impossible for a State to discharge the burden of proof’.[216]

Like the EU Environmental Liability Directive, Article 4 of the Supplementary Protocol does not stipulate how a causal link shall be established but only provides that this shall be done ‘in accordance with domestic law’.[217] It can be seen from the *travaux préparatoires* that, instead of placing the burden of proof either on the claimant or the respondent, the issue was deliberately left to domestic law.[218] Hence, states parties are free to provide in their domestic law that the existence of a causal link can be presumed when facts point to harm being caused by a certain LMO.[219] The operator held liable may rebut such a presumption in accordance with domestic

213 Article 5(4) EU Environmental Liability Directive (n. 18).

214 CJEU, Raffinerie Mediterranee (ERG) SpA et al. v. Ministero dello Sviluppo economico et al., Judgment (Grand Chamber) of 09 March 2010, C-378/08, para. 55.

215 *Ibid.*, paras. 56–57.

216 ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment of 20 April 2010, ICJ Rep. 14, Separate Opinion of Judge Greenwood, para. 26.

217 See *Gouritin* (n. 68), 164.

218 Cf. Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety (n. 151), 23–25, see especially operational text 6, which closely resembles the final wording of Article 4; also see IISD (n. 30), 10. Also see *Vanessa Wilcox*, Damage Caused by GMOs Under International Environmental Law, in: Bernhard A. Koch (ed.), Damage Caused by Genetically Modified Organisms (2010) 754, 775–776, assuming that the causality standards elaborated by states parties ‘will no doubt reflect domestic policies on LMOs’.

219 *Nijar* et al. (n. 12), 144; *Brans/Dongelmans* (n. 26), 186; on the presumption of liability, see *Fritz Nicklisch*, Rechtsfragen der modernen Bio- und Gentechnologie, 44 (1989) Betriebs-Berater 1, 7–8.

legal requirements by showing that the damage was *not* caused by the LMO in question.[220] In fact, many domestic regimes contain provisions 'easing' the burden of proving causation.[221]

Another way to reduce evidentiary burdens is by requiring the operator to share relevant information about the LMO in question. The Cartagena Protocol stipulates certain information-sharing obligations,[222] but some domestic GMO liability regimes expressly require the operator to share relevant information with potential claimants in the event of damage.[223] In common law systems, the instrument of *pre-trial discovery* provides a similar means to obtain evidence from the defendant.[224] In the United States, pre-trial discovery can also be used by parties to legal proceedings outside the United States.[225] Moreover, the *Hague Evidence Convention* of 1970,[226] which currently has 64 parties,[227] facilitates the transboundary taking of evidence by national courts.[228]

While the Supplementary Protocol does not bar states from adopting lowered evidentiary thresholds for establishing a causal link between the damage and the LMO in question, it does not *require* that the burden of proof be lowered or even reversed. Such a requirement also seems not to result from general international environmental law, especially the

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220 *Nijar* et al. (n. 12), 144.

221 *Bernhard A. Koch*, Damage Caused by GMOs: Comparative Analysis, in: Bernhard A. Koch (ed.), Damage Caused by Genetically Modified Organisms (2010) 882, MN. 38–43.

222 See Article (8) in conjunction with Annex I, and Articles 17(3), 20(3)(c), and 25(3) CP.

223 See, e.g., Gentechnikgesetz (Genetic Engineering Act) (16 December 1993), last amended by Article 8 of the law of 27 September 2021 (Bundesgesetzblatt, Pt. I, p. 4530), Section 35; *Jane M. Glenn*, Damage Caused by GMOs Under Canadian Law, in: Bernhard A. Koch (ed.), Damage Caused by Genetically Modified Organisms (2010) 663, MN. 29.

224 *Stephen N. Subrin*, Fishing Expeditons Allowed: The Historical Background of the 1938 Federal Discovery Rules, 39 (1998) Boston College Law Review 691.

225 United States, Assistance to Foreign and International Tribunals and to Litigants Before Such Tribunals, 28 U.S.C. § 1782.

226 Convention on the Taking of Evidence Abroad in Civil or Commercial Matters (18 March 1970; effective 17 October 1972), 847 UNTS 241.

227 Hague Conference on Private International Law, Status Table: Convention on the Taking of Evidence Abroad in Civil or Commercial Matters (17 June 2021), available at: https://www.hcch.net/en/instruments/conventions/status-table/?cid=82 (last accessed 28 May 2022).

228 See *Diego Zambrano*, A Comity of Errors: The Rise, Fall, and Return of International Comity in Transnational Discovery, 34 (2016) Berkeley Journal of International Law 101–159.

precautionary principle.[229] Although it could arguably lead to a lowered evidentiary threshold in situations of risk of harm,[230] the precautionary principle appears not to be recognized as lowering the burden of proof for establishing the causes of environmental harm that has already materialized.[231]

IV. Implementation of Response Measures (Article 5)

Article 5 is the core provision of the Supplementary Protocol on the implementation of response measures. When damage occurs, state parties shall require the 'appropriate operator' to immediately inform the competent authority, evaluate the damage, and take 'appropriate response measures' (para. 1). The 'competent authority' of the state party concerned shall identify the 'operator which has caused the damage', evaluate the damage and determine which response measures the operator should take (para. 2). The competent authority shall also order response measures when there is an 'imminent threat of damage' (para. 3). It may take response measures itself, particularly when the operator has failed to do so (para. 4), and it may recover from the responsible operator its expenses for such measures as well as for evaluating the damage (para. 5). Finally, the competent authority's decisions must be reasoned and open to legal review (para. 6).

1. Requirement of the Operator to Take Response Measures (para. 1)

According to Article 5(1), parties shall, in the event of damage, require the appropriate operator to immediately *inform* the competent authority, *evaluate* the damage, and *take appropriate response measures*. This provision correlates with Article 12(1), which requires parties to provide for rules

229 See chapter 4, section B.VI.

230 *Markus Benzing*, Das Beweisrecht vor internationalen Gerichten und Schiedsgerichten in zwischenstaatlichen Streitigkeiten (2010), 706–724; but see ICJ, Pulp Mills (n. 216), para. 164, where the Court expressly held that the precautionary approach did not operate as a reversal of the burden of proof in situations of (alleged) risk. Also see *Maria Monnheimer*, Due Diligence Obligations in International Human Rights Law (2021), 161–162.

231 *Xue* (n. 135), 178–182; *Benzing* (n. 230), 704–706; see UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the Fifth Instalment of "F4" Claims, UN Doc. S/AC.26/2005/10 (2005), paras. 204–205.

and procedures that address damage, including response measures, in their domestic law.[232] Hence, the Supplementary Protocol obliges its parties 'to enact domestic laws that address damage to biodiversity in a way that the operators are required to take response measures'.[233] Consequently, the Supplementary Protocol does not place obligations directly onto the operators but addresses them only indirectly. In other words, the provisions of the Supplementary Protocol are not designed to be *self-executing* or *directly applicable*[234] but need to be transposed into domestic law by additional legislative measures. This is also evidenced by the *travaux préparatoires*, because the inclusion of a provision directly requiring the operator to take response measures was proposed during the negotiations[235] but ultimately rejected.[236]

A different question is whether states are obliged to implement the obligations of operators as self-executing provisions. With regard to the obligation to immediately inform the competent authority, it is obvious that there must be a self-executing provision directly binding the responsible operator(s), as it would be pointless to impose this obligation only when

232 See *infra* section C.V.

233 *Shibata* (n. 8), 32.

234 Cf. *Karen Kaiser*, Treaties, Direct Applicability, in: Wolfrum/Peters (ed.), MPEPIL, MN. 1, who points to the fact that whether a treaty is directly applicable ultimately depends on the reception of international law by a domestic legal order (*ibid.*, MN. 6). Nevertheless, a treaty can only be applicable without further transposition when its terms are sufficiently precise and conclusively govern its legal consequences (see *ibid*., MN 11–20). This could be assumed for states that are characterized as 'monist', i.e. in which international law and domestic law are deemed to be parts of one and the same legal order, which means that rules of international law in general do not need to be transposed into domestic law. In contrast, 'dualist' states perceive international law and domestic law to constitute separate legal orders, which means that rules of international law need to be transposed into domestic law in order to become effective within the jurisdiction of these states. For details, see *Heinrich Triepel*, Völkerrecht und Landesrecht (1899), 111–155; *Crawford* (n. 57), 45–47.

235 Cf. CP COP-MOP, Proposed Operational Texts on Approaches and Options Identified Pertaining to Liability and Redress in the Context of Article 27 of the Biosafety Protocol: Outcomes of the Meeting of the Friends of the Co-Chairs, Bonn, 7–10 May 2008: Addendum to the Final Report of the Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, UN Doc. UNEP/CBD/BS/COP-MOP/4/11/Add.1 (2008), Section IV.A., Operational Text 11.

236 Cf. Group of Friends on L&R, Report of the […] First Meeting, UN Doc. UNEP/CBD/BS/GF-L&R/1/4 (2009), Article 7(2) on p. 12; see *Shibata* (n. 8), 32–33.

the authority has become aware of the damage. However, with regard to the obligation to take response measures, two avenues of implementation seem possible. According to the first alternative, the obligation to take response measures arises directly from a self-executing provision, which is only *concretized* by the competent authority. In the second alternative, the obligation to take response measures is *enacted* by the decision of the competent authority, which is empowered by law to do so.[237] The former approach, which is also followed by the EU Environmental Liability Directive,[238] is preferable since the responsible operator would be required to take response measures even before the competent authority has reacted. Nevertheless, both approaches seem to be consistent with the Supplementary Protocol.

2. Responsibilities of the Competent Authority (para. 2)

Article 5(2) specifies the responsibilities of the competent authority in the implementation of response measures. As soon as the competent authority becomes aware of the damage,[239] it shall *identify* the 'operator which has caused the damage', *evaluate* the damage and *determine* which response measures should be taken by the operator. This determination will culminate in a legally binding decision requiring the operator to undertake the indicated measures. Depending on the domestic legal framework, this

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237 The latter interpretation is supported by the wording of Article 5(6) SP, which refers to '[d]ecisions of the competent authority requiring the operator to take response measures'. The present view that both modes of implementation are permissible is shared, with reference to Article 5(8) SP, by *Akiho Shibata*, Conclusion: Beyond the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 240, 243. On the transposition of the Supplementary Protocol's provisions into domestic law, see *infra* section C.V.

238 Cf. EU Environmental Liability Directive (n. 18), Article 6(1), which directly obliges the operator to take both mitigation and remedial measures; and Article 6(2)(b) and (c), which empowers the competent authority to give instructions to the operator and to require him to take further remedial measures. See *Valerie Fogleman*, Enforcing the Environmental Liability Directive: Duties, Powers and Self-Executing Provisions, 4 (2006) Environmental Liability 127, 130–135.

239 The competent authority might become aware of the occurrence of damage either through a respective notification given by the responsible operator pursuant to Article 5(1)(a), or in any other way.

decision may either be rendered directly by the competent authority or by a judicial organ on the authority's request.[240]

3. Measures When There Is a Threat of Damage (para. 3)

Article 5(3) provides that 'where relevant information […] indicates that there is a sufficient likelihood that damage will result if timely response measures are not taken', the operator shall be required to take appropriate response measures to avoid such damage. Requiring the operator to engage in response action before damage has actually occurred is one of the main merits of the administrative approach, because it allows the competent authority to require preventive action rather than merely arranging for *ex post* clean-up measures or compensation.[241]

The present provision resembles the concept of 'imminent threat of damage' used widely in international environmental law.[242] However, the terms 'relevant information' and 'sufficient likelihood' used in the present provision could be construed as requiring a higher threshold or standard of proof than that of 'imminent threat of damage'. According to reports from the negotiations, the present wording was introduced to accommodate concerns by some parties that the concept of 'imminent threat of damage' might be used to erect trade barriers.[243] In any event, the responsibility to determine which information is 'relevant' and whether

240 In the United States, CERCLA empowers the Environmental Protection Agency to either issue an administrative order itself or pursue a judicial order through the Department of Justice to require a potentially responsible party to perform clean-up actions, cf. CERCLA (n. 17), 42 U.S.C. 9606(a); see *David M. Bearden*, Comprehensive Environmental Response, Compensation, and Liability Act: A Summary of Superfund Cleanup Authorities and Related Provisions of the Act (2012), 24.

241 Cf. *Lago Candeira* (n. 9), 98.

242 See, e.g., 1992 Oil Pollution Convention (n. 60), Article I(8); Basel Protocol on Liability for Hazardous Wastes (n. 60), Article 2(h); Bunker Oil Convention (n. 60), Article 1(8); EU Environmental Liability Directive (n. 18), Article 2(9); Antarctic Liability Annex (n. 19), Article 2(b); for more examples, see CBD Secretariat, The Concept of Imminent Threat of Damage and Its Legal and Technical Implications: Note by the Executive Secretary, UN Doc. UNEP/CBD/BS/GF-L&R/3/INF/2 (2010); *Yifru* et al. (n. 68), 23–26.

243 *Jungcurt/Schabus* (n. 6), 200; cf. CBD Secretariat (n. 242), para. 2; *Lago Candeira* (n. 9), 104. Retrospectively, this fear was unfounded, because any measures taken under the Supplementary Protocol also need to comply with applicable rules of international trade law. In this respect, the conclusions reached on

it indicates a 'sufficient likelihood' of damage lies with the states parties and their competent authorities. Hence, there is no clearly discernible difference between the concept of an 'imminent threat of damage' used in other instruments and that of 'sufficient likelihood that damage will result if timely response measures are not taken' used in the Supplementary Protocol.[244] In particular, it is not required that damage would occur *immediately* if no timely response measures were taken. Thus, response measures can also be required when there is a sufficient likelihood that damage will otherwise occur in the long term.[245]

4. Response Measures Taken Instead of the Responsible Operator (para. 4)

Article 5(4) provides that the competent authority may implement appropriate response measures itself, particularly when the operator has failed to do so. Notably, this does not stipulate an obligation of the party concerned but merely clarifies that it has the right to take response measures instead of the responsible operator.[246] The competent authority has full discretion to decide whether it implements response measures or not. Thus, at first sight, the present provision has only a declaratory effect. However, it might also serve to justify interference with fundamental rights necessary to implement certain response measures, such as the destruction of property (e.g. LMO seeds or crops) or the treatment of dwellings with pesti-

the relationship between the WTO law and international biosafety law (see chapter 3, section C) also apply to the Supplementary Protocol.

244 Cf. *Lago Candeira* (n. 9), 103–104, who describes the wording used in Article 5(3) SP as a 'diffuse reference to the imminent threat of damage'.

245 In this context, see ICJ, Gabčíkovo-Nagymaros Project (Hungary v. Slovakia), Judgment of 25 September 1997, ICJ Rep. 7, para. 55, noting that 'a "peril" appearing in the long term might be held to be "imminent" as soon as it is established, at the relevant point in time, that the realization of that peril, however far off it might be, is not thereby any less certain and inevitable.'

246 *Caroline E. Foster*, Diminished Ambitions? Public International Legal Authority in the Transnational Economic Era, 17 (2014) J. Int. Econ. L. 355, 368. In contrast, the Antarctic Liability Annex encourages the party of the operator and other parties to take prompt and effective response action, 'including through their agents and operators specifically authorised by them to take such action on their behalf', see Article 5(2) of the Antarctic Liability Annex (n. 19). This goes along with a mechanism to coordinate multiple actors willing to take response actions, see Article 5(3)–(5).

cides.[247] In any case, the express authorization of the competent authority to take response measures may also help to justify subsequent claims for reimbursement of expenses.

5. Recovery of Expenses by the Competent Authority (para. 5)

Under Article 5(5), the competent authority has the right 'to recover the costs and expenses of, and incidental to, the evaluation of the damage and the implementation of any such appropriate response measures'. It could be questioned whether this obligation is limited to response measures that the operator was required to but failed to take, or whether it also extends to response measures that the competent authority took without first requesting the operator to do so.[248] In other words, it is questionable whether the operator has the right to take the measures itself rather than just covering their costs.

Article 5(5) refers to 'any *such* appropriate response measures'.[249] The term 'such' refers to the measures specified in the preceding paragraph, which stipulates the right of the competent authority to implement appropriate response measures, 'in particular, when the operator has failed to do so'. Thus, the Supplementary Protocol makes clear that response action by the responsible operator is preferred over action taken by the competent authority. This resembles the approach taken by the Antarctic Liability Annex, under which the operator is only liable to pay the costs of response action taken by parties when it has itself failed to take prompt and effective response action.[250] In contrast, the EU's Environmental Liability Directive[251] and the United State's CERCLA[252] do not limit the right of the respective competent authorities to take action themselves (and, consequently, to recover the costs thereby incurred from the operator) to

247 See *James* et al. (n. 172), 13.
248 Arguably, this problem is less relevant when the obligation to take response measures pursuant to Article 5(1) SP (or the respective implementing law) is self-executing, as in this case the operator would be required to take appropriate response measures even without being explicitly ordered to do so by the competent authority.
249 Emphasis added.
250 Cf. Antarctic Liability Annex (n. 19), Article 6(1).
251 Cf. EU Environmental Liability Directive (n. 18), Articles 5(4), 6(2)(b) and 6(2)(e).
252 Cf. CERCLA (n. 17), 42 U.S.C. § 9607(a)(4)(A)-(D).

situations where the responsible operator has failed to act. Consequently, under the Supplementary Protocol the competent authority may only recover its expenses from the responsible operator when the latter has failed to implement appropriate response measures.

This entails the question of whether the phrase 'has failed' in Article 5(4) implies a requirement of fault in the sense that the responsible operator must have culpably omitted to take the required measures. But other language versions of the Supplementary Protocol show that 'has failed' is used synonymously to 'has not taken',[253] and that the notion 'failed' therefore does not imply a requirement of fault. The corresponding provision of the Antarctic Liability Annex also uses the term 'has failed' but additionally stipulates that liability shall be strict, which clarifies that fault of the operator is no requirement for liability to arise.[254] Consequently, the responsible operator must reimburse the costs for any appropriate response measures it was required to take but (culpably or not) failed to take. At the same time, the operator must cover all the costs incurred by the competent authority in evaluating the damage, regardless of whether it also undertook its own evaluation measures.

The second sentence of Article 5(5) authorizes states parties to provide, in their domestic law, 'for other situations in which the operator may not be required to bear the costs and expenses'. The reference to '*other* situations' might suggest a limitation to the effect that there are certain situations in which the operator may not be exempted from liability at all. However, the Supplementary Protocol does not indicate such situations in which the operator shall always be held liable.[255] Furthermore, the authoritative language versions of the Supplementary Protocol appear not

253 The French version refers to 'lorsque l'opérateur ne l'a pas fait', which translates to 'when the operator has not done so'. Similarly, the Spanish uses reads 'cuando el operador no las haya aplicado', which means that the operator has not applied them (i.e., the appropriate measures). See Vienna Convention on the Law of Treaties (23 May 1969; effective 27 January 1980), 1155 UNTS 331 (hereinafter 'VCLT'), Article 33(1), which provides that: 'When a treaty has been authenticated in two or more languages, the text is equally authoritative in each language.'

254 Article 6(1) and (3) Antarctic Liability Annex (n. 19); see *Vöneky* (n. 181), 184; also see chapter 2, section E.

255 In contrast, the Article VIII of the EU Environmental Liability Directive (n. 18) contains a conclusive list of cases in which an operator shall not be required to bear the cost of preventive or remedial action. Similarly, Article VIII of the Antarctic Liability Annex (n. 19) contains a conclusive list of cases in which an operator shall not be liable to pay the cost of response action.

to be consistent in this regard, as the French version merely refers to 'situations',[256] while the Spanish version also refers to 'other situations'.[257] When there is a difference in meaning between the authentic texts of a treaty, the meaning that best reconciles the texts, having regard to the object and purpose of the treaty, shall be adopted.[258] However, the different language versions are sufficiently clear that parties shall have the discretion to define situations in which the operator is exempted from liability. This also becomes clear when comparing Article 5(5) with Article 6, which also stipulates an option to adopt far-reaching exemptions from liability as parties 'may deem fit'.[259] In any event, such exemptions must not defeat the general object and purpose of the Supplementary Protocol,[260] which is to impose liability for biodiversity damage caused by LMOs on the responsible operator(s) by requiring them to take appropriate response measures or at least to cover their costs.

6. Reasoning and Legal Review of Decisions (para. 6)

Article 5(6) SP provides that decisions requiring the operator to take response measures shall be reasoned and shall be notified to the operator. Furthermore, domestic law shall provide for remedies, including the opportunity to seek administrative or judicial review of such decisions, and the operator shall be informed of these remedies. Depending on the domestic legal system, an appeal by the operator against the decision may have a suspensory effect, which means that the administrative act ordering the operator to take response measures might not be enforceable until the review process has been concluded. For this reason, Article 5(6) clarifies that recourse to such remedies shall not impede the competent authority from 'taking response measures in appropriate circumstances'. Having in mind that the competent authority may recover the costs for such response measures from the operator,[261] the term 'appropriate circumstances' can

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256 The French wording is 'situations dans lesquelles l'opérateur peut ne pas être tenu de supporter ces coûts et dépenses'.

257 The Spanish version reads 'otras situaciones según las cuales pudiera no requerirse que el operador se haga cargo de los costos y gastos'.

258 Article 33(4) VCLT (n. 253).

259 See *infra* section E.I; also see *Yifru/Garforth* (n. 9), 158–160.

260 Cf. *Oliver Dörr*, Article 31 VCLT, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 52–58.

261 Cf. Article 5(5), see *supra* section C.IV.5.

be construed as limiting the response measures under Article 5(6) to those which must be taken timely in order to contain the LMO and to avoid further damage. In other words, the competent authority shall not prejudice the outcome of the review process by taking measures that are not urgent and which can equally be taken at a later stage. The same applies to the liability of the operator for expenses incurred by the competent authority in implementing response measures.[262] When the administrative or judicial review results in the overturn of the order requiring the operator to carry out response measures, the operator should also not be liable to pay the costs incurred by the competent authority in the meantime.

V. Transposition into Domestic Law

The Supplementary Protocol addresses its implementation into its parties' domestic legal systems in three provisions. Article 12(1) requires parties to provide, in their domestic law, for rules and procedures that address damage (1.). At the same time, Article 5(7) allows parties to assess whether response measures are already addressed by their domestic law on civil liability (2.). Furthermore, Article 5(8) provides that response measures shall be implemented 'in accordance with domestic law' (3.).

1. Provision of 'Rules and Procedures That Address Damage' (Article 12(1))

Article 12(1) addresses the transposition of the Supplementary Protocol into the domestic legal system of parties. The provision reads:

> *'Parties shall provide, in their domestic law, for rules and procedures that address damage. To implement this obligation, Parties shall provide for response measures in accordance with this Supplementary Protocol and may, as appropriate:*
> *(a) Apply their existing domestic law, including, where applicable, general rules and procedures on civil liability;*
> *(b) Apply or develop civil liability rules and procedures specifically for this purpose; or*
> *(c) Apply or develop a combination of both.'*

262 *Ibid.*

Both the exact meaning and the rationale of this provision are unclear, especially concerning the references to 'rules and procedures on civil liability'. As shown earlier, the term 'civil liability' generally denotes the liability of an operator to make reparation to an injured person for damage sustained to the health, property or income of that person.[263] Thus, civil liability is a different approach than the 'administrative liability' approach followed by the Supplementary Protocol, which implies that liability is not enforced by injured persons seeking relief, but by an administrative authority requiring the operator to implement response measures to mitigate and repair the damage.[264] That the operator may also have to recover expenses incurred by others in implementing such measures[265] is only a corollary of the primary obligation to take appropriate response measures. Hence, at first sight, it appears to make little sense to require state parties to implement the administrative approach by adopting rules and procedures on civil liability.

On closer inspection, it becomes clear that Article 12(1) consists of a compulsory part and a voluntary part. According to the first sentence, parties shall 'provide for' (i.e. enact or maintain) rules and procedures that address biodiversity damage in their domestic law. This obligation is further specified by the first part of the second sentence, which stipulates that parties 'shall' (i.e. are legally required to) provide for response measures in accordance with the Supplementary Protocol. Hence, the first part of Article 12(1) closely relates to Article 5(1), which obliges parties to require the appropriate operator to take appropriate response measures in the event of damage.[266] Insofar, the provision merely restates the obligation already stipulated in Article 5(1), albeit with a specific focus on the provision of respective rules under the parties' domestic laws.[267]

The remainder of Article 12(1) SP provides that parties 'may' (i.e. are allowed to) additionally address biodiversity damage by either (a) applying their 'general rules and procedures on civil liability', (b) developing or applying civil liability rules 'specifically for this purpose' (i.e. to address biodiversity damage), or (c) applying or developing a combination of

263 See chapter 2, section G; also see *Sands* et al. (n. 150), 735.
264 Cf. *Lefeber* (n. 19), 84–87.
265 Article 5(5) SP; see *supra* section C.IV.4.
266 See *supra* section C.IV.1.
267 *Yifru/Garforth* (n. 9), 160.

both.[268] A close reading of the second sentence of Article 12(1) reveals the distinction between the compulsory part and the voluntary part: parties '*shall* provide for response measures' and, besides, '*may*, as appropriate' take said steps with regard to civil liability. Hence, developing and applying civil liability rules to address biodiversity damage as envisaged in subparagraphs (a)-(c) is not a legal obligation but an option expressly left to the parties' discretion. The present provision merely clarifies that parties may use domestic civil liability rules and procedures to address biodiversity damage caused by LMOs *in addition* to providing for response measures in their domestic law. This is also confirmed by the negotiating history of the Supplementary Protocol, since the second part of Article 12(1) was characterized as an 'enabling provision referencing civil liability approaches for damage to biodiversity'.[269]

At the same time, states are not allowed to adopt civil liability rules for biodiversity damage *instead* of providing for response measures. This results from Article 5(7), pursuant to which the obligation to provide for separate rules on response measures is only waived when the civil liability law of a party already yields the ordering of response measures.[270]

2. Response Measures Already Addressed by Domestic Civil Liability Law (Article 5(7))

Article 5(7) stipulates that parties have the right, when implementing the Supplementary Protocol's provisions on response measures, to 'assess whether response measures are already addressed by their domestic law on civil liability'. This provision was reportedly included on the demand of the delegation of Brazil, who argued that their national civil liability system already provided for the implementation of response measures, which would usually be ordered by a court.[271] It can thus be assumed that when the result of such an assessment is positive (i.e. when response measures

268 This interpretation is also supported by a comparison with Article 12(2), where 'shall' is used to indicate that parties must choose one of the options listed in the subparagraphs listed there.

269 IISD, Summary of the Second Meeting of the Group of Friends of the Co-chairs on Liability and Redress (n. 25), 10; also see IISD, Summary of the Second Meeting of the Group of Friends of the Co-chairs on Liability and Redress (n. 25), 7.

270 See next section.

271 *Shibata* (n. 8), 29 at footnote 36.

are indeed already addressed by a state's domestic law on civil liability), the party in question is not required to adopt specific legislation providing for response measures, because this would result in a mere restatement of law already in place.

In the view of some authors, Article 5(7) could also be interpreted extensively as allowing to maintain the *status quo ante* when a state has civil liability law in place that has the *same scope of application* as the provision of response measures envisaged by the Supplementary Protocol, even when such law does not actually require response measures.[272] But such an interpretation would jeopardize the effective implementation of the administrative approach, as it allowed parties to maintain 'business as usual'.[273] For this reason, it is doubtful that such an interpretation is permissible. Not only would it militate against the Supplementary Protocol's object and purpose, which is to establish a regime of administrative liability for damage resulting from the transboundary movement of LMOs,[274] but it would also allow bypassing the specific obligations contained in paragraphs 1 to 6 of Article 5.[275] Therefore, it must be assumed that parties may only rely on existing provisions of civil liability law when the application of these provisions will result in the implementation of effective measures to contain, mitigate, and restore damage to biodiversity resulting from LMOs. According to an even stricter interpretation, the application of civil liability law is only permissible when it is 'more effective in responding to biodiversity damage than implementing an administrative approach to liability established in accordance with Articles 5 and 12 of the Supplementary Protocol'.[276] In any event, the mere payment of financial compensation for the loss of biodiversity is insufficient under the Supplementary Protocol as long as it cannot be guaranteed that response measures are actually implemented.

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272 *Lago Candeira* (n. 9), 104; *Shibata* (n. 8), 29 at footnote 36; also see *Yifru/Garforth* (n. 9), 159.

273 Cf. *Lago Candeira* (n. 9), 104.

274 See Recital 4 of the Supplementary Protocol, which recognizes 'the need to provide for appropriate response measures where there is damage or sufficient likelihood of damage'. Article 31(1) of the VCLT (n. 253) provides that an international treaty shall be interpreted, *inter alia*, in light of its object and purpose.

275 *Shibata* (n. 8), 29 at footnote 36.

276 *Shibata* (n. 237), 245.

3. Implementation of Response Measures 'in Accordance With Domestic Law' (Article 5(8))

Article 5(8) provides that response measures 'shall be implemented in accordance with domestic law'. Again, the wording of this provision is ambiguous. In the first place, it is unclear whether the term 'implemented' refers to the adoption of domestic laws and regulations, their execution by the competent authority in the event of damage, or both.[277] Furthermore, it has been argued that Article 5(8) might be 'subjecting the provision on response measures to domestic law', which could mean that parties are allowed to deviate from the Supplementary Protocol's substantive rules on response measures.[278] However, it appears more reasonable to construe Article 5(8) as stipulating that the domestic implementation of response measures shall be accommodated within the existing national legal framework. For instance, it is left to domestic law whether the obligation of the operator to take response measures originates directly from a self-executing legal provision or is created by an order rendered in the individual case.[279] In other words, parties are free to choose their own ways of implementing response measures in accordance with their existing legal order as long as they do not compromise the objective of the Supplementary Protocol.[280] After all, Article 5(8) created the flexibility desired by parties who already had in place domestic systems of administrative liability and wanted to avoid having to modify these already-existing regimes.[281]

VI. Conclusions

As noted earlier, by providing for 'administrative liability' of operators, the Supplementary Protocol follows a recent trend in international law-

277 As explained above, the Protocol uses the term 'implementation' for both the adoption of domestic legislation and the enforcement of response measures by the competent authority in the event of damage. See *supra* C.IV.6.

278 *Yifru/Garforth* (n. 9), 159.

279 See *supra* section C.IV.1.

280 *Shibata* (n. 237), 245.

281 IISD, Summary of the First Meeting of the Group of Friends of the Co-Chairs on Liability and Redress in the Context of the Cartagena Protocol on Biosafety: 23–27 February 2009, ENB Vol. 9 No. 457 (2009), 11.

making on environmental liability.[282] However, the preceding section has shown that the administrative approach as reflected in the Supplementary Protocol also has weaknesses and disadvantages. Most importantly, there is usually no pre-emptive obligation of the operator to take certain measures once damage occurs.[283] Instead, the general duty to take response measures must first be translated into specific deliverables, which requires evaluating the damage, identifying the responsible operator, and determining the measures required in each individual case. Hence, the administrative approach is 'premised on the existence of a robust administrative apparatus'.[284] Many developing countries invoked that they did not have the expertise and capacity needed to implement the administrative approach.[285]

However, most of these weaknesses seem not to be owed to the administrative approach *per se* but rather to its lenient implementation. Already the Supplementary Protocol's scope of application is highly flexible, as parties may use their own criteria to determine whether there is a case of 'damage to biological diversity'.[286] Furthermore, states are largely free to identify the liable operator, which can be any person in direct control of the LMO.[287] With regard to the substantive content of response measures, the Supplementary Protocol clearly stipulates that the prevention of damage shall take priority over restoration, and that replacement measures shall be taken where the primary damage cannot be avoided. However, apart from these general principles, the Supplementary Protocol remains rather vague on how to determine which measures are 'reasonable' and 'appropriate' in a certain case.[288] There is also no obligation for parties to implement response measures when the responsible operator fails to do so.[289] After all, parties enjoy more or less full discretion on how to implement the administrative approach in their domestic law.[290]

282 Cf. *Shibata* (n. 8), 31–38, 46–48. The approach is termed by some as 'regulatory liability', cf. *Lefeber* (n. 19), 84; see chapter 2, section G.
283 This is assumed by *Shibata* (n. 237), 242. But see *supra* section C.IV.1.
284 *Shibata* (n. 8), 36.
285 *Jungcurt/Schabus* (n. 6), 202; *Thomas/Teshome Kebede* (n. 22), 126–127.
286 The most striking example is the European Union's implementing legislation, which only applies when there is damage to certain protected species and habitats, see *supra* section B.II.5.
287 See *supra* section C.II.
288 See *supra* section C.I.
289 *Foster* (n. 246), 368, see *supra* section C.IV.4.
290 *Lim Tung* (n. 6), 74; *Foster* (n. 246), 367; *Telesetsky* (n. 184), 106.

D. Civil Liability for Material and Personal Injury

As mentioned above, it was agreed during the negotiations that the Supplementary Protocol should focus on the administrative approach but also include a legally binding provision on civil liability.[291] The outcome of this agreement can be found in paragraphs 2 and 3 of Article 12, which address civil liability for material or personal damage that is 'associated' with damage to biodiversity (I.). Parties shall aim at providing for adequate rules and procedures on civil liability in their domestic law (II.). To this end, Article 12(3) provides a list of elements that parties shall address when developing specific legislation (III.). An essential question in this context is under which circumstances such rules are deemed 'adequate' (IV.).

I. Scope: Material or Personal Damage Associated with Biodiversity Damage

Article 12(2) applies to material or personal damage (1.), provided that such damage is associated with damage to biological diversity (2.).

1. Material or Personal Damage

Article 12(2) refers to 'material or personal' damage. Both terms are not defined in the Supplementary Protocol. 'Personal damage' appears to be used in place of the more common phrase 'personal injury', which means 'bodily or mental injury to a human person'.[292] Personal damage thus encompasses costs for medical treatment[293] but might also include compensation for pain and suffering as well as any consequential income losses.[294]

The meaning of 'material damage' is less clear, because 'material' can mean 'relating to physical matter' but can also denote a threshold in the

291 See *supra* section A.

292 Cf. 'personal injury', in: Black's Law Dictionary (n. 185), 939.

293 Note that the reference to 'risks to human health' in the definition of biodiversity damage might, in the view of some authors, give rise to compensation of these costs under the administrative approach, cf. *Espinosa* (n. 68), 326–327; see *supra* section B.II.4.

294 Cf. *ibid.*, 337–338.

sense of 'significant' or 'relevant'.[295] However, as shown above, the Supplementary Protocol refers to 'significant' rather than 'material' adverse effects to define the minimum threshold required for liability to arise.[296] Furthermore, 'material' is used in Article 12(2) as an alternative to 'personal' damage, which shows that it is not used *quantitatively* to define the amount or degree of injury, but *qualitatively* to describe the types of damage encompassed by the provision. Consequently, 'material damage' refers to a loss of, or damage to, tangible property. Nevertheless, it could be questioned whether it also includes damage to immaterial goods, economic loss and other negative socio-economic effects, such as loss of or damage to cultural, social and spiritual values (especially of indigenous and local communities), loss of or reduction of food security, damage to agricultural biodiversity or loss of economic competitiveness.[297]

According to the *travaux préparatoires*, the rules on civil liability were meant to address damage 'to legally protected interests', as opposed to the environment as such.[298] More specifically, civil liability was meant to address 'damage not redressed through [the] administrative approach' to avoid a double recovery of the same damage through both approaches.[299] Hence, the Supplementary Protocol clearly distinguishes between damage to biodiversity on the one hand and 'traditional damage' to individual rights and goods on the other.[300] However, whether certain detrimental effects of an LMO constitute compensable 'material damage' essentially depends on whether these effects impair a right or good that enjoys legal protection under the national laws of the state concerned. This is also true for economic loss and negative socio-economic impacts, which are both not mentioned in the Supplementary Protocol.[301]

295 Cf. 'material, adj.', in: Black's Law Dictionary (n. 185), 1170; 'material, adj., n., and adv.', in: Oxford English Dictionary (n. 69).
296 Article 2(2)(b)(ii) and 2(3) SP; see *supra* section B.II.3.
297 During the negotiations, some parties proposed a definition of 'damage to socio-economic conditions' which referred to the factors mentioned here, cf. Final report of WG L&R 2008 (n. 117), 9–10. However, all references to socio-economic considerations in the definition of damage were removed from the draft text in 2008; cf. CP COP-MOP Decision BS-IV/12 (2008) (n. 30). Also see *Gouritin* (n. 68), 157–158. On socio-economic considerations in the Cartagena Protocol, see chapter 3, section A.II.1.e).
298 Final report of WG L&R 2008 (n. 117), 8.
299 *Ibid.*
300 See *supra* section B.II.1 and chapter 2, section B.
301 *Lim Tung* (n. 6), 73–74; *Gouritin* (n. 68), 157–158; see *supra* section B.II.6.

After all, the Supplementary Protocol does not formulate a harmonized understanding of what is meant by 'material or personal damage'. Consequently, parties have large discretion in implementing this element, which will likely mean that such damage will be compensated differently, or even not at all, depending on where it occurs.[302]

2. Damage 'Associated' With Biodiversity Damage

In order to be addressed by the present provision, material and personal damage must be 'associated with the damage as defined in Article 2, paragraph 2 (b)'. The said provision defines the term 'damage' as 'an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.[303] Hence, Article 12(2) applies to material and personal damage that is 'associated' with the damage to biodiversity resulting from an LMO.

The Supplementary Protocol does not indicate under which circumstances traditional damage is deemed 'associated' with biodiversity damage. The adjective 'associated' denotes something as 'combined locally, circumstantially, or in classification (with)' something else.[304] Hence, a possible interpretation of the notion 'associated with biodiversity damage' would encompass all kinds of traditional damage that occur in relationship with (or alongside) damage to biodiversity, while a causal relationship between the two types of damage would not be necessarily required. But 'associated with' could also be construed as 'consequential to',[305] which would mean that only personal and material injury *resulting* from biodiversity damage caused by the LMO, but not damage directly caused by the LMO, was covered by Article 12(2).

302 *Lim Tung* (n. 6), 74.

303 Cf. Article 2(2)(b); see *supra* section B.II.

304 Cf. 'associated, adj.', section 3, in: Oxford English Dictionary (n. 69).

305 Cf. *Nijar* (n. 6), 274, who argues that that 'the [traditional] damage must be a consequence of damage to biodiversity'. However, the argument becomes inconsistent when the author provides an example where an LMO contaminates the environment and causes damage to the environment, and at the same time causes 'material and physical loss to a farmer whose field is affected by the contamination'. Here, it remains unclear whether the author deems a causal relationship between the biodiversity damage and the material and physical loss suffered by the farmer to be a requirement for the applicability of Article 12(2).

Contrary to what it may seem at first glance, this distinction is not only a terminological one. If a circumstantial relationship between biodiversity damage and traditional damage was sufficient, the occurrence of biodiversity damage would give rise to the full range of claims that may be related to the use of LMOs, which in many cases will relate to the contamination of non-LMO seeds or crops with the LMO. However, many developed countries strongly opposed to developing a liability regime for these types of damages in the context of the Cartagena Protocol, arguing that the latter was only concerned with protecting biological diversity.[306] Therefore, it must be assumed that the term 'associated with' requires that personal or material damage must be 'consequential to' biodiversity damage.[307] Traditional damage that occurs only coincidentally alongside biodiversity damage is not covered by Article 12(2), leaving it for the parties to decide whether and how they address this type of damage in their domestic law.[308] Consequently, it appears 'not easy to envision' what the damage covered by Article 12(2) could be.[309]

II. Provision of Adequate Rules and Procedures on Civil Liability (Article 12(2))

Article 12(2) addresses the measures that parties shall take with regard to civil liability for personal and material damage in the aforementioned sense. The provision reads:

> *'Parties shall, with the aim of providing adequate rules and procedures in their domestic law […]:*
> *(a) Continue to apply their existing general law on civil liability;*
> *(b) Develop and apply or continue to apply civil liability law specifically for that purpose; or*
> *(c) Develop and apply or continue to apply a combination of both.'*

306 Cf. *Shibata* (n. 8), 22; *Jungcurt/Schabus* (n. 6), 201; IISD, Summary of the Second Meeting of the Group of Friends of the Co-chairs on Liability and Redress (n. 25), 7; but see *Lefeber* (n. 19), 90, who argues that 'there is no legal impediment to address traditional damage in a liability instrument in the context of these Conventions'.

307 *Nijar* (n. 15), 113 reports that during the negotiations of the Supplementary Protocol, countries insisting 'on this narrowly circumscribed definition' were unable 'to concretely identify what such damage may be'.

308 *Yifru/Garforth* (n. 9), 160; *Brans/Dongelmans* (n. 26), 184.

309 *Nijar* (n. 15), 113.

This list closely resembles that contained in Article 12(1), which refers to the domestic implementation of response measures.[310] However, while Article 12(1) only provides that parties 'may' take any of the described steps, the present provision is formulated in a binding manner. Parties must either 'continue to apply' existing laws on civil liability or 'develop and apply' specific liability laws, and they must do so 'with the aim of providing adequate rules and procedures' to address material and personal damage. This means that parties are required to make *bona fide* and concrete efforts to provide for adequate rules on civil liability.[311] Hence, Article 12(2) can be characterized as being 'formulated in a binding manner, yet [having] a procedural nature'.[312] Parties are free to apply existing laws or to adopt new ones, and the content of such laws is completely left at the discretion of the parties, provided that the resulting level of protection is 'adequate'.[313]

III. List of Elements to be Addressed When Developing Civil Liability Law (Article 12(3))

Article 12(3) provides that when developing specific civil liability law for material and personal damage, parties shall

> '*address, inter alia, the following elements:*
> *(a) Damage;*
> *(b) Standard of liability, including strict or fault-based liability;*
> *(c) Channelling of liability, where appropriate;*
> *(d) Right to bring claims.*'

These elements are commonly found in international agreements dealing with liability for damage resulting from hazardous activities or substances.[314] However, in contrast to most of these instruments, the Supplementary Protocol does not define a substantive content or standard for these elements.[315] For example, most international agreements commonly require their parties to provide for *strict liability*, which means that liability

310 See *supra* section C.V.1.
311 *Nijar* (n. 15), 113.
312 *Lefeber/Nieto Carrasco* (n. 12), 65.
313 *Ibid.*; on the adequacy of rules and procedures, see *infra* section D.IV.
314 See the instruments referred to in n. 60.
315 *Nijar* (n. 15), 113–114.

arises irrespectively of whether the responsible actor has culpably caused the damage (i.e. acted with negligence or intention) and whether such fault can be proven by the plaintiff (which may be difficult in complex environmental damage situations).[316] The Supplementary Protocol only requires parties to 'address' the standard of liability but expressly leaves them free to choose a strict, fault-based or any other standard of liability.[317]

IV. The Meaning of 'Adequate' Rules and Procedures

As shown above, Article 12(2) obliges parties to aim to provide 'adequate' rules and procedures on civil liability. This poses the question of what is required for such rules to be 'adequate'. In legal English, the term 'adequate' is used to denote something as 'legally sufficient'[318] or 'satisfactory'.[319] Hence, the term does not represent an objective, generally applicable standard but requires a case-by-case evaluation of whether a particular measure, in the individual circumstances, is sufficient to achieve or preserve the objectives or values at stake.[320]

In international environmental law, the term 'adequate compensation' provides – as a quantitative element – that compensation must be sufficient to make good the damage, although it does not necessarily require 'full' compensation.[321] In the current context, the term appears to have a wider meaning, as it is not only used to describe compensation but more generally the rules and procedures on civil liability adopted by parties in their domestic law. However, it is difficult to identify an overarching objective that shall be pursued by establishing such national civil liability rules, in particular since the express objective of the Supplementary Protocol is not to ensure compensation for material and personal injury suffered

316 Cf. *Julio Barboza*, The Environment, Risk and Liability in International Law (2011), 25; see *supra* section C.III and chapter 2, section E.

317 Cf. *Jusoh* (n. 6), 193–195.

318 Cf. 'adequate', in: Black's Law Dictionary (n. 185), 49.

319 Cf. 'adequate, adj.', section 3, in: Oxford English Dictionary (n. 69).

320 See 'Adequate', in: Hay (ed.) (n. 206), 66–68, for examples on the meaning of the term 'adequate' in different contexts, including in 'adequate knowledge of either official language' and 'adequate fence'.

321 Cf. *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 323–324; ILC, Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, with Commentaries (2006), YBILC 2006, vol. II(2), p. 56, Principle 3 and commentary, paras. 3–5.

by individuals, but only to provide for response measures to mitigate and repair biodiversity damage.[322] This is even aggravated by the fact that the aforementioned list of elements to be addressed by national laws on civil liability is formulated indifferently and without establishing specific requirements.[323] Arguably, there may be situations in which such laws are obviously *inadequate*, for instance when plaintiffs who have suffered injury from an LMO have no legal basis to claim compensation or when they have no standing to bring their claims to court. However, above this minimum threshold, the term 'adequate' does not appear to denote an agreed standard for domestic civil liability laws in the context of traditional damage arising from LMOs.[324]

V. Conclusions

The preceding analysis has shown that the Supplementary Protocol does not impose any substantive obligations upon parties with regard to civil liability. The most striking limitation is the narrow scope of these provisions, as they only apply to damage 'associated' with biodiversity damage. But even within this scope, parties are free to decide whether they continue to apply their existing civil liability rules, develop new rules specifically for LMO damage, or combine both approaches. States are also not required to establish strict liability (which is commonly used in the context of liability for hazardous activities, because the fault of the operator may be difficult to prove for the plaintiff and because harm may also occur despite the operator acting diligently[325]), but may also adopt a fault-based liability standard.[326]

The Supplementary Protocol remains similarly vague about several other elements such as channelling of liability, standard of proof and the right to bring claims. In contrast to many other international civil liability instruments, which generally aim to harmonize the national law to certain minimum standards, the Supplementary Protocol merely requires states

322 Cf. Article 1 SP.
323 Cf. Article 12(3) SP; see *supra* section D.III.
324 Cf. *Lefeber/Nieto Carrasco* (n. 12), 65, who argue that the negotiators 'forewent the development of guidance for rules and procedures in domestic law on civil liability and, hence, what would be "adequate"'. On the draft civil liability guidelines, see *infra* section D.VI.
325 Cf. *Barboza* (n. 316), 25.
326 Cf. Article 12(3)(b) SP; see *Jusoh* (n. 6), 193–195.

parties to 'address' the aforementioned elements in their domestic liability regimes without establishing any substantive standards. In fact, the Supplementary Protocol does not offer *any* guidance on how domestic liability regimes should be designed in order to be 'appropriate'. Furthermore, it remains silent on a number of issues critical in transboundary situations, e.g. access to court for foreigners, or mutual recognition and enforcement of judgments.[327]

In conclusion, Article 12(2) contains an important procedural obligation with regard to traditional damage, as parties are required to assess their existing civil liability regimes and determine whether they are (still) adequate to deal with damage resulting from LMOs.[328] However, the Supplementary Protocol cannot be considered to establish a 'hard' obligation of international law to establish a civil liability system, which is mainly due to the lack of specific standards for such a regime.[329] As a result, some parties to the Supplementary Protocol have special liability for regimes for LMO damage, while others continue to rely on pre-existing general liability rules.[330]

VI. Excursus: Draft Guidelines on Civil Liability and Redress

As mentioned above,[331] Article 12 is the result of a compromise reached during the negotiations of the Supplementary Protocol in 2008, where it was agreed to develop a legally binding instrument that follows an administrative approach but also includes a provision on civil liability.

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327 Cf. *Jungcurt/Schabus* (n. 6), 201–202, who point to the fact that recognition of foreign judgments remains a complex procedural issue, as countries use different approaches to take into account the specific characteristics of their own legal systems and those of other countries when deciding whether to recognize foreign judgments. Also see *Lim Tung* (n. 6), 74; *Jusoh* (n. 6), 201–202 and *infra* section F.II.

328 *Nijar* (n. 15), 123; *Thomas/Teshome Kebede* (n. 22), 129–130; but see *Yifru/Garforth* (n. 9), 160, who assume that Article 12(2) SP 'may provide legitimate grounds for a Party to ignore traditional damage associated with damage to biodiversity if that Party so wishes'.

329 *Jungcurt/Schabus* (n. 6), 203; *Nijar* (n. 15), 117; *Nijar* (n. 15), 117; *Lim Tung* (n. 6), 73–74; also see *John M. Marshall*, Commentary: The Cartagena Protocol in the Context of Recent Releases of Transgenic and Wolbachia-Infected Mosquitoes, 19 (2011) Asia-Pacific Journal of Molecular Biology and Biotechnology 91, 96.

330 See *Wilcox* (n. 218), 777–778, and the country reports contained in that volume.

331 See *supra* section A.

Initially, this provision was meant to be complemented by a set of legally non-binding *Guidelines on Civil Liability*. An outline for these Guidelines was compiled from proposals for operative provisions on civil liability submitted by parties,[332] and a consolidated draft was circulated by the co-chairs at a late stage of the negotiations.[333] However, as discussions on civil liability focused on the legally binding provisions now contained in Article 12, the Guidelines were never subject to substantive negotiations. Ultimately, the negotiating parties agreed not to further elaborate the Guidelines[334] and all references to them were removed from the text of the Supplementary Protocol.[335]

Although the Draft Guidelines were never finalized, they still offer some insight into the degree of agreement among parties about rules on civil liability. The stated objective of the Guidelines was 'to provide guidance to Parties regarding domestic rules and procedures on civil liability'.[336] The Guidelines' scope should extend to personal injury and material damage, although it was disputed whether such damage should only be covered when it was 'incidental' to biodiversity damage.[337] Economic loss was also meant to be covered, but only when it was incurred as a result of damage to the conservation and sustainable use of biodiversity.[338] Another proposed category of damage was socio-economic losses, which referred

332 *Jungcurt/Schabus* (n. 6), 203.

333 Draft Guidelines on Civil Liability and Redress, Proposal by the Co-Chairs of 7 June 2010 (n. 33); see Third World Network, Comments on the Draft Guidelines on Civil Liability and Redress in the Field of Damage Resulting from Transboundary Movements of Living Modified Organisms, in: Third World Network (ed.), Liability and Redress for Damage Resulting from GMOs (2012) 46.

334 Cf. Report of COP-MOP 5 (n. 34), para. 129.

335 For details, see *Jungcurt/Schabus* (n. 6), 203.

336 Group of Friends on L&R, Draft Guidelines on Civil Liability and Redress: Consolidated Text, UN Doc. UNEP/CBD/BS/GF-L&R/3/4, p. 16–22 (2010), Guideline 1, para. 2.

337 *Ibid.*, Guideline 2, Option 1, para. 2(a). This issue is also virulent with regard to the Supplementary Protocol, see *supra* section D.I.2.

338 Cf. *ibid.*, Guideline 2, Option 1, para. 2(c); the limitation that economic loss should only be covered when it was incurred as a result of biodiversity damage was already contained in the consolidated draft presented by the Co-Chairs, cf. Draft Guidelines on Civil Liability and Redress, Proposal by the Co-Chairs of 7 June 2010 (n. 33), Guideline 2, para. 2(c).

to damage to cultural, social or spiritual values, damage to indigenous or local communities, or a reduction of food security.[339]

With regard to the applicable standard of liability, it remained disputed whether liability should be generally strict, strict only for LMOs that had been identified as hazardous, or whether the standard of liability should be fully left to the discretion of the parties.[340] Like the Supplementary Protocol, the Draft Guidelines do not contain provisions that would allow to conclusively identify the liable operator or operators, albeit they provided for channelling of liability and, in the case of multiple liable parties, for joint and several liability.[341] The provisions on exemptions, time and financial limits, and financial security remained similarly vague as those in the Supplementary Protocol.[342]

The Draft Guidelines provide that any affected person should be entitled to bring claims for compensation and that parties should provide for civil law procedures to settle such claims.[343] Where agreed by all parties, claims could also be submitted to arbitration under the *Optional Rules for Arbitration of Disputes Relating to Natural Resources and/or the Environment* of the *Permanent Court of Arbitration*.[344] Depending on the circumstances, arbitration could be preferable over litigation in regular courts since the recognition of foreign arbitral awards is governed by the *New York Convention* of 1958,[345] which currently has 170 parties.[346] In contrast, there is

339 Cf. Draft Guidelines on Civil Liability and Redress, Draft as per 19 June 2010 (n. 336), Guideline 2, Option 1, para. 2(a)(vi).

340 Cf. *ibid.*, Guideline 4.

341 Cf. *ibid.*

342 Cf. *ibid.*, Guidelines 5–8; see *infra* sections E.I and II.

343 *Ibid.*, Guidelines 9–10; see *Jusoh* (n. 6), 201–202.

344 Draft Guidelines on Civil Liability and Redress, Draft as per 19 June 2010 (n. 336), Guideline 10, para. 2; see PCA, Optional Rules for Arbitration of Disputes Relating to Natural Resources and/or the Environment (2001); *Dane P. Ratliff*, The PCA Optional Rules for Arbitration of Disputes Relating to Natural Resources and/or the Environment, 14 (2001) Leiden J. Int'l L. 887; *Tamar Meshel*, Optional Rules for Arbitration of Disputes Relating to Natural Resources And/or the Environment, MPILux Working Paper 1 (2017).

345 Convention on the Recognition and Enforcement of Foreign Arbitral Awards (10 June 1958; effective 07 June 1959), 330 UNTS 3; see *Jan Kleinheisterkamp*, Recognition and Enforcement of Foreign Arbitral Awards, in: Wolfrum/Peters (ed.), MPEPIL, MN. 14–15.

346 Cf. UN OLA, Status of the Convention on the Recognition and Enforcement of Foreign Arbitral Awards, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXII-1&chapter=22&clang=_en (last accessed 28 May 2022).

no comparable treaty providing for the recognition and enforcement of foreign judgments at the global level.[347]

In conclusion, the Draft Guidelines offer some interesting perspectives on how the negotiating parties conceived the issue of civil liability. However, they also share most of the Supplementary Protocol's weaknesses, including the restriction to losses incidental to biodiversity damage, the lack of agreement regarding the applicable standard of liability, and the consideration of problems arising in situations involving multiple jurisdictions. Furthermore, as the Supplementary Protocol does not contain a clear obligation to adopt an effective civil liability regime, it has been argued that the importance of the Guidelines as a soft law element of the international regime would have been very limited.[348] For these reasons, the fact that the Guidelines were never finally adopted cannot be said to be a great loss.

E. Other Provisions

Besides the operative provisions on response measures and civil liability discussed above, the Supplementary Protocol also contains a number of other provisions.

I. Exemptions From Liability, Time and Financial Limits, and Right of Recourse (Articles 6 to 9)

Pursuant to Articles 6 to 8, states parties may restrict the liability of the operator in their domestic law on a number of grounds. Article 6 stipulates that parties may provide for exemptions in case of *force majeure*, war or civil unrest (para. 1). Besides, parties are allowed to provide 'for any other exemptions or mitigations as they may deem fit' (para. 2). According to Article 7, parties may provide for relative and/or absolute time limits and the commencement of the period to which such time limits apply. This expressly includes time limits 'for actions related to response measures', which refers to actions challenging administrative orders requiring such

347 See *infra* section F.V and chapter 2, section F.

348 *Jungcurt/Schabus* (n. 6), 203.

response measures.[349] Article 8 allows parties to provide for financial limits for the recovery of costs and expenses related to response measures. Article 9 provides that the Supplementary Protocol shall not limit or restrict any recourse or indemnity that an operator may have against any other person.[350]

In principle, exemptions from liability and financial limits are deemed to be fundamental prerequisites for the availability of private insurance policies, as insurers generally do not accept coverage of risks that are unlimited in both amount and time and that do not exclude certain events outside the influence of the insured persons, such as war or *force majeure*.[351] On the other hand, financial caps on liability seriously impair the victims' right to full compensation as well as the 'polluter-pays principle', which provides that the costs of environmental damage shall be fully internalized.[352] This concern could be (partially) resolved by establishing supplementary compensation schemes.[353]

However, the present provisions are problematic as they do not clearly indicate whether they refer to the administrative approach, civil liability, or both. Against this background, it has been argued that the provisions 'do not seem to fit well with the administrative approach' but were rather 'suited to the adversarial nature of civil liability'.[354] Indeed, other liability instruments following the administrative approach provide for exemptions and limitations only with respect to the liability of the operator for response measures it failed to take.[355] However, in the absence of such an express limitation, it must be assumed that Article 6 allows parties to provide for exemptions not only from financial liability but also from the principal requirement to take response measures.

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349 See Article 5(6) and *supra* section C.IV.6. In addition, 'actions related to response measures' may also refer to actions in which a competent authority seeks a judicial order of the operator to take response measures. See *supra* note 240 and accompanying text, and *supra* section C.V.2.

350 On the role of Article 9, see *supra* section C.II.

351 *Jungcurt/Schabus* (n. 6), 205. In the context of the Biodiversity Compact, see *J. T. Carrato* et al., The Industry's Compact and Its Implications for the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 218, 233.

352 Cf. *Faure/Wibisana* (n. 192), 565–566.

353 Cf. *Jungcurt/Schabus* (n. 6), 205; see *Yifru* et al. (n. 68), 32–40; *Förster* (n. 5), 365–370.

354 *Yifru/Garforth* (n. 9), 163.

355 See Antarctic Liability Annex (n. 19), Articles 8 and 9; EU Environmental Liability Directive (n. 18), Article 10.

A similar problem is posed by Article 8 on financial limits, which only addresses 'the recovery of costs and expenses related to response measures'. If limits were to be imposed on the obligation to make financial payments, but not on the obligation to take response measures in the first place, operators could refrain from taking such measures and opt for financial liability. This perverse incentive could be avoided by penalizing deliberate failures to take response measures. Furthermore, a limitation of liability should not only be applied to the obligation of the operator to recover costs and expenses incurred by others, but also to its own obligation to take response measures (e.g. by providing that, when taking response measures, an operator does not need to incur expenses exceeding the maximum amount for which it would be liable to third parties).

In any event, the provisions contained in Articles 6 to 8 grant a considerable degree of liberty to states parties to limit the liability of operators under their jurisdiction. This contrasts sharply with other civil liability instruments, which usually precisely outline the circumstances in which liability may be capped or limited.[356] In particular, the right to provide for 'any other exemptions or mitigations' in domestic law as parties 'may deem fit' considerably limits the Supplementary Protocol's effectiveness in harmonizing liability rules for LMO damage.[357]

II. Financial Security (Article 10)

Article 10 addresses the right of states parties to provide for 'financial security' in their domestic law. The first paragraph retains the right of parties

356 Cf. e.g. 1992 Oil Pollution Convention (n. 60), Articles III-V; HNS Convention (n. 60), Article 9; 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 60), Articles IV-V; Kiev Liability Protocol (n. 60), Articles 4(2), 9 and 10; but see Antarctic Liability Annex (n. 19), Articles 8 and 9, which also limits the financial liability to recover costs for response measures taken by others, but not the principal obligation of the operator to take response measures itself; also see *Johan G. Lammers*, International Responsibility and Liability for Damage Caused by Environmental Interferences, 31 (2001) Environmental Policy and Law 42–50 and 94–105, 100–103.

357 *Lim Tung* (n. 6), note 92 at p. 83 suggested that this may be used to exempt the operator from liability when damage is caused exclusively by an act or omission of other states or non-state actors or a third party. However, in these situations it would be more adequate not to hold the operator liable on grounds of him not having 'caused' the damage in the sense of Article 5(2)(a) SP. See *supra* section C.II.

to provide for financial security (1.). The second paragraph provides that this right shall be applied consistently with the parties' other rights and obligations under international law (2.). The third paragraph envisages a comprehensive study of issues related to financial security (3.).

1. Right of Parties to Provide for Financial Security (para. 1)

Article 10(1) stipulates that parties 'retain the right to provide, in their domestic law, for financial security'. Unlike most other international liability regimes,[358] the Supplementary Protocol does not establish an obligation to provide for financial security but only states that parties 'retain the right' to do so. Contrary to what the provision implies, the right to provide for financial security is not expressly recognized elsewhere, but rather flows directly from the general sovereignty of states under international law.[359] Article 10(1) thus only has a declaratory effect. Moreover, the Supplementary Protocol remains silent on the modalities of such financial security requirements. Hence, whether or not to adopt a financial security requirement at all, as well as the question of how such a requirement would be implemented under domestic law, is left to the discretion of the parties.[360]

The Supplementary Protocol does not define the meaning of the term 'financial security'. Generally, financial security denotes instruments like insurance policies or compensation funds established to ensure that sufficient financial resources are available when damage occurs, regardless of whether the responsible operator still exists and is solvent.[361]

In the context of damage arising from LMOs, three types of mechanisms can be envisaged. First, potentially liable operators might obtain financial security to cover the risk of being held liable for damage resulting from an

358 Cf. e.g. 1992 Oil Pollution Convention (n. 60), Article VII; HNS Convention (n. 60), Article 12; Bunker Oil Convention (n. 60), Article VII; 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 60), Article VII; Basel Protocol on Liability for Hazardous Wastes (n. 60), Article 14; Kiev Liability Protocol (n. 60), Article 11; Antarctic Liability Annex (n. 19), Article XI; see *Yifru* et al. (n. 68), 31–32.

359 See *supra* n. 57.

360 *Jusoh* (n. 6), 196.

361 See *Michael G. Faure*, Economic Criteria for Compulsory Insurance, 31 (2006) The Geneva Papers on Risk and Insurance 149, 154–155; *Förster* (n. 5), 362–364; *Jungcurt/Schabus* (n. 6), 204; *Yifru* et al. (n. 68), 27; *Lim Tung* (n. 6), 85–86; *Jusoh* (n. 6), 107–122.

LMO under their control (so-called *third party insurance*).[362] Besides insurance policies, financial security may take various forms, including bonds, bank guarantees, internal reserves, and industry pooling schemes.[363] Secondly, potential victims might also seek protection against damage caused by LMOs, such as farmers obtaining cover for possible income losses due to the contamination of conventionally grown crop stocks with LMOs (so-called *first party insurance*).[364] A third possible group of instruments are private or public compensation funds which enable rapid response measures in situations where the responsible operator has not yet been identified or to cover damage when no responsible party can be identified at all.[365]

Because the Supplementary Protocol only addresses operator liability but does not contain provisions on supplementary sources of compensation, it can be assumed that Article 10 primarily concerns the first scenario, i.e. financial security obtained by operators to cover their risk of being held liable. In this context, it should be recalled that the Supplementary Protocol also does not conclusively determine the liable party but leaves it with the parties to identify the responsible operator (which may be any person in direct or indirect control of the LMO[366]) in accordance with the criteria laid down in their domestic law.[367] Consequently, the Supplementary Protocol also does not stipulate which of the potentially liable operators shall be required to maintain financial security.[368] This could result in situations in which, depending on the jurisdiction, different operators have to maintain financial security for the one and the same LMO.[369] Moreover, since the Supplementary Protocol also applies to transboundary movements from non-parties,[370] maintenance of financial security may theoretically also be required from exporters situated in non-party states.[371]

In principle, it appears appropriate to impose the obligation to maintain financial security on the developer or producer of an LMO rather than on individual traders or farmers. In contrast to the latter, the developer or

362 Cf. *Yifru* et al. (n. 68), 19; *Faure/Wibisana* (n. 192), 567; *Jusoh* (n. 6), 108.
363 *Jungcurt/Schabus* (n. 6), 204; *Lim Tung* (n. 6), 86; *Jusoh* (n. 6), 122.
364 *Faure/Wibisana* (n. 192), 567–568; *Jusoh* (n. 6), 108.
365 *Jungcurt/Schabus* (n. 6), 204; *Lim Tung* (n. 6), 85; *Yifru* et al. (n. 68), 19.
366 Cf. Article 2(2)(c) SP.
367 Cf. Article 5(2)(a) SP; see *supra* section C.II.
368 *Lima* (n. 58), 135.
369 *Ibid.*
370 Cf. Article 3(7) SP, also see *supra* section B.III.4.
371 *Lima* (n. 58), 135.

patent-holder should be able to fully internalize the costs associated with obtaining financial security by incorporating these costs in the price of the product (e.g. the seeds). This approach would also implement the idea of 'channelling' liability to a specific party.[372] If, however, a distinction is made between damage caused by a 'development risk' (for which the developer or patent-holder would be held liable) and damage caused by inappropriate handling of the LMO (for which the operator in control at the relevant time would be held liable),[373] the obligation to maintain financial security should be imposed accordingly on each of the potentially liable operators.

2. Consistency of Financial Security Provisions With Existing International Law (para. 2)

Article 10(2) provides that parties shall exercise the aforementioned right 'in a manner consistent with their rights and obligations under international law, taking into account the final three preambular paragraphs of the [Cartagena] Protocol'.[374] These preambular paragraphs state that the relationship between trade and environmental agreements should be mutually supportive and that the Cartagena Protocol shall neither imply a change to rights and obligations arising from existing international agreements nor be subordinate to such other agreements.[375] Hence, Article 10(2) of the Supplementary Protocol primarily addresses the compatibility

372 Cf. *Xue* (n. 135), 80–86; but see *Jing Liu*, Compensating Ecological Damage (2013), 110, who argues that channelling of liability 'creates more uncertainties threatening the insurability of environmental liability', since the policy-holder may have to bear the costs produced by other parties.

373 See *supra* section C.II.

374 Throughout the text of the Supplementary Protocol, the Cartagena Protocol is referred to as 'the Protocol', while the Supplementary Protocol is expressly referred to as 'this Supplementary Protocol'.

375 The last three preambular paragraphs of the Cartagena Protocol, to which Article 10(2) of the Supplementary Protocol refers, read as follows: '*Recognizing* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,
Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,
Understanding that the above recital is not intended to subordinate this Protocol to other international agreements.'

of domestic rules on financial security with international trade law. The provision was included in the Supplementary Protocol to accommodate concerns that requirements to obtain financial security could result in unwarranted obstacles to international trade,[376] because it may be difficult or even impossible to obtain insurance cover for the strict liability attached to LMOs.[377] For this reason, the reference to said paragraphs of the Cartagena Protocol's preamble can be construed as an affirmation that any financial security measure adopted by a party would need to comply with international trade law.[378]

3. Study on Financial Security Mechanisms (para. 3)

Article 10(3) required the first COP-MOP after the entry into force of the Supplementary Protocol to request the CBD Secretariat to undertake a comprehensive study addressing, *inter alia*, the modalities of financial security mechanisms, an assessment of the environmental, economic and social impacts of such mechanisms and an identification of the appropriate entities to provide financial security. After the request was formally made by COP-MOP 9 in 2018,[379] the study was commissioned from an external contractor and tabled in October 2021.[380]

The study finds that there was little information available on existing financial security mechanisms for damage to biodiversity caused by LMOs and that existing literature on the subject rather focused on traditional

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376 Cf. *Lefeber/Nieto Carrasco* (n. 12), 66; *Tladi* (n. 103), 176–177; *Nijar* et al. (n. 12), 283–293.

377 Cf. *Paul Brown*, Insurers Refuse to Cover GM Farmers, The Guardian, 08 October 2003, available at: https://www.theguardian.com/science/2003/oct/08/gm.sciencenews (last accessed 28 May 2022); PartnerRe, GMO: Not New, but Still an Emerging Liability Risk, PartnerReviews May 2013, available at: https://partnerre.com/wp-content/uploads/2017/08/GMO_-_Not_New_But_Still_An_Emerging_Liability_Risk.pdf (last accessed 28 May 2022); see *Jusoh* (n. 6), 226–230.

378 On the relevant rules of international trade law and their relationship to the Cartagena Protocol, see chapter 3, section C.

379 CP COP-MOP, Decision 9/15. Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress, UN Doc. CBD/CP/MOP/DEC/9/15 (2018), para. 8.

380 *Michael G. Faure/Minzhen Jiang*, Study on Financial Security Mechanisms (Article 10 of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress), UN Doc. CBD/CP/MOP/10/INF/1, Annex (2021).

damage.[381] It then generally describes different types of financial security mechanisms, namely *first party* and *third party insurance*, *self-insurance*, *risk pooling* and *compensation funds*.[382] It discusses the suitability of each of these mechanisms to cover damage to biodiversity caused by LMOs and assessed their economic, environmental and social impacts, particularly on developing countries. The authors note that, given the uncertainties surrounding the risk type, there was a high reluctance among insurers to provide cover for LMO-related damage to biodiversity.[383] However, they suggest that other actors, such as large operators in the supply chain, could be willing to provide financial security either via self-insurance or via risk-sharing agreements.[384] The study concludes that governments could play a facilitative role by creating enabling conditions for the development of a variety of mechanisms and that it would be beneficial that information on existing financial security mechanisms was shared.[385]

4. Conclusions

Requiring the operator to hold appropriate financial security is an important element of any strict liability scheme because it ensures that liquid funds are available when damage occurs. By making import authorizations contingent upon proof that appropriate financial security is available in the receiving state, it is even possible to place the burden on foreign operators, such as the developer or producer of an LMO. However, the Supplementary Protocol does not oblige its parties to introduce compulsory insurance for LMOs in their domestic regimes but merely provides that the parties 'retain the right' to do so. Moreover, compulsory insurance schemes also run the risk of creating trade barriers that may not be justifiable under international trade law. It remains to be seen whether the treatment of the topic by the meeting of the parties to the Supplementary Protocol will yield any further development.

381 *Ibid.*, 11.
382 *Ibid.*, 15–43; see *supra* section E.III.1.
383 *Ibid.*, 14.
384 *Ibid.*, 45.
385 *Ibid.*

III. Relationship to State Responsibility (Article 11)

Article 11 provides that the Supplementary Protocol shall not affect the rights and obligations of states under the rules of general international law on state responsibility for internationally wrongful acts.[386] This relates to the Supplementary Protocol's general *leitmotif*, which is to impose liability on the 'appropriate operator' rather than the state where a noxious LMO was developed, produced, or into which it was imported.[387] Language providing for residual state liability in cases where a claim for damages has not been satisfied by an operator was proposed during the negotiations[388] but eventually not included in the Supplementary Protocol.[389]

IV. Review of Effectiveness (Article 13)

According to Article 13, the effectiveness of the Supplementary Protocol shall be reviewed every five years after its entry into force. Since the Supplementary Protocol entered into force in March 2018,[390] its first review is due in 2023. Article 13 also provides that the review shall be undertaken 'in the context of' the review of the Cartagena Protocol under its Article 35 unless otherwise decided by the parties to the Supplementary Protocol. The Cartagena Protocol's review cycles usually comprise two of the biannual COP-MOP meetings, and its fourth review will be concluded at COP-MOP 10 (currently scheduled for the third quarter of 2022[391]).[392] As a result, the first review of the Supplementary Protocol will likely be initiated along with the fifth review of the Cartagena Protocol at COP-MOP 11 (currently expected to take place in 2024) and concluded at the following

386 See chapter 9.

387 Cf. *Shibata* (n. 8), 38–39; *Jusoh* (n. 6), 189–190.

388 Cf. Group of Friends on L&R, Report of the […] Third Meeting, UN Doc. UNEP/CBD/BS/GF-L&R/3/4 (2010), 23.

389 *Shibata* (n. 8), 39.

390 Cf. UN OLA (n. 37).

391 The tenth meeting of the parties to the Cartagena Protocol (COP-MOP) will be held as part of the face-to-face segment of CBD COP 15, which was postponed several times due to the COVID-19 pandemic and, as of May 2022, is scheduled for the third quarter of 2022; see CBD Secretariat, Calendar of SCBD Meetings (25 May 2022), available at: https://www.cbd.int/meetings/ (last accessed 28 May 2022).

392 Cf. CP COP-MOP, Decision 9/6. Assessment and Review of the Effectiveness of the Cartagena Protocol (Article 35), UN Doc. CBD/CP/MOP/DEC/9/6 (2018).

COP-MOP two years later. However, the parties to the Supplementary Protocol could also decide to launch an independent review process already at COP-MOP 10.

The first review shall specifically review the effectiveness of Articles 10 and 12 (on financial security) and Article 12 (relating to implementation and civil liability). With regard to the latter, it has been argued that the review might provide an opportunity to assess whether parties have made efforts to assess their domestic laws and put in place the necessary 'adequate' laws on civil liability.[393] Indeed, the review might be an opportunity to strengthen certain terms of the Supplementary Protocol by way of interpretation.[394] As a downside, the subsequent reviews of the Supplementary Protocol are under the condition that the parties submit 'information requiring such a review', which essentially puts the performance of these reviews at the discretion of the parties.[395]

V. Relationship to Rights and Obligations Under International Law (Article 16)

Article 16 addresses the Supplementary Protocol's relationship with the CBD, the Cartagena Protocol, and international law generally. Paragraphs 1 and 2 clarify that the Supplementary Protocol shall only supplement the Cartagena Protocol and shall neither modify nor otherwise affect the rights and obligations stipulated in the Cartagena Protocol and the CBD. Paragraph 3 provides that the provisions of these instruments shall apply *mutatis mutandis* to the Supplementary Protocol.[396]

According to Article 16(4), the Supplementary Protocol 'shall not affect the rights and obligations of a Party under international law'. Since it is the very nature of international treaties to create – and thus to 'affect' the – legal rights and obligations of their parties,[397] the purpose and effect of Article 16(4) were called into question.[398] If Article 16(4) indeed meant

393 *Nijar* (n. 15), 123.
394 *Tladi* (n. 103), 174; see chapter 5, section B.II.
395 *Nijar* (n. 6), 289.
396 Article 16(3) SP; for an example of the practical implications of this provision, see *supra* text at n. 46.
397 *Crawford* (n. 57), 29–30: cf. VCLT (n. 253), Article 26; see *Kirsten Schmalenbach*, Article 26, in: Oliver Dörr/Kirsten Schmalenbach (eds.), Vienna Convention on the Law of Treaties (2nd ed. 2018), MN. 33.
398 *Yifru/Garforth* (n. 9), 162.

that the Protocol had no legal effect on the rights and obligations of its parties, it would undermine the objective of the Supplementary Protocol of 'providing international rules and procedures in the field of liability and redress relating to living modified organisms'.[399] Therefore, Article 16(4) should be construed as a *conflict clause* in the sense of Article 30(2) VCLT, pursuant to which the Supplementary Protocol is not meant to affect rights and obligations deriving from other sources of international law.[400] Although this still might have the questionable effect of subordinating the Supplementary Protocol to any other – in particular, older – rules of international law,[401] Article 16(4) does not render the Supplementary Protocol legally non-binding as long as no conflicting obligations arise from other sources of international law.[402]

VI. Governance- and Process-Related Provisions (Articles 14 to 21)

Six out of the twenty-one Articles of the Supplementary Protocol do not concern the instrument's subject matter but address governance- and process-related issues.[403] Articles 14 and 15 assign the Supplementary Protocol to the institutions already established by its framework instruments, namely the meeting of the parties to the Cartagena Protocol (COP-MOP) and the CBD Secretariat. Article 19 provides that parties may make no reservations to the Supplementary Protocol,[404] which is a provision that the Supplementary Protocol shares with both the Cartagena Protocol[405] and the CBD.[406] The remaining Articles 17 to 21 contain formal provisions relating to signature, entry into force, withdrawal, and the authentic language versions.

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399 Cf. Article 1 SP.
400 Cf. *Nele Matz-Lück*, Treaties, Conflict Clauses, in: Wolfrum/Peters (ed.), MPEPIL, MN. 8.
401 *Yifru/Garforth* (n. 9), 162 assert that Article 16(4) is both retrospective and prospective and thus could even subordinate the Supplementary Protocol to any possible future rules of international law.
402 See chapter 3, section C.III.
403 *Yifru/Garforth* (n. 9), 150.
404 Cf. VCLT (n. 253), Article 19(a).
405 Cf. Article 38 Cartagena Protocol.
406 Cf. Article 37 CBD.

F. Issues Not Addressed by the Supplementary Protocol

The preceding part of this chapter has focused on the provisions that are included in the Supplementary Protocol. However, there are also a number of problems that the Supplementary Protocol addresses only insufficiently or not at all. In terms of scope, the Supplementary Protocol does not apply to transboundary harm *stricto sensu* (I.). Substantively, the provisions on administrative liability do not address the designation of a competent authority by the parties (II.), the right of affected individuals to request action (III.), and the international coordination of response measures (IV.). Finally, the Supplementary Protocol contains no provisions relating to jurisdiction, applicable law, and the mutual recognition and enforcement of judgments (V.)

I. Transboundary Harm

As discussed earlier, the Supplementary Protocol only applies to biodiversity damage resulting from LMOs that find their origin in a *transboundary movement*, i.e. a movement of the LMO from one party to another.[407] Apart from *intentional* transboundary movements, this also includes situations in which an LMO *unintentionally* moves into another state (e.g. by natural gene flow or as an unintended consequence of human activity) and subsequently causes – or threatens to cause[408] – damage to biodiversity in that state.[409]

While the scope of the Supplementary Protocol is premised on transboundary *movements*, it does not encompass transboundary *damage*. The mere unsolicited presence of an LMO in the environment of another state is not regarded as 'damage' covered by the Supplementary Protocol as long as the LMO does not cause or threaten to cause harm to the biological diversity in that state.[410] In this respect, the Supplementary Protocol is in line with general international law on the prevention of transboundary harm, since the mere presence of an LMO does not *per*

407 Cf. Article 3(1) SP and Article 3(k) CP, see *supra* section B.III.

408 Cf. Article 5(3) SP, see *supra* section C.IV.3.

409 Cf. Article 3(3) SP. In these situations, Article 17 of the Cartagena Protocol requires the state of origin to notify and consult with the (potentially) affected states, which can arrange for the necessary response measures to be taken. See chapter 3, section A.II.2.b).

410 See *supra* section B.II.6.

se reach the threshold of 'significant harm' required for the preventive obligations under customary international law to apply.[411] Besides, the Supplementary Protocol also does not apply to *significant transboundary harm* to biodiversity that is not related to the transboundary movement of an LMO, namely secondary effects on biodiversity such as the spread of an invasive species into neighbouring states following the removal of a predator species by means of an engineered gene drive.[412] Given that the Supplementary Protocol does not address these situations, they are only subject to the general customary rules on the prevention of transboundary harm[413] and, in case of a breach, the rules of state responsibility.[414]

II. Designation of a Competent Authority

As shown above, the Supplementary Protocol provides for a number of tasks to be carried out by a 'competent authority'.[415] The Protocol thus presupposes that a competent authority exists in each state party. However, it does neither define the term nor expressly require its parties to establish or designate such an authority. Such an obligation can be found in Article 19(1) of the Cartagena Protocol, which provides that:[416]

> *'Each Party shall designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions.'*

According to Article 19(2) CP, parties must notify the name and address of their competent national authority and, in the case of multiple authorities, information on their respective responsibilities to the CBD Secretariat. In line with Article 19(3) CP, the CBD Secretariat maintains a list of

411 See chapter 4, section B.VII.2. In the context of engineered gene drives, see chapter 5, section D.II.
412 See *supra* section B.III.2.
413 See chapter 4.
414 Cf. *Jusoh* (n. 6), 202; see chapter 9.
415 See *supra* section C.IV.2.
416 Note that the Cartagena Protocol uses a slightly different terminology, as it refers to 'competent *national* authorities'.

all competent national authorities, which is available online and updated weekly.[417]

As the provisions of the Cartagena Protocol apply *mutatis mutandis* to the Supplementary Protocol,[418] it could be assumed that the obligations stipulated in Article 19 CP also apply to the designation of competent authorities responsible for implementing the Supplementary Protocol. This would result in an obligation to notify the name, address and responsibilities of the respective 'competent authority' (which does not necessarily need to be identical with the 'competent national authority' responsible for implementing the Cartagena Protocol[419]) to the CBD Secretariat. As of May 2022, however, only 12 parties to the Supplementary Protocol have expressly notified a competent authority responsible for issues concerning liability and redress.[420]

III. Right of Affected Individuals to Request Action

As shown above, the process of implementing the liability of the responsible operator is largely left to the discretion of the competent national authorities, which are responsible for deciding whether and to what extent

417 Cf. CBD Secretariat, Cartagena Protocol on Biosafety, Biosafety Clearing-House and Article 17 National Focal Points (27 May 2022), available at: https://www.cbd.int/doc/lists/cpb-bch-a17-fp.pdf (last accessed 28 May 2022).

418 Article 16(3) SP, see *supra* note 46 and accompanying text.

419 In Germany, for example, the federal government regulates the release of LMOs (see Gentechnikgesetz (Genetic Engineering Act) (n. 223), Section 14, while the *Länder* (federated states) are responsible for implementing administrative liability for environmental damage (including biodiversity damage caused by LMOs) in accordance with the EU Environmental Liability Directive (see Umweltschadensgesetz (Environmental Damage Act) (10 May 2007), revised version promulgated on 5 March 2021, Bundesgesetzblatt Pt. I, p. 346 in conduction with Article 83 of the Grundgesetz (Basic Law) (23 May 1949), revised version published in Bundesgesetzblatt, Pt. III, classification number 100–1, as last amended by Articles 1 and 2, second sentence, of the Act of 20 September 2020 (Bundesgesetzblatt Pt. I, p. 2048)).

420 Slovakia, Slovenia, the Czech Republic and Italy have each notified a designated 'Supplementary Protocol Competent Authority' to the BCH, while Colombia, Denmark, Hungary, Ireland, Mongolia, Uganda, the United Kingdom, and Vietnam have notified competent authorities that have an 'administrative function' for liability and redress, see Biosafety Clearing-House, Search for National Contacts, available at: https://bch.cbd.int/en/search?schema=contact&schema=authority&schema=supplementaryAuthority (last accessed 28 May 2022).

response measures shall be taken in each case.[421] Concerns have been raised that this might lead to 'arbitrary or uneven implementation', particularly because affected individuals have no right to demand the competent authority to take action.[422] In the EU Environmental Liability Directive, this issue has been solved by providing natural or legal persons affected by the environmental damage or who have a legal interest (e.g. environmental non-governmental organizations) the right to request the competent authority to take action.[423] Such a request for action must be accompanied by relevant information, and the competent authority is obliged to render a reasoned decision whether it does or does not take action.[424] Moreover, the decision shall be subject to a legal review by a court at the request of the affected individual.[425] However, no similar provisions have been included in the Supplementary Protocol.

IV. International Coordination of Response Measures

The Supplementary Protocol also does not provide rules on cooperation between affected states or international coordination of response measures. In the event of an *unintentional* transboundary movement, the only relevant provision is Article 17(4) of the Cartagena Protocol, which requires the state of origin to consult the affected states to enable them to determine appropriate responses.[426] With regard to LMOs subject to an *intentional* transboundary movement, Article 18(2)(c) of the Cartagena Protocol merely provides that such LMOs shall be accompanied by documentation specifying, *inter alia*, 'any requirements for the safe handling, storage, transport and use' of the LMO in question.[427] In addition, the importing party will be in possession of the information it has received during the AIA procedure. Hence, the Cartagena Protocol and the Supplementary Protocol merely provide for minimal information-sharing with the affected party. In contrast to other liability instruments, such as the Antarctic

421 See *supra* section C.IV.2.
422 *Lago Candeira* (n. 9), 99.
423 EU Environmental Liability Directive (n. 18), Article 12.
424 *Ibid.*, Article 12(2).
425 *Ibid.*, Article 13.
426 See chapter 3, section A.II.2.b).
427 See chapter 3, section A.II.2.d).

Liability Annex,[428] there is no substantive obligation to cooperate and consult with other states concerned.

V. Jurisdiction, Applicable Law, and Mutual Recognition and Enforcement of Judgments

Finally, the Supplementary Protocol does not address issues relating to the transboundary enforcement of liability. This is unproblematic as long as the responsible operator is a national of, or situated in, the state where the damage occurs.[429] However, in many cases, the responsible operator will not be situated under the jurisdiction of the state where the LMO was imported and subsequently caused damage. Hence, enforcing the liability of these actors requires that the state which has jurisdiction over the responsible operator recognizes and enforces the administrative or judicial decisions of the state where the damage occurred.[430]

As shown above, states have no general obligation to recognize and enforce foreign judgments.[431] Therefore, comparable liability instruments contain specialized rules on jurisdiction, applicable law, and mutual recognition and enforcement of judgments, which allows holding operators liable even if they are not located in the state where the damage occurred.[432] But the Supplementary Protocol contains no such rules.[433] Thus, whether the liability of foreign operators can be enforced will depend on the legal systems and eventually also on the goodwill of the states involved.[434]

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428 Cf. Antarctic Liability Annex (n. 19), Article 5.

429 *Yifru/Garforth* (n. 9), 158.

430 *Jungcurt/Schabus* (n. 6), 201–202; *Yifru/Garforth* (n. 9), 158; *Lefeber* (n. 19), 90.

431 See chapter 2, section F.

432 See *ibid.*, n. 93.

433 A rule providing that parties 'shall recognize and enforce foreign judgments' was proposed during the negotiations on civil liability, see Report of the First Meeting of the Group of Friends of the Co-Chairs on Liability and Redress (2009) (n. 236), 14. Eventually, no such rule was included in the Supplementary Protocol since 'some countries upheld their categorical opposition' to such a provision, cf. IISD, Summary of the Second Meeting of the Group of Friends of the Co-chairs on Liability and Redress (n. 25), 7.

434 *Yifru/Garforth* (n. 9), 158. Within the European Union, the applicable law, jurisdiction and the enforcement of judgments are subject to harmonized rules. Rules relevant in the present context are Regulation (EU) No 1215/2012 on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters (12 December 2012), OJ L 351, p. 1, and Regulation (EC)

This omission is particularly striking given that a transboundary situation is a precondition for the Supplementary Protocol to apply. As shown above, the Supplementary Protocol only applies when the LMO that caused the damage has previously been subject to a transboundary movement.[435] This usually implies that the development or production of the LMO has taken place in a state other than where the damage occurred.[436] Furthermore, the Supplementary Protocol suggests that the range of potentially liable operators extends to the developer, producer, and exporter of the LMO[437] who, by definition, are not situated in the territory of the party of import. This means that the Supplementary Protocol proposes to hold operators liable who are located in foreign jurisdictions but does not provide the legal means for accomplishing this.[438] Consequently, liability will most likely be imposed on domestic operators, regardless of whether they are actually responsible for the damage[439] and capable of taking the

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No 864/2007 on the Law Applicable to Non-Contractual Obligations (11 July 2007), OJ L 199, p. 40; see *Thomas Kadner Graziano/Matthias Erhardt*, Cross-Broder Damage Caused by Genetically Modified Organisms: Jurisdiction and Applicable Law, in: Bernhard A. Koch (ed.), Damage Caused by Genetically Modified Organisms (2010) 784.

435 See *supra* section B.III.

436 It may well be that the responsible operators are spread over multiple foreign jurisdictions. An example for this is the case of transgenic mosquitoes imported to Burkina Faso by Target Malaria, which were developed in the United Kingdom, tested in laboratories in the United States and Italy, and subsequently exported to Burkina Faso, cf. *Keith R. Hayes* et al., Risk Assessment for Controlling Mosquito Vectors with Engineered Nucleases: Controlled Field Release for Sterile Male Construct: Risk Assessment Final Report (2018), 137; also see chapter 3, section A.II.1.g)aa).

437 See the definition of the term 'operator' in Article 2(2)(c) SP and *supra* section C.II.

438 *Jungcurt/Schabus* (n. 6), 201–202, see *Lefeber* (n. 19), 90, who points to the Compact, which allows for recourse against foreign developers and thus 'adds value to the Supplementary Protocol', but overlooks that the Compact is designed not as an *additional* but an *alternative* liability scheme, see chapter 7.

439 Pursuant to Article 5(2)(a) SP, liability shall be imposed on the 'operator which has caused the damage'. It has therefore been suggested above that where the damage results from the inherent characteristics of an LMO rather than its circumstances of release or application, liability should be imposed on the developer or producer of the LMO which, in most cases to which the Supplementary Protocol applies, will be located in a foreign jurisdiction, see *supra* section C.II.

necessary response measures or meeting the consequential financial obligations.[440]

G. Excursus: CropLife International's Implementation Guide

In 2013, *CropLife International*, an industry association of crop protection and agrochemical corporation, published an *Implementation Guide* to the Supplementary Protocol.[441] Being published by a private entity, the Guide has no direct bearing on the legal obligations of states under the Supplementary Protocol. Nevertheless, it may be considered relevant by states seeking to implement the Supplementary Protocol into their domestic law, particularly considering the relative sparsity of in-depth assessments of the Protocol's provisions.[442]

The Guide's stated objective is to 'assist countries that do not have existing mechanisms to address damage to the conservation and sustainable use of biological diversity to develop a system for identifying responsible operators and requiring response measures in conformity with the […] Supplementary Protocol'.[443] The Guide provides an example text for implementing the Supplementary Protocol in a stand-alone legal instrument. This draft legislation essentially restates the text of the Supplementary Protocol while making modifications and additions where the Supplementary Protocol refers to domestic law.[444]

In terms of scope, the Implementation Guide proposes to treat alike imported and domestically-developed LMOs (I.). To identify the liable operator, it fully relies on the 'control test' stipulated by the Supplementary Protocol (II.). Damage shall be determined only on the basis of peer-reviewed or peer-reviewable scientific information (III.). The Implementation Guide also addresses the determination of suitable response measures (IV.). Concerning civil liability, the Guide suggests that states would not have to take any implementation measures (V.).

440 In can be assumed that in most cases, developer, patent-holder or producer of the LMO may also be better equipped to take response measures than local actors and may also have higher financial resources to cover the costs of response measures and to serve compensation.
441 CropLife Implementation Guide (n. 146).
442 See *supra* n. 6.
443 CropLife Implementation Guide (n. 146), 4.
444 See text at n. 482.

I. Proposed Scope of Domestic Implementing Legislation

As shown earlier, the Supplementary Protocol only applies to LMOs which have been subject to a transboundary movement, but not to LMOs which have only been developed and used domestically.[445] But the Implementation Guide argues that it was 'irrelevant' whether the damage was caused by domestic or foreign operators. Consequently, the Guide suggests that national legislation implementing the Supplementary Protocol should apply equally to domestic activities and those involving a transboundary movement, 'thus avoiding any WTO implications or violations'.[446]

Furthermore, the Guide proposes that the scope of domestic implementing legislation should extend to damage resulting from 'unapproved activities and activities that are illegal under national law'.[447] This would rectify a major shortcoming of the Supplementary Protocol, which excludes damage resulting from LMOs that were lawfully *imported*, but subsequently *used* without appropriate authorization.[448]

II. Identification of the Liable Operator and Exemptions

Concerning the identification of the responsible operator, the Implementation Guide proposes to fully rely on the 'control test' as introduced by the Supplementary Protocol,[449] under which liability should be placed on the 'the person in direct or indirect control of the product or the activity that caused the Damage'.[450] The Implementation Guide advises not to adopt the examples of who might be an 'operator' contained in Article 2(2)(c) SP, arguing that the 'control' test was sufficient to establish the identity of the operator.[451] However, as shown above, it will often be difficult to attribute damage to a single event or a particular activity.[452] Hence, the Implementation Guide not only fails to provide additional guidance in this respect but even increases the ambiguity created by the Supplementary Protocol.

445 See *supra* section B.III.6.
446 CropLife Implementation Guide (n. 146), 12.
447 *Ibid.*
448 See *supra* section B.III.1.
449 Cf. Article 2(2)(c) SP.
450 CropLife Implementation Guide (n. 146), 10.
451 *Ibid.*
452 See *supra* section C.II.

The Implementation Guide also proposes that an operator should not be held liable when the damage was caused by the realization of a risk that was specifically assessed in the risk assessment carried out as part of the AIA procedure under the Cartagena Protocol.[453] This would result in exempting the operator from liability for all risks known in advance and despite which the competent national authority authorized the import and release of the LMO. Consequently, the scope of liability would be limited to the realization of risks that were unknown when the import was authorized. But it is hardly conceivable how this could be in line with the overall objective of the Supplementary Protocol, which makes no distinction between known and unknown risks.

III. Determination of Damage

Determination of damage is addressed by the Implementation Guide in an annex to the draft legislation. The annex proposes two alternative texts, which are based on the *EU Environmental Liability Directive*[454] and the *Biodiversity Compact*,[455] respectively. Under both alternatives, damage shall be established by comparing the nature and quantum of change in the species or ecosystem with the *baseline*, i.e. the conditions that prevailed before the incident.[456] The baseline shall be established by referring to the 'best available information', which is defined as 'peer-reviewed or peer-reviewable information obtained through the generally accepted scientific methodology used in the relevant scientific community of endeavour'.[457] The annex provides numerous criteria that shall be taken into account when establishing the baseline and comparing it with subsequent changes, including the number of species, their density or the area covered, the role of the particular species in relation to other species and their capacity to propagate and recover naturally.[458] Compared to the Supplementary Protocol,[459] the Implementation Guide sets a high threshold for determining the existence of damage, particularly because peer-reviewed (or peer-re-

453 CropLife Implementation Guide (n. 146), 15.
454 See EU Environmental Liability Directive (n. 18).
455 See Biodiversity Compact (n. 66); for details on the Compact, see chapter 7.
456 CropLife Implementation Guide (n. 146), 19–20.
457 *Ibid.*, 11.
458 *Ibid.*, 19.
459 See *supra* section B.II.3.

viewable) information about the *status quo ante* may not necessarily be available.

IV. Identification of Suitable Response Measures

A second annex to the Implementation Guide addresses the determination of response measures by the competent authority.[460] Again, two alternative texts are provided that build upon the EU Environmental Liability Directive and the Biodiversity Compact. Although the alternatives use different terminology, both emphasize the primacy of restoration over compensation, i.e. the principle that response measures should preferably *restore* the affected components of biodiversity to their baseline condition rather than *compensate* for losses by improving other elements of biodiversity. Notably, the text adapted from the Biodiversity Compact goes beyond the Supplementary Protocol by providing that the operator should pay financial compensation where restoration is not possible.[461] At the same time, the Implementation Guide remains silent on who should be the beneficiary of such financial compensation and how it should be spent.[462]

V. Civil Liability

With regard to Article 12(2) SP, which requires parties to provide rules and procedures on civil liability for material and personal damage, the Implementation Guide asserts that parties would not need to take any measures to discharge this obligation.[463] It argues that 'nearly every country already has a system providing for civil liability and redress' and that parties could thus simply apply existing law to discharge the obligation to provide for civil liability.[464] But this overlooks that parties are required to provide for *adequate* rules to address damage, which requires at least

460 CropLife Implementation Guide (n. 146), 21–23.
461 *Ibid.*
462 Cf. *ibid.*
463 See *supra* section D.II.
464 CropLife Implementation Guide (n. 146), 5, pointing to *Lucas Bergkamp*, Liability and Redress: Existing Legal Solutions for Traditional Damage, in: CropLife International (ed.), Compilation of Expert Papers Concerning Liability and Redress and Living Modified Organisms (2004) 21.

that parties evaluate whether their existing rules are equipped to address personal and material injury caused by LMOs.[465]

VI. Conclusions

It is doubtful that the Implementation Guide published by CropLife International provides a real added value for states seeking to implement Supplementary Protocol. Instead of providing specific guidance on how to establish the administrative apparatus required to effectively implement administrative liability, the Guide proposes to implement the Supplementary Protocol into domestic law by largely restating its terms.

Substantial additions can only be found in a few aspects, where the Implementation Guide tries to fill gaps left by the Supplementary Protocol by adapting language from the EU Environmental Liability Directive and the Biodiversity Compact. For instance, the Guide suggests specifying the rudimentary definitions of 'damage' and 'response measures' in the Supplementary Protocol by adopting the procedural approaches to these issues taken by the aforementioned instruments. Yet, the proposition that the occurrence of damage should always be established on the grounds of peer-reviewed or peer-reviewable information[466] appears to be rather unrealistic, especially considering that damage might often occur in situations where the receiving environment, and the risks posed to it by the LMO in question, have not been assessed carefully enough.

In addition, the Implementation Guide offers no helpful solutions for some of the most significant weaknesses of the Supplementary Protocol, including the question of how the 'control test' can be practically applied to identify the responsible operator. Against this background, it is quite astonishing that the co-chairs of the negotiations leading to the adoption of the Supplementary Protocol contributed a foreword in which they commended the Implementation Guide as a 'valuable tool for governments to better understand and consequently better apply at the domestic level the provisions of the Supplementary Protocol'.[467]

465 See *supra* section D.IV.
466 CropLife Implementation Guide (n. 146), 11.
467 *Ibid.*, 3.

H. Summary and Outlook

While the Supplementary Protocol's adoption in 2010 was hailed as a great success, its entry into force in 2018 was barely noticed by the international community, although it was by far the more remarkable event. For more than three decades, international law-making efforts on environmental liability have suffered from persistent failure due to the refusal of states to ratify the instruments they had previously agreed to in negotiations.[468] Therefore, the Supplementary Protocol is not only the first global agreement on liability for damage to a global common, and the first global agreement providing for an administrative approach to liability,[469] but also the first global agreement dealing with environmental liability outside the context of maritime oil pollution and nuclear damage that has ever entered into force.

One of the main keys to success of the Supplementary Protocol was certainly its 'administrative approach' to liability. Instead of providing simply for the payment of monetary compensation by the responsible operators, the Supplementary Protocol stipulates that damage shall be prevented, mitigated and restored by implementing response measures. However, parties to the Supplementary Protocol enjoy too much leeway in implementing the administrative approach in their domestic legal and administrative systems. Apart from stipulating the primacy of prevention over restoration, and of restoration over compensation,[470] the Supplementary Protocol does not define any specific criteria for what constitutes damage to biological diversity, how to identify the liable actor, and what kinds of response measures shall be taken. It has been criticized that this might result in 'discretionary implementation' of the Supplementary Protocol by its parties.[471] At the same time, it might be an inherent necessity of

468 See the surveys in *Robin R. Churchill*, Facilitating (Transnational) Civil Liability Litigation for Environmental Damage by Means of Treaties, 12 (2002) YB Int'l Env. L. 3, 31–32; *Noah Sachs*, Beyond the Liability Wall: Strengthening Tort Remedies in International Environmental Law, 55 (2007) UCLA Law Review 837, 854–857; *Daniel* (n. 28), 225–235; *Jutta Brunnée*, Of Sense and Sensibility: Reflections on International Liability Regimes as Tools for Environmental Protection, 53 (2004) ICLQ 351, 356–364. The last notable entry into force of any international treaty on environmental liability was that of the Bunker Oil Convention (n. 60) in 2008.

469 *Lefeber* (n. 19), 89.

470 See *supra* section C.I.

471 *Lim Tung* (n. 6), 74.

the 'administrative liability' approach to grant states a certain margin of appreciation, as it is not possible to pre-emptively regulate what measures will be required in individual cases of damage.

In any event, the administrative approach is 'premised on the existence of a robust administrative apparatus' which has both the capacity and expertise to implement liability in individual cases.[472] It has been argued that many developing countries do not have these capacities and that the administrative approach thus might reinforce pre-existing imbalances between developing and developed countries.[473] There is a consensus that the Supplementary Protocol must be accompanied by extensive capacity-building measures,[474] and such measures have indeed been organized by the CBD Secretariat.[475]

With respect to personal injury and property damage, the Supplementary Protocol does not even attempt to harmonize substantive and procedural rules on civil liability. This is not surprising if one considers that states widely refuse to accept the harmonization approach, as aptly demonstrated by the numerous civil liability treaties that have failed to enter into force.[476] Had the Supplementary Protocol attempted to provide substantive rules on civil liability in the context of LMO damage, it would have likely suffered a similar fate. This also became clear during the Supplementary Protocol's negotiations, where many states strongly opposed the inclusion of substantive rules on civil liability.[477] Therefore, the resulting provisions represent a carefully balanced compromise between those parties who sought a fully-fledged international civil liability regime and those who opposed the adoption of rules on civil liability altogether.[478] Consequently, the Supplementary Protocol does not commit the parties

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472 *Shibata* (n. 8), 36.

473 *Jungcurt/Schabus* (n. 6), 206; *Thomas/Teshome Kebede* (n. 22), 126–127.

474 Cf. CP COP-MOP Decision BS-V/11 (2018) (n. 35), paras. 8–9; *Shibata* (n. 237), 248–249; *Jungcurt/Schabus* (n. 6), 206.

475 See CBD Secretariat, The N–KL Supplementary Protocol: Capacity Building Activities (01 January 2018), available at: https://bch.cbd.int/protocol/supplementary/NKL_workshops.shtml#tab=0 (last accessed 28 May 2022).

476 See *supra* n. 468.

477 Also see ILA, International Law on Biotechnology: Draft Final Report and Draft Final Recommendations (2010), para. 68, assuming that 'international law should be limited to adopting a minimal standard of product liability while allowing nations to impose stricter standards commensurate with their interests', since the matter was 'not suitable for legal harmonization'.

478 See *supra* section A, text at n. 21; cf. *Nijar* (n. 15), 120–123; *Thomas/Teshome Kebede* (n. 22); *Nijar* (n. 6), 277–278; *Gupta/Orsini* (n. 6), 449–450.

to particular standards on civil liability but only stipulates a procedural duty requiring states to 'aim' for 'appropriate rules and procedures' in their domestic law.[479] It has been assumed that as a result of these provisions, 'the parliamentary approval processes in many States will involve a comprehensive assessment and discussion of domestic law related to personal injury, property damage and economic loss (traditional damage) caused by LMOs'.[480] But this prediction has not come true, at least concerning the approval processes in the European Union and Germany, during which the provisions on civil liability were largely ignored.[481]

There are 18 references to 'domestic law' spread over nine articles of the Supplementary Protocol. Only four of these occurrences are used in provisions relating to the implementation of the Supplementary Protocol *into* domestic law.[482] All of the other 14 references are used in provisions that subordinate certain rules of the Supplementary Protocol to the domes-

479 Cf. Article 12(2); see *supra* section D.V.

480 *Lefeber* (n. 19) also see *Lim Tung* (n. 6), 89; *Thomas/Teshome Kebede* (n. 22), 130.

481 The European Commission assumed that '[t]he liability provisions of the Nagoya-Kuala Lumpur Supplementary Protocol are covered by the Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004, on environmental liability with regard to the prevention and remedying of environmental damage', cf. European Commission, Proposal for a Decision of the European Parliament and of the Council on the Conclusion of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (05 June 2012), COM(2012) 236, Explanatory Memorandum, para. 12. This assessment was not challenged during the legislative processes, see EUR-Lex, Procedure 2012/0120/NLE, available at: https://eur-lex.europa.eu/legal-content/EN/HIS/?uri=CELEX:32013D0086 (last accessed 28 May 2022). In the parliamentary approval process, the Federal Government of Germany assumed that there is no need for implementation measures, as the existing national rules already complied with the content and obligations of the Supplementary Protocol, cf. Federal Government, Entwurf eines Gesetzes zu dem Zusatzprotokoll von Nagoya/Kuala Lumpur vom 15. Oktober 2010 über Haftung und Wiedergutmachung zum Protokoll von Cartagena über die biologische Sicherheit (Draft Law on the Nagoya/Kuala Lumpur Supplementary Protocol of 15 October 2010 on Liability and Redress to the Cartagena Protocol on Biosafety), BT-Drs. 17/12337 (2012).

482 Article 3(7) provides that domestic law shall also apply to damage resulting from transboundary movements of LMOs from non-parties. Article 5(6) provides that domestic law shall provide for remedies against the decisions of the competent authority. Pursuant to Article 12(1) parties shall provide, in their domestic law, for rules and procedures that address damage. Article 12(2) commits parties to the 'aim of providing adequate rules and procedures in their domestic law on civil liability' for traditional damage.

tic law of its parties.[483] In fact, almost all of the Supplementary Protocol's substantive provisions are either 'subject' to domestic law or shall only be implemented 'in accordance with' domestic law.[484] The sweeping use of domestic law safeguards results in an instrument that may have more optional than binding rules.[485] Consequently, parties enjoy more or less full discretion on how to implement the Supplementary Protocol into their domestic legal systems.[486] For this reason, it has been rightly criticized as a treaty that is largely 'subject to domestic law'.[487] As a result, it is difficult to predict whether the resulting domestic regimes will provide satisfactory responses to biodiversity damage caused by LMOs.[488]

One of the most striking omissions of the Supplementary Protocol is its failure to address transboundary recognition and enforcement. Although it only applies to damage resulting from LMOs that find their origin in a transboundary movement,[489] it remains silent on how to deal with situations in which the responsible operator is located in one state and biodiversity damage occurs in another.[490] The Supplementary Protocol fails to address the issues that naturally arise in these situations, including jurisdiction, applicable law, and recognition and enforcement of judgments.[491] Thus, the Supplementary Protocol only applies to transboundary situations but treats liability in these situations as if they were a purely domestic matter.[492]

Against this background, it is doubtful that the Supplementary Protocol will be of particular use when LMOs have unintended transboundary effects. As shown above, the emergence of so-called *self-spreading LMOs*, which can disseminate genetic modifications at much higher rates than under the Mendelian rules of inheritance or even 'horizontally' to already-living organisms, substantially increases the likelihood of uncontrolled transboundary spreads.[493] Although the Supplementary Protocol expressly

483 These provisions can be found in Articles 2(2)(c), 3(6), 4, 5(5), 5(6), 5(7), 5(8), 6(1), 6(2), 7, 8, 10(1) and 12(2) SP.
484 *Yifru/Garforth* (n. 9), 155.
485 Cf. *ibid.*
486 *Foster* (n. 246), 367; *Lim Tung* (n. 6), 74.
487 *Yifru/Garforth* (n. 9), 165; *Gupta/Orsini* (n. 6), 448.
488 *Sands* et al. (n. 150), 799.
489 Article 3(1) SP.
490 See *supra* section F.V.
491 *Yifru/Garforth* (n. 9), 158; see chapter 2, section F.
492 Cf. *Jungcurt/Schabus* (n. 6), 201–202; *Lefeber* (n. 19), 90.
493 See chapter 1, sections C and D.

applies to unintentional transboundary movements, it does not provide any means to deal with such situations.[494] Unless the 'operator which has caused the damage' has assets in the affected state that can be seized to enforce liability, and in the absence of other instruments, a state facing adverse effects of an LMO that uncontrolledly entered its territory has no remedies to enforce either the civil or administrative liability of foreign operators. In such situations, the only options are seeking civil law remedies in states where the responsible operator is situated or has assets, or invoking the international responsibility of the state that has authorized the release, provided it has breached preventive obligations under international law.

Despite the criticism, some positive conclusions can be drawn as well. Most importantly, the Supplementary Protocol represents a general agreement that LMOs may cause damage to biological diversity and that speedy restoration measures are the most effective response to such damage.[495] Moreover, the Supplementary Protocol is innovative in that it distinguishes between damage to the environment *per se* on the one hand and 'traditional damage', i.e. injury to rights and interests of individuals, on the other.[496] Biodiversity damage shall be addressed by response measures to mitigate and restore the damage, whereas material and personal damage shall be subject to conventional rules on civil liability. The obligation of states to implement domestic legal frameworks that provide for 'response measures' to address environmental damage is the principal contribution made by the Supplementary Protocol to the 'toolbox' of international environmental law-making.[497]

Finally, it should again be recognized that the Supplementary Protocol is one of the few multilateral agreements on environmental liability concluded in the last three decades that have attracted enough ratifications to enter into force. It is also the first international treaty on environmental liability to enter into force that adopts the administrative approach to liability.[498] At least in its specific context and institutional framework, the Supplementary Protocol has overcome the paralysis under which the

494 Article 3(3) SP, see *supra* section B.III.2.
495 *Yifru/Garforth* (n. 9), 164–165; *Shibata* (n. 237), 242.
496 *Shibata* (n. 237), 242.
497 *Telesetsky* (n. 184).
498 The other instruments which provide for an administrative approach is the Antarctic Liability Annex (n. 19) which, as of May 2022, still required nine more approvals to enter into force (see *Alan D. Hemmings*, Liability Postponed: The Failure to Bring Annex VI of the Madrid Protocol into Force, 8 (2018) The

development of international rules on environmental liability has been suffering for many years.[499] However, it also demonstrates the low level of agreement among states about substantive standards for environmental liability. This becomes particularly visible in the context of civil liability, where the sense of negotiating agreements with little prospect of ever entering into force has been repeatedly called into question.[500] Hence, it remains to be seen whether the Supplementary Protocol indeed signifies the urgently-needed 'paradigm evolution' in international liability law[501] and whether it will serve as a role model for developing other instruments in the future.[502] In any event, adopting instruments on transboundary environmental liability that do not actually address the challenges arising from transboundary situations will likely prove to be a Pyrrhic victory.

Polar Journal 315), and the Kiev Liability Protocol (n. 60), which has received only one out of 16 required ratifications.

499 Cf. *Shibata* (n. 237), 241, who characterizes the phenomenon as 'liability occlusion'. Also see *Lefeber* (n. 19), 91, who sees the adoption of the Supplementary Protocol as part of a 'paradigm evolution' away from harmonisation of domestic civil liability and towards the administrative approach.

500 See, in particular, *Daniel* (n. 28); *Brunnée* (n. 468), 98.

501 Cf. *Lefeber* (n. 19), 91.

502 Cf. *Telesetsky* (n. 184), 106; *Lefeber* (n. 19), 90–91; *Li C. Lim/Li L. Lim*, Gene Drives: Legal and Regulatory Issues (2019), 40–43.

Chapter 7: A Private Liability Scheme: The 'Biodiversity Compact'

As shown in the previous chapter, one of the Supplementary Protocol's major shortcomings is that it does not provide a basis for the transboundary enforcement of liability. This is particularly striking if one considers that the Supplementary Protocol only applies when a harmful LMO has been subject to a transboundary movement, but stipulates no rules on the recognition and enforcement of foreign administrative or judicial decisions. Consequently, whether it is possible to hold foreign operators liable for biodiversity damage caused by a noxious LMO will depend on the domestic legal systems of the states involved and their interaction.[1]

Besides the conclusion of international treaties between states, an alternative approach to addressing transboundary environmental concerns is through *self-regulation* undertaken by private actors whose activities are the cause of concern. The approach is based on the hypothesis that involving business and industry by means of voluntary undertakings and contractual arrangements might be more effective in implementing environmental policies than conventional instruments of international law such as treaties.[2] Self-regulation may also involve private compensation schemes for environmental damage. For instance, the *Offshore Pollution Liability Agreement* is a voluntary agreement of oil-producing companies establishing a liability scheme for pollution damage caused by incidents in the production of offshore oil.[3] A similar scheme, called the *Biodiversity Compact*, was established for damage to biological diversity caused by the release of LMOs into the environment.[4]

1 See chapter 6, section F.V.

2 See *Jürgen Friedrich*, Environment, Private Standard-Setting, in: Wolfrum/Peters (ed.), MPEPIL.

3 Oil Companies Offshore Pollution Liability Agreement (OPOL) (04 September 1974), 13 ILM 1409, as last amended effective 21 June 2017; see *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 789.

4 The Compact: A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a Living Modified Organism, Second

The Compact was concluded by six major biotechnology corporations in June 2010, only a few months before the Supplementary Protocol was adopted.[5] The corporations involved hoped that establishing a voluntary compensation scheme would weaken the demands for a legally binding international regime on civil liability.[6] At the same time, they wanted to demonstrate their confidence in the safety of their products by voluntarily assuming responsibility.[7] According to the Compact's preamble, the member corporations 'have tremendous confidence in the safety and their stewardship of the LMOs they develop and Place [sic[8]] on the Market'.[9]

Pursuant to the Compact, each member undertakes and agrees to respond to damage caused by any of its LMOs by taking restoration measures or paying financial compensation. Technically, the Compact is designed as a *third-party beneficiary contract*,[10] under which the signatories grant states an enforceable right to response action or compensation. Thus, states are the beneficiaries of the contract despite not being themselves parties to it.[11] The Compact can be signed by any legal person engaged with the release of LMOs, provided that it meets the membership criteria (A.).

The Compact's substantive provisions parallel those of the Supplementary Protocol to a certain degree. The Compact applies in the event that the release of an LMO by one of the signatories causes damage to biological diversity (B.). However, it specifies in much greater detail than the Supplementary Protocol under which circumstances damage to biodiversity gives rise to liability. It contains detailed provisions on the requirement

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Amended Text (18 September 2012), available at: http://www.biodiversitycompact.org/wp-content/uploads/Compact-Second-Amended-Text-with-translation-reference-January-2014-2.pdf (last accessed 28 May 2022).

5 For more details on the historical background, see *Amandine Orsini*, Business as a Regulatory Leader for Risk Governance? The Compact Initiative for Liability and Redress Under the Cartagena Protocol on Biosafety, 21 (2012) Environmental Research 960; *J. T. Carrato* et al., The Industry's Compact and Its Implications for the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 218.

6 *Stefan Jungcurt/Nicole Schabus*, Liability and Redress in the Context of the Cartagena Protocol on Biosafety, 19 (2010) RECIEL 197.

7 *Ibid.*, 205; *Orsini* (n. 5), 961.

8 In quotations from the text of the Compact, the capitalizations used therein (indicating terms for which a definition is given in Article 2.4) are reproduced unchanged in the present text.

9 Biodiversity Compact (n. 4), 10.

10 *Thijs F. Etty*, 7. Biotechnology, 22 (2011) YB Int'l Env. L. 318, 327.

11 Cf. *Carrato* et al. (n. 5), 223.

of causation, the identification of the party liable, and the standard of liability (C.). The Compact also provides for a number of defences that exclude liability, including that the damage resulted from a known risk (D.). With regard to potential remedies, the Compact follows a two-pronged approach, providing for both restoration and compensation (E.). Liability is limited by strict financial and time limits (F.). One of the Compact's main merits is a compulsory dispute settlement mechanism that is able to produce internationally enforceable awards (G.).

A. Membership

The signatories of the Compact, referred to as 'Members', currently comprise five major biotechnology companies.[12] Membership in the Compact is open to all entities with legal personality that are engaged in the release of LMOs,[13] provided that they meet the membership criteria.[14] Members must, *inter alia*, participate in stewardship programmes and perform rigorous assessments of their LMOs prior to any release. Moreover, members must demonstrate their capacity to meet their potential financial obligations in case they are held responsible under the terms of the Compact.[15] According to the bylaws to the Compact, this capacity shall be demonstrated by means of a third-party certificate of insurance, documentation of provision for self-insurance, or by other means that satisfy criteria determined by an *Executive Committee* established by the Compact.[16] At the same time, the Compact acknowledges that its membership goals are difficult to achieve as long as commercial insurance or financial support

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12 The current members of the Compact are *BASF*, *Bayer CropScience*, *Dow Agrosciences*, *DuPont*, and *Syngenta*, see CropLife International, The Compact, available at: http://www.biodiversitycompact.org/ (last accessed 28 May 2022). *Monsanto Company*, which was the sixth founding member, ceased to exist as a separate legal entity in 2018 after being acquired by Bayer.

13 According to Article 2.4.xli, 'release' denotes 'any instance in which an LMO enters the environment'. This includes the 'placing on the market' of LMOs, which is defined in Article 2.4.xxxv as 'making an LMO available for any use in a State'.

14 Biodiversity Compact (n. 4), Article 3.1.

15 *Ibid.*, Article 3.5.

16 *Ibid.*, Appendix A, Article 4.2.c.

for potential obligations of small and medium enterprises is not available or affordable.[17]

B. Scope

The Compact applies when the release of an LMO by one of the signatories causes damage to biological diversity.[18] So-called 'traditional damage', such as personal injury, property damage, and loss of profits,[19] is expressly excluded from the Compact's scope.[20]

'Damage to biological diversity' is defined as either a 'Measurable, Significant and Adverse Change in a Species' or an ecosystem change 'that results in a loss of a natural resource service essential to sustain any Species'.[21] Such damage shall be determined by comparing the nature and quantum of change in the species or ecosystem from the baseline,[22] which refers to the state of a species or ecosystem prior to the changes alleged to constitute damage.[23] A measurable change is only deemed 'significant and adverse' when a particular species can no longer maintain itself on a long-term basis as a consequence of that change.[24] Both the determination of the baseline and its comparison with the conditions alleged to constitute damage shall be based on 'science-based evidence',[25] which means that such evidence must be obtained by the 'peer-reviewed, published and generally accepted scientific methodology used in the relevant scientific community of endeavour'.[26] If pre-existing inventories are not available,

17 *Ibid.*, Article 5.4; also see *Carrato* et al. (n. 5), 227, referring to an analysis of the CBD Executive Secretary, according to which the lack of insurance policies was a key reason why states did not ratify the Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal (10 December 1999; not yet in force), UNEP/CHW.5/29, p. 88, see CBD Secretariat, Status of Third-Party Liability Treaties and Analysis of Difficulties Facing Their Entry into Force: Note by the Executive Secretary, UN Doc. UNEP/CBD/BS/WG-L&R/1/INF/3 (2005).
18 Biodiversity Compact (n. 4), Article 1.2.
19 See chapter 2, section B.
20 Biodiversity Compact (n. 4), Articles 1.6 and 2.4.liii.
21 *Ibid.*, Article 6.2.
22 *Ibid.*, Article 7.1.
23 *Ibid.*, Article 2.4.vii.
24 *Ibid.*, Article 8.1.
25 *Ibid.*, Article 7.2.
26 *Ibid.*, Article 2.4.xliv.

data or evidence for establishing the baseline may be gathered during the investigation of the alleged damage.[27] The Compact provides that such data or evidence 'must be from twenty-five years immediately preceding the date when the alleged [… damage] occurred'.[28] The implications of this provision are controversial. While industry representatives claim that it reduced the burden of retrieving historical information on both parties,[29] representatives of environmental NGOs have criticized the period as being 'far too long'.[30]

C. Causation, Identification of the Party Liable and Standard of Liability

The Compact provides that each member is responsible for biodiversity damage 'Caused by the Release of an LMO by that Member'.[31] The term 'Release' denotes any instance in which an LMO enters the environment. Moreover, any 'Placing on the Market'[32] that results in an LMO entering the environment is also regarded as a release.[33]

For a member to be liable, there must be a causal link between the release of the LMO in question and the damage to biodiversity.[34] This means that the LMO must be the 'Cause-in-fact[35] and proximate Cause of Damage' to biodiversity.[36] There is no requirement of fault, which results in a form of strict liability.[37] Moreover, unlike the Supplementary Protocol, the Compact does not require a transboundary movement and

27 *Ibid.*, Article 2.4.vii.
28 *Ibid.*
29 *Carrato* et al. (n. 5), 231.
30 Cf. *Orsini* (n. 5), 970.
31 Biodiversity Compact (n. 4), Article 6.1.
32 'Placing on the Market' is defined as the 'action of intentionally making available an LMO for any use in a State' (*ibid.*, Article 2.4.xxx).
33 *Ibid.*, Article 2.4.xli.
34 This can be derived from Article 6.1, which refers to 'Damage to Biological Diversity *Caused* by the Release of an LMO by that Member'.
35 'Cause in fact' refers to the cause without which the event could not have occurred, i.e. the *conditio sine qua non*; cf. 'but-for cause', in: *Bryan A. Garner* (ed.), Black's Law Dictionary (11th ed. 2019), 273.
36 Biodiversity Compact (n. 4), Article 2.4.x; see *Carrato* et al. (n. 5), 232.
37 *Ibid.*; on strict liability for environmental harm, see *Hanqin Xue*, Transboundary Damage in International Law (2003), 299–312; *Julio Barboza*, The Environment, Risk and Liability in International Law (2011), 25.

applies to the release of any LMO, whether moved internationally or used only domestically.[38]

A member is not liable to the extent that the damage was caused by 'misuse' of the LMO by a third party. A case of misuse is assumed when a third party has violated a relevant law, safety measure or standard governing the LMO and thereby caused the damage.[39] In this case, the member who has released the LMO shall only be liable to the extent of its proportional responsibility under the terms of the Compact.[40] If the third party responsible for the misuse is also a Compact member, the response obligations shall be apportioned among them according to each member's proportional responsibility, but *joint and several liability*[41] among members is expressly ruled out.[42] Moreover, if the third party is not a member, it cannot be held responsible under the Compact unless it has elected to participate in the adjudication of the claim.[43]

The Compact's provisions on the attribution of responsibility are complex. In essence, the member who placed an LMO on the market is strictly liable for any damage resulting from that LMO, save to the extent to which third parties are responsible for the damage under principles of fault-based liability.[44] In other words, it is legally presumed that the damage was caused by the inherent characteristics of the LMO (and thus by the member who placed the LMO on the market) unless it can be proven that it was caused culpably by a third party.[45]

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38 *Carrato* et al. (n. 5), 237.

39 Biodiversity Compact (n. 4), Article 10.4; cf. *Carrato* et al. (n. 5), 233–234; the concept of misuse is misunderstood by *Caroline E. Foster*, Diminished Ambitions? Public International Legal Authority in the Transnational Economic Era, 17 (2014) J. Int. Econ. L. 355, 370, who assumes that the misuse of an LMO is a prerequisite for liability under the Compact.

40 Biodiversity Compact (n. 4), Article 12.2 and 12.3.

41 Under joint and several liability, each liable party is individually responsible for the entire obligation, which benefits victims insofar as they only need to address one solvent tortfeasor to collect the entirety of the damages; a tortfeasor held liable may seek redress from other liable parties which were not directly addressed by the victim according to each of the parties' proportional responsibility, see 'joint and several liability', in: Black's Law Dictionary (n. 35), 1098.

42 Biodiversity Compact (n. 4), Article 12.4.

43 *Ibid.*, Article 10.1.

44 See chapter 2, section E.

45 This is in line with the allocation of responsibility suggested for the Supplementary Protocol in chapter 6, section C.II.

D. Defences

Article 10 of the Compact provides for an exhaustive catalogue of six defences that preclude or reduce the liability of the responsible member. Besides acts of God and acts of war, terrorism or civil unrest, defences include the misuse of the LMO by a third party, as discussed above.[46] Moreover, liability is excluded when damage is caused by compliance with compulsory measures imposed by the state other than necessary and appropriate preventive or remedial measures related to the LMO.[47] Comparable defence clauses can also be found in the *Offshore Pollution Liability Agreement* mentioned above.[48]

However, under the Biodiversity Compact, a member shall also not be liable when damage results from the realization of a risk which was specifically assessed and accepted as part of the state's authorization process.[49] This includes risks for which risk management measures were proposed in the assessment, regardless of whether such measures were actually imposed by the state when granting the authorization.[50] This defence is a substantial limitation since it essentially restricts the Compact's scope to risks that were not identified before the LMO was placed on the market. Any risks that were known but deemed acceptable, be it for their low probability or because the potential effects were considered negligible, are excluded from the scope of the Compact. However, the defence is limited to damage that is 'consistent with the type, magnitude and probability of harm' identified in the risk assessment, which means that it does not apply to any damage that was not objectively foreseen.[51] According to authors involved in the development of the Compact, this requires that the state was 'fully and accurately warned that such damage may occur'.[52] Consequently, it is argued here that an operator cannot evade liability by 'inflating' the risk assessment with purely hypothetical risks that remain unspecified in terms of the type, magnitude and probability of potential harm.

Finally, a defence can be raised when damage is caused by the 'realization of a risk posed by an activity specifically authorized or specifically

46 Biodiversity Compact (n. 4), Article 10.3(a)-(c); see *supra* section C.
47 *Ibid.*, Article 10.3(d).
48 Oil Companies Offshore Pollution Liability Agreement (OPOL) (n. 3), Clause IV(B).
49 Biodiversity Compact (n. 4), Article 10.3(e).
50 *Ibid.*
51 *Ibid.*, Article 10.3(e)(ii).
52 *Carrato* et al. (n. 5), 231.

permitted by applicable law or regulations of the State'.[53] If construed literally, this would be a far-reaching exemption since releases of LMOs (insofar as they are regulated by domestic laws[54]) are virtually always subject to a specific authorization. As a result, it would be questionable whether the Compact had any scope of application. Therefore, the present defence must be seen in the context of the defences mentioned above, which refer to risks explicitly accepted by the state[55] or even created by it by imposing additional compulsory measures.[56] Consequently, the defence does not apply to every authorized release, but only to activities exceeding the normal use of the LMO, which create additional risks and are therefore 'specifically' authorized by the state in consideration of these risks.[57]

E. Response

Under the Compact, each member undertakes and agrees to 'respond' to biodiversity damage caused by their LMOs.[58] The types of responses envisaged by the Compact are 'restoration' and 'compensation'.[59]

Although not clearly defined, *restoration* seems to denote practical measures to recover the affected species or ecosystem,[60] in line with the terms of the Supplementary Protocol. The objective of restoration is to restore the condition that existed before the damage occurred, which is satisfied when the affected species is again able to maintain itself on a long-term basis.[61] Restoration measures shall be implemented in accordance with a 'restoration plan', which is either agreed between the affected state and the responsible member or determined by way of arbitration.[62]

Compensation, on the other hand, means financial payments determined by valuing the loss of function, value, use and natural resource services

53 Biodiversity Compact (n. 4), Article 10.3(f).
54 See chapter 3, sections A.I.1 and A.IV.
55 Biodiversity Compact (n. 4), Article 10.3(e).
56 *Ibid.*, Article 10.3(d).
57 This interpretation seems to be shared by *Carrato* et al. (n. 5), 233.
58 Biodiversity Compact (n. 4), Article 6.1.
59 *Ibid.*, Article 9.1.
60 Cf. *ibid.*, Article 9.2.
61 *Ibid.*, Article 2.4.xlii; see *Carrato* et al. (n. 5), 234.
62 Biodiversity Compact (n. 4), Article 9.2; see *infra* section G.

incurred from the damage.[63] This contrasts sharply with the Supplementary Protocol, which does not provide for financial compensation at all, but stipulates that elements of biodiversity that cannot be *restored* shall be *replaced* with other components of biological diversity at the same or an alternative location.[64]

The Compact lists a number of factors that should be taken into account when determining the appropriate response. These factors include, *inter alia*, the characteristics of the affected ecosystem,[65] the benefits brought by the release of the LMO despite the damage, and whether natural restorative processes would reverse the loss without human intervention.[66] Moreover, the restoration plan or valuation of damage shall take into account any negative impacts on 'Public Health'.[67] It has been argued that this allows a response order to include measures to address imminent and substantial endangerments to human health arising from the biodiversity damage.[68] In this respect, the Compact is broader than the Supplementary Protocol, which refers to risks to human health in the definition of biodiversity damage, but does not mention measures to address such risks in the substantive provisions on liability.[69]

F. Financial Caps and Time Limits

Article 13 of the Compact provides for financial limits on the liability of Compact members. The limits for expenses for restoration measures are 30 million *Special Drawing Rights* (SDR)[70] for a single incident and 150 mil-

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63 *Ibid.*, Article 9.3 and 9.4. The Compact expressly refers to CBD Secretariat, An Exploration of Tools and Methodologies for Valuation of Biodiversity and Biodiversity Resources and Functions, CBD Technical Series No. 28 (2007). Under the Antarctic Liability Annex, the amount of financial liability shall reflect the costs of response action that should have been taken; cf. Article 6(2)(b) Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty: Liability Arising from Environmental Emergencies (14 June 2005; not yet in force), ATCM Measure 1 (2005). Also see chapter 11.

64 See Article 2(2)(d)(ii)(b) SP and chapter 6, section C.I.

65 Biodiversity Compact (n. 4), Article 9.2.b.

66 *Ibid.*, Article 9.5.

67 *Ibid.*, Article 9.2.c and 9.4.d.

68 *Carrato* et al. (n. 5), 235.

69 Cf. Supplementary Protocol, Article 2(2)(b); see chapter 6, section B.II.4.

70 Special Drawing Rights are a unit of monetary account used by the International Monetary Fund. The currency value of SDR is calculated daily on the basis of

lion SDR for all incidents caused by a particular LMO. For compensation, the corresponding limits are 15 million SDR per incident and 75 million SDR per LMO. The stated reason for the lower limits on compensation is to encourage restoration as the preferred form of response. When both restoration and compensation are owed because of the same incident, the higher amount shall be apportioned among both forms of response.[71] The total limits apply across all claims and affected states, which means that when multiple claims are pending, the financial limits will be apportioned among the respective claims, and once the limit has been reached, no further claims may be brought under the Compact.[72]

The limits have been justified as required for persuading members to voluntarily sign the Compact and make the Compact accessible to smaller companies and research facilities.[73] As mentioned in the previous chapter, financial limits are also an essential prerequisite for coverage by commercial insurers.[74] The Compact expressly acknowledges that the unavailability of insurance coverage poses an obstacle to achieving a broad membership to the Compact and ensuring that members demonstrate their capacity to meet their financial obligations potentially arising from the Compact.[75]

Only time will tell whether the financial limits stipulated in the Compact are adequate to address actual cases of damage. Notably, the limits apply regardless of the global spread of an LMO, i.e. the number of states into which the LMO has been imported and placed on the market. Thus, the Compact does not take into account that the potential damage caused by a globally marketed LMO may be significantly greater than the damage caused by an LMO that is spread less widely. As the financial limits shall be reviewed every five years,[76] the members could rectify these shortcomings. Yet, the last publicly available revision of the Compact is from 2012.[77]

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a basket of major currencies. As of May 2022, 1 SDR equals 1.349150 USD. See IMF, SDR Valuation (27 May 2022), available at: https://www.imf.org/external/np/fin/data/rms_sdrv.aspx (last accessed 28 May 2022).

71 Biodiversity Compact (n. 4), Article 13.2.
72 *Ibid.*, Article 13.3.
73 *Carrato* et al. (n. 5), 236.
74 See chapter 6, section E.I.
75 See Biodiversity Compact (n. 4), Article 5.4 in connection with Article 3.1 and 3.5.
76 *Ibid.*, Article 13.5.
77 See CropLife International (n. 12).

Besides financial limits, the Compact also provides for time limits. Claims must be brought no later than three years after the state knew or should have known of the damage, and only within 20 years of the first approval or release of the LMO.[78] Again, time will tell whether the absolute time limit is sufficient or rules out claims for slow-onset damage to biodiversity. In any event, the limit only applies to the Compact and states retain any other available means of redress under applicable domestic or international law.[79]

G. Claims Process, Arbitration and Enforcement

Only states may submit claims for damage that has occurred within the limits of their respective national jurisdiction.[80] Private actors and NGOs have to avail themselves of domestic remedies or ask the state concerned to file a claim.[81] No claim may be made under the Compact when the same incident is already subject to domestic judicial or administrative action,[82] and a claimant state has to agree not to seek double recovery or to initiate parallel proceedings.[83]

The Compact provides that any claim shall be addressed in several steps. After a state has filed a claim, it will first be reviewed by a *Commissioner*, which shall be appointed by the *Permanent Court of Arbitration* (PCA) from a roster of neutrals.[84] The Commissioner shall verify that the formal requirements are met and that the claim is supported by 'Plausible Evidence',[85] which is defined as 'facts that support the reasonable interference' that a claim may result in a finding that the member concerned is indeed responsible under the Compact.[86] Industry representatives have defended the plausibility standard as a reasonable 'minimal threshold' to ensure that

78 Biodiversity Compact (n. 4), Article 11.
79 *Carrato* et al. (n. 5), 229.
80 Biodiversity Compact (n. 4), Article 14.1.
81 *Carrato* et al. (n. 5), 229. On the exercise of *diplomatic protection* on behalf of nationals, see chapter 9, section C.II.
82 Biodiversity Compact (n. 4), Article 14.2.
83 This is provided in Article 12 of the Arbitration Agreement, which can be found in Appendix B to the Compact and to which a state must agree in order to bring claims under the Compact (cf. Article 14.3.a of the Compact's main text).
84 Biodiversity Compact (n. 4), Article 14.5.
85 *Ibid.*, Article 14.6.
86 *Ibid.*, Article 2.4.xxxvi.

a tribunal is only convened for reasonable claims.[87] Others warned that the 'plausibility' criterion could, in fact, lead to the exclusion of valid claims and should thus be read in a way not to preclude an assessment by a full tribunal.[88] Moreover, it has been argued that the 'gateway' to claims created by the prior inquiry process could have the effect of time-barring claims that are not initially pursued at the time damage begins to materialize because they are still difficult to substantiate scientifically.[89]

If the Commissioner concludes that a claim is properly submitted, a conciliation period of 90 days is set in motion during which parties shall seek to resolve the claim through settlement or conciliation.[90] If no settlement can be reached, the claim proceeds to binding arbitration under the auspices of the PCA. The General Secretary of the PCA shall appoint a three-person tribunal to adjudicate the claim in accordance with the PCA's *Environmental Arbitration Rules*[91] as modified by the bylaws to the Compact.[92]

The standard of proof for each element of the claim and all defences shall be 'clear and convincing evidence',[93] which is the standard of proof formulated by the arbitral tribunal in the *Trail Smelter* case.[94] According to the Compact, 'clear and convincing evidence' means a 'degree of proof that will produce in the mind of the decision maker [sic] a firm belief or conviction as to the truth of the allegations sought to be established'.[95] However, it has been pointed out that this evidentiary threshold may be too high to be met by plaintiffs in environmental cases.[96] Consequently, tribunals under the Compact should rather rely on the 'preponderance of

87 *Carrato* et al. (n. 5), 229.
88 *Foster* (n. 39), 371–372.
89 *Ibid.*, 371.
90 Biodiversity Compact (n. 4), Article 15.
91 Cf. PCA, Optional Rules for Arbitration of Disputes Relating to Natural Resources and/or the Environment (2001); see chapter 6, section D.VI.
92 Biodiversity Compact (n. 4), Article 16.
93 *Ibid.*, Article 16.5.a.
94 See Trail Smelter Case (United States v. Canada), Decision of 11 March 1941, III RIAA 1938, 1965; see *Carrato* et al. (n. 5), 230. The Trail Smelter arbitration is expressly referred to in the Biodiversity Compact (n. 4), Article 2.4.xlix, n. 4.
95 *Ibid.*, Article 2.4.xlix.
96 *Foster* (n. 39), 372–373, referring to *Patricia W. Birnie* et al., International Law and the Environment (3rd ed. 2009), 154; ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment of 20 April 2010, ICJ Rep. 14, Separate Opinion of Judge Greenwood, para. 26; see chapter 6, section C.III.

the evidence' test usually applied in adjudication and arbitration under public international law.[97]

All decisions rendered by the arbitral tribunal are final and cannot be appealed.[98] Arbitral awards rendered under the Compact shall be enforceable pursuant to the rules of the *New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards*.[99] As noted earlier, the New York Convention makes arbitration more attractive than litigation in domestic courts because there is no comparable instrument providing for the transnational recognition and enforcement of foreign court judgments.[100] However, many states apply the New York Convention only to awards concerning commercial disputes.[101] To overcome this problem, the Compact and the included draft of an *Arbitration Agreement* provide that an award rendered under the Compact shall be deemed as addressing 'differences arising out of legal relationships which are commercial'.[102]

H. Conclusions

The *Biodiversity Compact* is a voluntary private compensation scheme under which its members – currently six agricultural biotechnology corporations – assume liability for biodiversity damage caused by any of their LMOs. The Compact adopts the 'administrative approach' to liability used in the Supplementary Protocol but specifies the modalities of liability in much greater detail, particularly concerning the determination of damage and the required response. Together with bylaws and annexes, the Compact covers about 135 pages, while the text of the Supplementary Protocol is about ten pages long. The Compact's greater precision can be seen as an advantage over the Supplementary Protocol which, as shown in the

97 *Foster* (n. 39), 372–373.
98 Biodiversity Compact (n. 4), Article 16.6.
99 Convention on the Recognition and Enforcement of Foreign Arbitral Awards (10 June 1958; effective 07 June 1959), 330 UNTS 3; see *Jan Kleinheisterkamp*, Recognition and Enforcement of Foreign Arbitral Awards, in: Wolfrum/Peters (ed.), MPEPIL, MN. 14–15.
100 See chapter 2, section F, and chapter 6, section D.VI.
101 Cf. Article 3 of the New York Convention; see UN OLA, Overview of Declarations and Reservations to the New York Convention, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=XXII-1&chapter=22&clang=_en (last accessed 28 May 2022).
102 Article 19.2 and Appendix B, Article 12.2; also see *Carrato* et al. (n. 5), 236.

preceding chapter, remains ambiguous on a number of issues and leaves considerable leeway to states for domestic implementation.

The Compact channels liability to a clearly identifiable actor, namely to the developer or producer who has placed an LMO on the market. Its binding arbitration mechanism provides a state with the means to enforce liability even when the responsible member is situated outside of the state's jurisdiction.[103] In this regard, the Compact avoids one of the most significant shortcomings of the Supplementary Protocol which, as shown above, does not provide any means for enforcing the liability of operators situated abroad.[104] Furthermore, due to its nature as a third-party beneficiary contract, the Compact also benefits those states which have not ratified the Supplementary Protocol or do not have in place adequate liability rules in their domestic law.[105] While this is certainly one of the Compact's greatest advantages, it has been asserted that it might also discourage states from ratifying the Supplementary Protocol.[106]

Despite its merits, the Compact has several substantial limitations. Like the Supplementary Protocol, it suffers from limited participation and representativeness.[107] The shortcomings in participation are likely to become more pronounced, seen as the emergence of genome editing techniques has led to a substantial increase in bio-enterprise investment. Many new companies have emerged and have begun to commercialize these techniques.[108] Furthermore, the main proponents of self-spreading techniques such as engineered gene drives are currently not the biotechnology industry but rather research institutions and philanthropic organizations.[109] It currently seems unlikely that these actors will feel compelled to sign the Compact.

However, the Compact's most significant weakness is its exclusion of damage resulting from risks that were specifically assessed in a risk assess-

103 *Ibid.*, 237; see *supra* section G.

104 Cf. *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 88–89; see chapter 6, section F.V.

105 *Carrato* et al. (n. 5), 237.

106 Cf. *Orsini* (n. 5), 974–975.

107 Cf. *ibid.*, 974.

108 *Katelyn Brinegar* et al., The Commercialization of Genome-Editing Technologies, 37 (2017) Critical Reviews in Biotechnology 924; see chapter 1, section B.III.

109 See chapter 1, section C.III.1.c); also see *Florian Rabitz*, The International Governance of Gene Drive Organisms (2021) Environmental Politics 1, 12.

ment during the authorization procedure.[110] As a result, an LMO producer is not liable for the realization of any risks already known when the LMO was authorized for marketing or release. Consequently, these risks are shifted from the producer to the state that has authorized the use of a particular LMO. Such a one-sided risk allocation is uncommon for liability regimes addressing hazardous activities or substances, even when these activities or substances bring social benefits that are deemed to outweigh the (residual) risks.[111] It might also motivate operators to include every conceivable risk in the risk assessment, even if it is merely theoretical, to minimize their liability. It is doubtful that this helps to increase the thoroughness and overall quality of risk assessments for LMOs.

Moreover, the Compact's definition of damage, its provisions for determining the adequate response, and the claims process are highly complex. For instance, the requirement that data for establishing damage to biodiversity must cover a period of 25 years preceding the occurrence of the damage will likely be a major obstacle to successful claims. Although biodiversity inventories and baseline studies are becoming more common,[112] they will often not cover such long periods, or perhaps not cover the affected species, or not allow to prove complex ecosystem effects. Additionally, the requirement that claims must be brought within three years after a state has become aware of the damage severely limits the time available to gather the necessary data.[113]

Like the Supplementary Protocol, the Compact makes it difficult to anticipate how potential response measures might look. When the immediate damage cannot be restored, the Compact provides for financial compensation.[114] However, there is no guarantee that the state will use those funds to mitigate the consequences of the damage or to improve other elements of the environment.[115] In this regard, the Supplementary Protocol uses a better approach by providing that unrestorable damage shall be compensated by improving other components of biodiversity.[116]

Since the Compact, unlike the Supplementary Protocol, was exclusively developed by potentially liable parties and creates directly enforceable

110 Cf. Article 10.3(e); see *Etty* (n. 10), 327.
111 The same limitation can be found in CropLife International's Implementation Guide to the Supplementary Protocol, see chapter 6, section G.II.
112 See chapter 6, section B.II.3.
113 Cf. Article 11; see *Foster* (n. 39), 371.
114 Biodiversity Compact (n. 4), Article 9.3 and 9.4.
115 See *supra* section E.
116 Supplementary Protocol, Article 2(2)(d)(ii); see chapter 6, section C.I.

rights of states, the aforementioned limitations are arguably not surprising. However, considering that the Compact was meant to be a confidence-building measure,[117] one wonders whether it accomplishes this objective. At the same time, the considerable complexity of the Compact's text demonstrates the challenges involved in implementing the Supplementary Protocol into specific legislation at the domestic level. It has been suggested that the Compact's terms and processes could serve as a model in this regard,[118] although, considering the said limitations, legislators should be cautious about rashly incorporating the Compact's language into domestic law.

In conclusion, the Compact must rather be seen as a (failed) attempt to avert the adoption of a legally binding international regime on liability for damage caused by LMOs.[119] During the negotiations of both the Cartagena Protocol and the Supplementary Protocol, representatives of the biotechnology industry participated as observers. Considering the difficulties of states to reach an agreement on liability, it has been observed that the involvement of the industry demonstrated a 'relative vacuum in public international law', which 'invited industry to take control, both of dispute resolution processes, and of setting the substantive conditions on which foreign industry will be liable for transboundary harm'.[120] This vacuum was filled at least partially when the Supplementary Protocol entered into force in 2018.

117 Cf. *Jungcurt/Schabus* (n. 6), 205; *Carrato* et al. (n. 5), 223.
118 *Carrato* et al. (n. 5), 238.
119 *Jungcurt/Schabus* (n. 6), 205; *Orsini* (n. 5), 968.
120 *Foster* (n. 39), 373.

Chapter 8: A Customary Obligation to Ensure Prompt and Adequate Compensation for Transboundary Damage?

The preceding chapters have shown that the *Nagoya–Kuala Lumpur Supplementary Protocol* is premised on the existence of a transboundary situation but only insufficiently addresses the challenges in implementing liability in such situations. The *Biodiversity Compact* can only partially mitigate this shortcoming because its membership is limited to a few biotechnology corporations, it only applies to biodiversity damage, and only states – not individuals – can make claims.

Besides these instruments, however, it has been argued that there is a general obligation of states under customary international law to ensure the prompt and adequate compensation of foreign victims of transboundary damage.[1] This approach is also reflected in the *Principles on the Allocation of Loss in the Case of Transboundary Harm Arising out of Hazardous Activities* adopted by the International Law Commission (ILC) in 2006.[2] The Principles concluded the work of the ILC on the topic of 'liability for the injurious consequences of acts not prohibited by international law', which had been on the Commission's agenda since the late 1970s.[3] Due to the persistent controversy over the role of state liability,[4] the ILC decided in 1997 to treat the topics of prevention and liability separately.

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1 Cf. *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 229–299.

2 ILC, Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, with Commentaries (2006), YBILC 2006, vol. II(2), p. 56 (hereinafter 'ILC, Allocation of Loss Principles'). See generally *Alan E. Boyle*, Globalising Environmental Liability: The Interplay of National and International Law, 17 (2005) J. Envt'l L. 3, 16–17; *Caroline E. Foster*, The ILC Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, 14 (2005) RECIEL 265, 267–270; *Alan E. Boyle*, Liability for Injurious Consequences of Acts Not Prohibited by International Law, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 95, 95–97; *Julio Barboza*, The Environment, Risk and Liability in International Law (2011), 129–132.

3 For accounts of the development of the issue in the ILC, see *Boyle* (n. 2), 95–97; *Barboza* (n. 2), 73–152.

4 See chapter 10, section D.

Thus, the Principles on Allocation of Loss complement the *Articles on Prevention of Transboundary Harm* of 2001, which left the issues of liability and reparation unaddressed.[5]

The Principles apply to transboundary damage caused by hazardous activities not prohibited by international law (A.). Their stated purpose is two-fold. On the one hand, they seek to ensure 'prompt and adequate compensation' to victims of transboundary damage (B.). On the other hand, they aim to 'preserve and protect the environment' in cases of such damage, especially by ensuring the mitigation of damage to the environment and its restoration or reinstatement (C.).[6] Hence, the Principles recognize that different approaches are needed to compensate injury to individuals and remediate damage to the environment *per se*.[7] To implement these approaches, states shall provide adequate administrative and legal remedies (D.). The Principles envisage operator liability and, therefore, complement the law of state responsibility (E.). In conclusion, it is argued here that the Allocation of Loss Principles have a 'customary core' that is already binding upon states (F.).

A. Scope of Application and Use of Terms

The Principles stipulate that they apply to 'transboundary damage caused by hazardous activities not prohibited by international law'.[8] The ILC's commentary notes that the Principles are intended to have the same scope of application as the *Articles on Prevention*.[9] Consequently, in line with the definition of 'harm' in the latter, the Principles define the term 'damage' as 'damage caused to persons, property or the environment'.[10]

5 Cf. ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148 (hereinafter 'ILC, Articles on Prevention'); see chapter 4.
6 ILC, Allocation of Loss Principles (n. 2), Principle 3.
7 See UNEP, Guidelines for the Development of Domestic Legislation on Liability, Response Action and Compensation for Damage Caused by Activities Dangerous to the Environment: Annex to Governing Council Decision SS.XI/5 B, UN Doc. A/26/25, p. 16 (2010), which also combine administrative liability for environmental damage and civil liability principles for traditional damage. For an analysis of the UNEP Guidelines, see *Amy Hindman/René Lefeber*, International/Civil Liability and Compensation, 21 (2010) YB Int'l Env. L. 178, 179–181.
8 ILC, Allocation of Loss Principles (n. 2), Principle 1.
9 *Ibid.*, Commentary to Principle 1, para. 1.
10 On the use of the terms 'harm' and 'damage', see chapter 4, section B.I.

The 'environment' is broadly defined as including both biotic and abiotic natural resources and their interaction, as well as 'the characteristic aspects of the landscape'.[11] 'Environmental damage' includes not only the costs of reasonable response and reinstatement measures but also 'loss or damage by impairment of the environment'. The commentary notes that this refers to damage to the environment *per se*, which includes loss of income derived from economic use of the environment,[12] but may also extend to the loss of 'non-use value' of the environment.[13] The ILC apparently saw fewer problems in the general compensability of such damage than in the question of who should have standing to make appropriate claims.[14]

The Principles apply to '*transboundary* damage', which is defined as 'damage caused to persons, property and the environment in the territory or other places under the jurisdiction or control of a State other than the State of origin'.[15] Hence, the Principles do not address damage to the areas beyond the limits of national jurisdiction or 'global commons'. The ILC assumed that such damage, as well as harm from multiple sources, had 'their own particular features' and therefore required 'separate treatment'.[16] While this aligns the scope of the Principles with that of the ILC's Articles on Prevention,[17] some of the principles could nevertheless be applied to damage to global commons, such as the obligation to ensure that appropriate response measures are taken.[18]

Like in the Prevention Articles, the term 'hazardous activity' is defined as 'an activity that involves a risk of causing significant harm'.[19] While this clearly applies to activities that were identified as hazardous before damage occurred,[20] it is questionable whether it also includes cases in which the

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11 ILC, Allocation of Loss Principles (n. 2), Principle 2(b).
12 *Ibid.*, Commentary to Principle 2, para. 13.
13 *Ibid.*, Commentary to Principle 2, para. 18; see *Barboza* (n. 2), 134–135.
14 Cf. ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 2, para. 14; see *Barboza* (n. 2), 136–137. On the compensability of 'pure' environmental damage, see chapter 11, section B.I.
15 ILC, Allocation of Loss Principles (n. 2), Principle 2(e).
16 Cf. ILC, Report of the Commission to the General Assembly on the Work of Its Fifty-Fourth Session, YBILC 2002, vol. II(2) (2002), para. 447; ILC, Allocation of Loss Principles (n. 2), General commentary, para. 7.
17 Cf. ILC, Articles on Prevention (n. 5), Article 2(c).
18 Cf. ILC, Allocation of Loss Principles (n. 2), Principle 5(b).
19 *Ibid.*, Principle 2(c). On the element of 'risk', see chapter 4, section B.V.
20 As shown in chapter 4, section B.VII, the development and release of LMOs can, in principle, constitute hazardous activities.

harm was not foreseeable.[21] While state responsibility for transboundary harm requires a breach of *due diligence*, which presupposes that the harm was (at least objectively) foreseeable,[22] it could be argued that obligations concerning the allocation of loss arise regardless of a legal wrongdoing and are therefore independent of the question of whether the damage could have been foreseen (or indeed avoided). But it should also be kept in mind that the precautionary principle requires a diligent approach once there are indications, albeit no proof, of a risk of harm.[23] Therefore, human activities rarely result in completely unforeseen damage, which would arguably come close to a case of *force majeure*. But even force majeure does not relieve a state of its international responsibility vis-à-vis the injured state(s).[24] Thus, the issue of allocation of loss is not generally void simply because the damage was not foreseeable to the state of origin. This is also recognized in the commentary to the Principles, which notes that the ILC did not include a test of 'foreseeability' or 'proximate cause' of damage, since it considered this to be 'a highly discretionary and unpredictable branch of law' and thus not adequately addressed by a general model on loss allocation.[25]

B. Requirement to Ensure Prompt and Adequate Compensation

Principle 4(1) stipulates that each state should take all necessary measures to ensure that 'prompt and adequate compensation is available for victims of transboundary damage'. The commentary explains that this principle 'responds to and reflects a growing demand and consensus in the international community' that states are expected, when they permit hazardous activities, to make sure that adequate mechanisms are available to respond to claims for compensation in case of any damage.[26] The commentary also observes that 'some commentators regard this as a customary law obligation'.[27] Indeed, the general principle that states shall ensure that foreign

21 Cf. *Boyle* (n. 2), 17; *Foster* (n. 2), 270.
22 See chapter 4, section B.VI.
23 See *ibid.*
24 See chapter 9, section A.IV.6.
25 ILC, Allocation of Loss Principles (n. 2), Commentary to Article 4, para. 16.
26 *Ibid.*, Commentary to Principle 4, para. 3.
27 *Ibid.*, Commentary to Principle 4, para. 6, citing *Peter-Tobias Stoll*, Transboundary Pollution, in: Fred L. Morrison/Rüdiger Wolfrum (eds.), International, Regional, and National Environmental Law (2000) 169, 169–175.

victims of transboundary harm caused by activities under their jurisdiction do not remain uncompensated seems to be no longer controversial.[28]

I. The Standard of 'Prompt and Adequate' Compensation

According to the ILC's commentary, the notion of prompt and adequate compensation 'reflects the understanding and the desire that victims of transboundary damage should not have to wait long in order to be compensated'.[29] The standard of *promptness* is defined as 'procedures that would govern access to justice, and that would influence the time and duration for the rendering of decisions on compensation payable in a given case'.[30] The commentary also notes that litigation in domestic courts over compensation claims can be 'costly and protracted over several years'.[31] Nevertheless, the commentary does not indicate a time span that would be regarded as fulfilling the standard of promptness.

As to the requirement that compensation shall be *adequate*, the ILC does not provide any substantive criteria either. It notes that adequate compensation could be either determined by way of lump-sum agreements or through litigation in the domestic courts of the state of origin. The commentary even assumes that compensation was '*ipso facto* adequate' as long as due process requirements are met and the compensation given is not arbitrary or 'grossly disproportionate to the damage actually suffered'.[32] At the same time, the ILC assumed that compensation need neither be full nor sufficient to be regarded as adequate.[33] This takes into account that most existing international liability treaties allow for the application of limits or caps to liabilityin order to, *inter alia,* ensure the 'insurability' of the risk.[34]

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28 See ILC, International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law: Comments and Observations Received from Governments, YBILC 2006, vol. II(1), p. 89 (2006); *Pemmaraju S. Rao*, Third Report on the Legal Regime for the Allocation of Loss in Case of Transboundary Harm Arising Out of Hazardous Activities, UN Doc. A/CN.4/566 (2006), 3(e).

29 ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 3, para. 3.

30 *Ibid.*, Commentary to Principle 4, para. 7.

31 *Ibid.*

32 *Ibid.*, Commentary to Article 4, para. 8.

33 *Ibid.*

34 Cf. *ibid.*, Commentary to Article 4, para. 19–23; see, e.g., International Convention on Civil Liability for Oil Pollution Damage (29 November 1969; effective 19 June 1975), 973 UNTS 3, as amended by the Protocol of 27 November 1992

II. Imposition of Strict Operator Liability

Principle 4(2) provides that measures to ensure prompt and adequate compensation should include the imposition of strict liability on the 'operator', which is defined as 'any person in command or control of the activity at the time the incident causing transboundary damage occurs'.[35] Besides the operator, the Principles also allow the imposition of liability on another person or entity, where appropriate. According to the commentary, the 'real underlying principle is not that "operators" are always liable, but that the party with the most effective control of the risk at the time of the accident or with the ability to provide compensation is made primarily liable'.[36] Hence, while the Principles suggest that liability should be 'channelled' to one particular actor,[37] they offer no conclusive guidance on how this actor shall be identified. Hence, the Principles remain vague like the *Nagoya – Kuala Lumpur Supplementary Protocol*, which provides that any person in direct or indirect control of an LMO could be regarded as an operator.[38] As shown earlier, determining the responsible operator can be particularly difficult in cases of damage caused by LMOs, since it may be impossible to identify a single incident that has given rise to the damage, especially in situations of *slow-onset damage* that occurs long after it has been caused.[39] The ILC's commentary merely acknowledges that the looser and less concrete the link between the incident in question

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(effective 30 May 1996), 1956 UNTS 255, Article V; Convention on Limitation of Liability for Maritime Claims (19 November 1976; effective 01 December 1986), 1456 UNTS 221, as amended by the Protocol of 2 May 1996 (effective 13 May 2004), RMC I.2.340 II.2.340; Vienna Convention on Civil Liability for Nuclear Damage (25 May 1963; effective 12 September 1997), 1063 UNTS 358, as amended by the Protocol of 12 September 1997 (effective 4 October 2003), IAEA Doc. INFCIRC/566, Article V; also see ILC, Survey of Liability Regimes Relevant to the Topic of International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law (International Liability in Case of Loss from Transboundary Harm Arising Out of Hazardous Activities): Prepared by the Secretariat, UN Doc. A/CN.4/543 (2004), paras. 605–622.

35 ILC, Allocation of Loss Principles (n. 2), Principle 2(g).

36 *Ibid.*, Commentary to Principle 4, para. 10.

37 On the issue of 'channelling', see *Hanqin Xue*, Transboundary Damage in International Law (2003), 80–86.

38 Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64 (hereinafter 'Supplementary Protocol'), Article 2(2)(c).

39 See chapter 6, section C.II.

and the damage claimed, the less certain the right to compensation.[40] But at the same time, the option to impose liability on appropriate persons other than the operator might allow a distinction between liability for 'development risks' and liability for inappropriate handling or use of an LMO.[41] Yet, since the Principles are confined to liability for transboundary damage,[42] it appears difficult to argue that they include an obligation of third states to provide for liability of developers or producers situated in their jurisdiction. As noted earlier, such situations fall outside the remit of international environmental law,[43] and transnational product liability would need to be ensured by commercial agreements.[44]

Principle 4(2) also provides that liability 'should not require proof of fault'. As noted above, many legal systems provide for 'strict liability' for damage caused by certain hazardous or dangerous activities to allocate the risk to those persons who derive benefit from a particular activity.[45] But the commentary also notes that strict liability does not eliminate the difficulties that can be involved in establishing the necessary causal link between the damage and its source.[46] Moreover, Principle 4(2) provides that any conditions, limitations or exceptions to liability shall be consistent with the overarching objective of the Principles of ensuring adequate compensation. Arguably, the extent to which limitations are acceptable may also depend on the availability of supplementary funding.[47]

III. Compensation Funding

Principle 4(3) stipulates that operators should be required to establish and maintain financial security, such as insurance, bonds or other financial guarantees. This is a common feature of many liability instruments

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40 ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 2, para. 34.
41 See *Boyle* (n. 2), 21.
42 See *supra* section A.
43 See chapter 4, section B.III.
44 See generally *Albert A. Ehrenzweig*, Products Liability in the Conflict of Laws–Toward a Theory of Enterprise Liability Under Foreseeable and Insurable Laws, 69 (1960) Yale L.J. 794. Also see Convention on the Law Applicable to Products Liability (02 October 1973; effective 01 October 1977), 1056 UNTS 187, which addresses choice of law issues but not jurisdiction or recognition and enforcement of judgments.
45 Cf. ILC, Survey of liability regimes (n. 34), paras. 29–112; see chapter 2, section E.
46 ILC, Allocation of Loss Principles (n. 2), Commentary to Article 4, para. 16.
47 Cf. *Boyle* (n. 2), 21.

because it ensures that the operator is actually able to meet claims of compensation in the event of damage.[48] Besides, Principle 4(4) provides that states should require the establishment of industry-wide funds at the national level in appropriate cases.[49] Moreover, Principle 4(5) maintains the idea that there could be an obligation on states to provide for subsidiary or supplementary compensation.[50] In the event that the aforementioned measures are insufficient to provide for adequate compensation, the state of origin 'should ensure that additional financial resources are made available'.[51] But the commentary also notes that these options are only indicative, and that states may choose between these options in accordance with their particular circumstances.[52] Thus, once again, states are free to choose their means as long as they succeed in ensuring 'prompt and adequate compensation' for victims of transboundary harm.[53]

C. Obligation to Provide for Response Measures

Principle 5 addresses the implementation of response measures. Although the Principles do not define what is meant by 'response measures', Principle 3(b) indicates that their purpose is the 'mitigation of damage to the environment and its restoration or reinstatement'. Thus, in line with other international instruments providing for response measures,[54] the Principles envisage that measures are taken both to prevent (further) damage and to remediate the damage that has already materialized.[55] The commentary notes that response measures should not only include clean-up and restoration measures within the jurisdiction of the state of origin, but also extend to containing the geographical range of the damage to prevent

48 See ILC, Survey of liability regimes (n. 34), paras. 690–708.
49 ILC, Allocation of Loss Principles (n. 2), Principle 4(4).
50 See chapter 10.
51 ILC, Allocation of Loss Principles (n. 2), Principle 4(5); see *Foster* (n. 2), 267–277.
52 ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 4, para. 39.
53 Cf. *Boyle* (n. 2), 102–103.
54 See Directive 2004/35/CE on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage (21 April 2004), OJ L 143, p. 56, Article 2(10) and (11), and Annex II; Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty: Liability Arising from Environmental Emergencies (14 June 2005; not yet in force), ATCM Measure 1 (2005), Article 2(f); Supplementary Protocol (n. 38), Article 2(2)(d).
55 *Barboza* (n. 2), 147.

it from becoming transboundary if this is still possible.[56] Moreover, the state of origin must notify the states affected or likely to be affected.[57] As shown above, these obligations are already established as binding rules of customary international law.[58]

Besides the state of origin, the affected states shall also take all feasible measures to mitigate the damage they are exposed to and, if possible, eliminate the effects of such damage.[59] This approach is convincing, considering that the law of territorial sovereignty prevents the state of origin from implementing response measures in the territory of another state without the latter's consent. Nevertheless, the provision is innovative since it imposes a responsibility on the 'innocent victim state' to address environmental damage occurring in its territory but caused by foreign sources. At the same time, the affected state shall not bear the material burden of implementing response measures, as the costs of 'reasonable response measures' are expressly included in the heads of compensable damage.[60] Hence, the party that is ultimately liable must also bear the cost of such measures, thereby 'becoming part of compensation'.[61] But the ILC's commentary also notes that expenditures should not be disproportionate and that the aim was not to restore or return the environment to its original state but to enable it to maintain its permanent functions.[62]

Principle 5 also stipulates that the state of origin should, as appropriate, consult with and seek the cooperation of all states affected or likely to be affected.[63] Besides, the states concerned should seek the assistance of competent international organizations or other states, 'where appropriate' and 'on mutually acceptable terms and conditions'.[64] Arguably, these principles are expressions of policy rather than legal rules. At the same time, special regimes may provide for more stringent obligations. For instance, parties to the *Cartagena Protocol on Biosafety* are required to notify uninten-

56 ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 5, para. 1.
57 Cf. *ibid.*, Priciple 5(a).
58 See chapter 4, section D.VI.
59 ILC, Allocation of Loss Principles (n. 2), Principle 5(d) and commentary thereto, para. 10.
60 *Ibid.*, Principle 2(a)(v) and commentary thereto, para. 17.
61 *Barboza* (n. 2), 148.
62 ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 3, para. 7; see chapter 11.
63 *Ibid.*, Principle 5(d).
64 *Ibid.*, Principle 5(e).

tional or illegal transboundary movements of Living Modified Organisms to the *Biosafety Clearing-House* established under the Protocol.[65]

D. Obligation to Provide for International and Domestic Remedies

Principle 6 addresses the procedural measures expected from a state to ensure prompt and adequate compensation of foreign victims of transboundary damage. The underlying idea is that the state of origin should provide such victims with non-discriminatory access to justice within the national legal system of the state of origin.[66] As shown above, there are no internationally harmonized rules on the choice of forum, applicable law, and recognition and enforcement of judgments in cases of transboundary damage, which means that the victims will mostly have to seek legal remedies in the state of origin.[67] Therefore, Principle 6(2) provides that victims of transboundary damage should have access to remedies in the state of origin that are no less prompt, adequate and effective than those available to victims that suffer damage from the same incident within the territory of that state.[68] The right to non-discriminatory remedies in national law has already been recognized in a number of international agreements, including the 1982 *Law of the Sea Convention*,[69] the 1992 *Rio Declaration*,[70]

65 Cf. Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 January 2000; effective 11 September 2003), 2226 UNTS 208, Articles 17(1) CP and 25(3); see chapter 3, section A.II.2.b).

66 ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 6, para. 1; *Barboza* (n. 2), 148.

67 See chapter 2, section F.

68 ILC, Allocation of Loss Principles (n. 2), Principle 6(2).

69 Cf. United Nations Convention on the Law of the Sea (10 December 1982; effective 16 November 1994), 1833 UNTS 3, Article 235(2); see *Tim Stephens*, Article 235 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017), MN. 18–21.

70 Cf. Rio Declaration on Environment and Development (14 June 1992), UN Doc. A/CONF.151/26/Rev.1 (Vol. I), Principle 10, which reads: 'Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.'

the 1997 *Watercourses Convention*,[71] and the 2001 *Articles on Prevention* of the ILC.[72]

However, non-discriminatory access to justice does not provide prompt and adequate remedies as long as a state awards its own nationals no adequate level of protection.[73] For this reason, Principle 6(1) stipulates that states shall provide their domestic judicial and administrative bodies with the necessary jurisdiction and competence and ensure that these bodies have 'prompt, adequate and effective remedies' available in the event of transboundary damage.[74] States should also guarantee appropriate access to information relevant to the pursuance of such remedies.[75] Moreover, the provision of adequate remedies shall be without prejudice to the right of victims to seek remedies other than those available in the state of origin.[76] This allows for so-called 'forum shopping', which is justified in the case at hand because it allows victims of transboundary harm to seek legal remedies in the most suitable jurisdiction – be it for legal reasons or because assets of the defendant are situated there.[77]

E. Relationship to the Law of State Responsibility

The preamble to the Principles on Allocation of Loss notes that 'States are responsible for infringements of their obligations of prevention under international law'.[78] The ILC's commentary adds that the Principles are 'without prejudice to the rules relating to State responsibility and any claim that may lie under those rules in the event of a breach of the obliga-

71 Cf. Convention on the Law of the Non-Navigational Uses of International Watercourses (21 May 1997; effective 17 August 2014), UN Doc. A/RES/51/229, Article 32, which provides that states should not discriminate persons affected by significant transboundary harm on the basis of nationality, residence, or place where the injury occurred, in granting them access to judicial or other procedures to claim compensation.

72 ILC, Articles on Prevention (n. 5), Article 15.

73 *Barboza* (n. 2), 148.

74 ILC, Allocation of Loss Principles (n. 2), Principle 6(1).

75 *Ibid.*, Principle 6(5); also see chapter 4, section D.V.

76 *Ibid.*, Principle 6(3).

77 Cf. *Boyle* (n. 2), 9–10; ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 6, para. 8; *André Nollkaemper*, Cluster-Litigation in Cases of Transboundary Environmental Harm, in: Michael G. Faure/Ying Song (eds.), China and International Environmental Liability (2008) 11, 14–16.

78 ILC, Allocation of Loss Principles (n. 2), Preamble, recital 7.

tions of prevention'.[79] Although it is assumed for the purposes of the Principles that the state of origin has complied with its preventive obligations and is therefore not internationally responsible for transboundary damage, cases in which the state of origin has *not* complied with these obligations are not generally excluded from their scope. The commentary notes that 'the non-fulfilment of the duty of prevention […] could engage State responsibility without necessarily giving rise to the implication that the activity itself is prohibited' and thus falls outside the Principles' scope.[80]

Hence, the ILC envisaged civil liability under the Principles and the law of state responsibility as potentially complementary regimes.[81] A state could be internationally responsible for having failed to prevent transboundary damage (and would thus be obliged to make reparation under the law of state responsibility) and, additionally, be required to ensure prompt and adequate compensation in line with the Allocation of Loss Principles.[82] This could potentially lead to double recovery of the same damage. Therefore, claims on the intergovernmental level could be barred by the so-called *local remedies rule* as long as victims of transboundary damage have not sought to obtain compensation through the domestic remedies available in the state of origin.[83] However, as shown below, it is questionable whether this rule applies in cases of transboundary damage.[84]

79 *Ibid.*, General commentary, para. 6.
80 *Ibid.*, Commentary to Article 1, para. 6.
81 *Foster* (n. 2), 269; *Boyle* (n. 2), 99.
82 See ILC, Allocation of Loss Principles (n. 2), Commentary to Principle 1, para. 6, which notes that '[i]n such a case, State responsibility could be invoked to implement not only the obligations of the State itself but also the civil responsibility or duty of the operator.' But this appears to confuse the origins of state responsibility and civil liability: While the obligation to make reparation under the law of state responsibility is a *secondary obligation* that follows from a breach of a *primary obligation* (namely, the failure to prevent transboundary harm), the obligation to provide for civil liability of the operator is a separate *primary obligation* that exists independently from a breach of preventive obligations. Notably, a failure to provide for civil liability could *by itself* result in a breach of international law and thus entail (*secondary*) obligations to make reparation.
83 Cf. ILC, Draft Articles on Diplomatic Protection with Commentaries (2006), YBILC 2006, Vol. II(2), p. 26, Article 14; see *Foster* (n. 2), 268–269.
84 See chapter 9, section C.II.2.

F. Legal Status: Emerging Customary International Law?

In its commentary, the ILC described the Allocation of Loss Principles as 'a non-binding declaration of draft principles',[85] which 'did not attempt to identify the current status of […] customary international law'.[86] Moreover, the ILC noted that 'recommended draft principles would have the advantage of not requiring a harmonization of national laws and legal systems, which is fraught with difficulties'.[87] Hence, the Commission seemingly wanted to avoid developing another binding instrument on liability that would have likely suffered the same fate as many previous instruments and failed to attract enough ratifications to enter into force.[88] But this raises the question of why the ILC adopted principles at all on a topic where states persistently refuse to accept international harmonization.[89] One could even argue that the ILC attempted to undertake progressive development of international law in a direction that had already proven to be a dead end.[90]

However, there is a notable difference between earlier instruments and the ILC's Allocation of Loss Principles: while the former attempted to provide more or less harmonized rules on the substantive content of liability as well as the related procedural aspects,[91] the Principles only stipulate the desired result, namely the provision of prompt and adequate compensation to victims of transboundary damage. They do not seek to impose a particular standard of liability (but merely provide that 'liability should not require proof of fault'[92]) and do not require the mutual recognition and enforcement of foreign judgments, which are both issues that may be difficult to integrate into existing legal orders.[93] Instead, it is left to the states *how* they ensure prompt and adequate compensation and effective and non-discriminatory remedies, provided that they meet these objectives.

85 ILC, Allocation of Loss Principles (n. 2), General commentary, para. 11.
86 *Ibid.*, General commentary, para. 13.
87 *Ibid.*, General commentary, para. 12.
88 Cf. *Foster* (n. 2), 273; see *Anne Daniel*, Civil Liability Regimes as a Complement to Multilateral Environmental Agreements, 12 (2003) RECIEL 225.
89 See *Boyle* (n. 2), 25–26.
90 This seems to be the underlying assumption by *Jutta Brunnée*, Of Sense and Sensibility: Reflections on International Liability Regimes as Tools for Environmental Protection, 53 (2004) ICLQ 351, 355–356.
91 See ILC, Survey of liability regimes (n. 34).
92 ILC, Allocation of Loss Principles (n. 2), Principle 4(2); see chapter 2, section E.
93 See *Daniel* (n. 88), 236–237.

Besides, the Principles take a different approach to damage to the environment *per se*: by providing for the implementation of response measures rather than monetary compensation, the Principles reflect the approach taken by the more recent liability instruments, including the *Nagoya – Kuala Lumpur Supplementary Protocol*.[94] As shown further below, reimbursement of the costs incurred in taking 'reasonable response measures' is widely recognized in both state practice and international treaties.[95]

The question remains whether – and if so, to what extent – the ILC's Principles on Allocation of Loss already reflect customary international law. While some governments and scholarly authors have questioned[96] or clearly denied[97] the customary status of the ILC's Principles, others have argued that the obligation to ensure prompt and adequate compensation is already established in customary international law[98] or at least represents 'emerging international law'.[99] In any event, accepting the existence of a general obligation to ensure prompt and adequate compensation is the only way to reconcile the repeated recognition by states that transboundary damage should not be left unaddressed with their persistent refusal to accept strict state liability where they are not internationally responsible for the damage.[100] Apparently, this view was also shared by the majority

94 See chapter 2, section G, and chapter 6, section C.

95 See chapter 11, section A.

96 Cf. *Foster* (n. 2), 276–277.

97 See the comments by the United Kingdom and by the United States, in: ILC, Comments by Governments on the 2004 draft of the Allocation of Loss Principles (n. 28), 93; also see *Barbara Saxler* et al., International Liability for Transboundary Damage Arising from Stratospheric Aerosol Injections, 7 (2015) Law, Innovation and Technology 112, 130.

98 Cf. *Lefeber* (n. 1), 229–299, arguing in favour of a customary obligation to ensure prompt, adequate and effective compensation; but see *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 86, assuming the 'it cannot be said that a customary obligation of States has yet emerged to ensure prompt, adequate and effective response measures in case of environmental loss or threat of such loss'; also cf. *Boyle* (n. 2), 19; *Boyle* (n. 2), 100–101; moreover, see the comment by the Netherlands, the Czech Republic, and Mexico, in ILC, Comments by Governments on the 2004 draft of the Allocation of Loss Principles (n. 28).

99 Cf. *Nollkaemper* (n. 77), 16. No government expressly argued that the Principles represented already-binding customary international law, cf. ILC, Comments by Governments on the 2004 draft of the Allocation of Loss Principles (n. 28).

100 See chapter 10.

of states that offered comments on the 2004 draft of the Principles.[101] As aptly summarized by the ILC's Special Rapporteur on the topic,

> '*it is regarded as no longer acceptable under international law for a State to authorize a hazardous activity within its territory with a risk of causing transboundary harm and not have legislation in place which guarantees suitable remedies and compensation in case of an incident causing transboundary damage*'.[102]

Hence, although there may be disagreement about the extent to which the Principles elaborated by the ILC represent already-established customary international law, it can be assumed that the Principles have a 'customary core'. When activities under their jurisdiction cause transboundary harm, states must ensure that foreign victims have access to non-discriminatory remedies and can obtain prompt and adequate compensation. States must also take response measures to prevent and mitigate further damage, including by notifying and cooperating with all other states likely to be affected. This is also reflected in Principles 5 and 6(1) which, unlike the 2004 draft,[103] are now cast in obligatory terms: they provide that states 'shall' – and not only 'should' – provide for response measures and adequate remedies.[104]

Notably, the obligation to implement response measures is confined to the territory of each state; the state of origin is neither required nor generally allowed to take response measures in the territory of affected states.[105] Affected states, on their part, do not bear an obligation to take response measures under general customary international law,[106] although such an

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101 Cf. ILC, Comments by Governments on the 2004 draft of the Allocation of Loss Principles (n. 28); see ILC, Text of Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities Adopted by the Commission on First Reading, YBILC 2004, vol. II(2), para. 175 (2004).

102 *Rao* (n. 28), para. 3(e).

103 See ILC, Draft Principles on Allocation of Loss as adopted on first reading (2004) (n. 101).

104 Cf. *Rao* (n. 28), para. 44, defending the format of cast principles but also noting that 'the Commission may give some serious consideration to reflecting the basic obligation on the duty to pay compensation and the right to seek remedies in language that is more prescriptive'. Also see *Boyle* (n. 2), 19; *Foster* (n. 2), 280–281; *Boyle* (n. 2), 99; *Barboza* (n. 2), 150–151.

105 See *supra* section C.

106 But see ICJ, Gabčíkovo-Nagymaros Project (Hungary v. Slovakia), Judgment of 25 September 1997, ICJ Rep. 7, para. 80, noting that 'an injured State which has failed to take the necessary measures to limit the damage sustained would

obligation might well arise from international treaties. For instance, if a self-spreading LMO exceeds its intended target range and becomes an 'invasive alien species' threatening biodiversity, almost all states are required by Article 8(h) of the CBD to control and eradicate that species.[107] If an affected state takes reasonable mitigation and reinstatement measures, the expenses incurred in doing so become part of the damage for which the state of origin must ensure prompt, adequate and effective remedies under its domestic legal system.[108]

not be entitled to claim compensation for that damage which could have been avoided'.

107 See chapter 3, section B.V.

108 ILC, Allocation of Loss Principles (n. 2), Principle 2(a)(v) and commentary thereto, para. 17; commentary to Principle 5, para. 10; see chapter 11, section A.

Part Four:
Responsibility and Liability of States

Chapter 9: State Responsibility for Transboundary Harm Caused by Biotechnology

Chapters 6 to 8 have analysed the rules of international law relating to operator liability, i.e. the liability of persons and entities who carry out activities involving biotechnology or products of biotechnology. However, as mentioned above, liability may be imposed not only on the responsible operator but also on the state on whose territory or under whose jurisdiction a hazardous activity is conducted, or a noxious LMO is released.[1] The present chapter discusses the liability[2] of a source state (or 'state of origin'[3]) for such damage under the international law of *state responsibility*, which governs the consequences of breaches of international legal obligations by states.

Although the international law of state responsibility for internationally wrongful acts can certainly be described as one of the cornerstones of the modern international legal order, it has never been codified in a binding international treaty. After several decades of work on this topic,[4] the ILC adopted *Draft Articles on the Responsibility of States for Internationally Wrongful Acts* (ARSIWA) in 2001.[5] While the Articles did not culminate in the

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1 See chapter 2, section D.

2 On the use of the term 'liability' in relation to 'responsibility', see the clarifications in chapter 2, section C.

3 The terms 'state of origin' and 'source state' are used synonymously to refer to the state from which transboundary harm originates; see chapter 2, section D.

4 On the historical development of the topic, see *James Crawford*, State Responsibility: The General Part (2013), 3–44.

5 ILC, Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries (2001), YBILC 2001, vol. II(2), p. 31 (hereinafter 'ARSIWA'). On the reference to 'draft' articles, see UN OLA, Materials on the Responsibility of States for Internationally Wrongful Acts, UN Doc. ST/LEG/SER.B/25 (2012), ix, which states: 'In accordance with its Statute, the International Law Commission adopts "draft" instruments, including "draft articles". In the recent practice of the General Assembly, when draft articles, as presented by the Commission, are taken note of by the Assembly and annexed to one of its resolutions, the reference to "draft" is excluded.'

adoption of a treaty either,[6] the UN General Assembly expressly commended the Articles to governments.[7] Today, they are generally regarded as largely reflecting the pertinent rules of customary international law.[8]

While the Supplementary Protocol, as shown above, provides a dedicated legal framework on liability for damage resulting from LMOs, the general regime on state responsibility remains relevant for two reasons. *Firstly*, there will be situations in which the Supplementary Protocol is inapplicable or insufficient.[9] This may be the case, for instance, when the state concerned is not a party to the Supplementary Protocol, when the organism causing harm does not fulfil the definition of an LMO, when the resulting damage does not qualify as an adverse effect on the conservation and sustainable use of biological diversity, or when the resulting damage does not qualify as an adverse effect on the conservation and sustainable use of biological diversity.

Secondly, the Supplementary Protocol focuses on *operator liability*, i.e. the liability of legal or natural persons who carry out activities involving LMOs.[10] However, the state in which such activities are carried out may

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6 See *James Crawford/Simon Olleson*, The Continuing Debate on a UN Convention on State Responsibility, 54 (2005) ICLQ 959.

7 See UNGA, Resolution 56/83. Responsibility of States for Internationally Wrongful Acts, UN Doc. A/RES/56/83 (2001).

8 Cf. *Daniel Bodansky/John R. Crook*, Symposium: The ILC's State Responsibility Articles, 96 (2002) AJIL 773; in ICJ case law, see e.g., ICJ, Application of the Convention on the Prevention and Punishment of the Crime of Genocide (Bosnia and Herzegovina v. Serbia and Montenegro), Judgment of 26 February 2007, ICJ Rep. 43, paras. 385–415; on the reception of the ARSIWA by the ICJ generally, see *James Crawford*, The International Court of Justice and the Law of State Responsibility, in: Christian J. Tams/James Sloan (eds.), The Development of International Law by the International Court of Justice (2013) 71, 81–85; UN OLA (n. 5); in investment arbitration, see e.g. ICSID, Biwater Gauff (Tanzania) Ltd. v. Tanzania, Award of 24 July 2008, ICSID Case No. ARB/05/22, paras. 773–774; ICSID, Corn Products International Inc. v. Mexico, Decision on Responsibility of 15 January 2008, ICSID Case No. ARB(AF)/04/01, para. 76. For critical views on the widespread perception of the ARSIWA as codifications of customary international law, see *David D. Caron*, The ILC Articles on State Responsibility: The Paradoxical Relationship Between Form and Authority, 96 (2002) AJIL 857; *Fernando L. Bordin*, Reflections of Customary International Law: The Authority of Codification Conventions and ILC Draft Articles in International Law, 63 (2014) ICLQ 535.

9 *Gurdial S. Nijar* et al., Developing a Liability and Redress Regime Under the Cartagena Protocol on Biosafety: For Damage Resulting from the Transboundary Movements of Genetically Modified Organisms (2005), 8.

10 See chapter 2, section D.

also be responsible for damage, namely when it has not complied with its own obligations under international law. In this regard, it is important to note that states cannot discharge their own responsibility for environmental damage under international law by entering into agreements providing for operator liability, even when the damage is ultimately caused by a private actor.[11] The Supplementary Protocol expressly recognizes this by providing that it shall not affect 'the rights and obligations of States under the under the rules of general international law with respect to the responsibility of States for internationally wrongful acts'.[12]

The ARSIWA are rooted in the principle that 'every internationally wrongful act of a State entails the international responsibility of that State'.[13] The Articles are divided into four parts, which also set the framework for the present chapter: *Part One* sets out requirements under which state responsibility arises, namely that there is conduct that is attributable to the state in question and that constitutes a breach of an international obligation of that state (A.).[14] *Part Two* addresses the legal consequences arising from state responsibility once it has been established; besides ceasing the wrongful conduct and, where necessary, offering assurances of non-repetition, the responsible state must make full reparation for any injury caused by the damage (B.).[15] *Part Three* addresses the implementation of state responsibility (C.).[16] *Part Four* contains general provisions on the relationship between the ARSIWA and other rules of international law.[17]

A. Requirements of the International Responsibility of a State

As set out above, the international responsibility of a state arises from an 'internationally wrongful act'. Article 2 of the ILC's Articles on State Responsibility provides:

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11 *Nijar* et al. (n. 9), 8.
12 Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64 (hereinafter 'Supplementary Protocol'), Article 11; see chapter 6, section E.III.
13 ARSIWA (n. 5), Article 1.
14 *Ibid.*, Articles 1–27.
15 *Ibid.*, Articles 28–41.
16 *Ibid.*, Articles 42–54.
17 *Ibid.*, Articles 55–59.

> *'There is an internationally wrongful act when conduct consisting of an action or omission*
> *(a) is attributable to the State under international law; and*
> *(b) constitutes a breach of an international obligation of the State.'*

Consequently, three requirements must be met for a state to be internationally responsible for transboundary harm: Firstly, there must be *conduct*, which may consist of an action or omission (I.). Secondly, this conduct must be *attributable* to the state in question (II.). Thirdly, such conduct must constitute a *breach of an international obligation* of that state (III.). But under certain circumstances, the *wrongfulness* of conduct which would otherwise be in breach of international law is *precluded* (IV.).

I. Conduct Consisting of an Action or Omission

Article 2 ARSIWA postulates that the conduct of a state that can give rise to international responsibility may consist of an action or an omission. While *actions* are usually easy to identify, identifying an *omission* from the relevant surrounding circumstances can be more difficult.[18] In legal terms, the term 'omission' denotes neglect of duty, i.e. a failure to act despite a legal duty to do so.[19] Therefore, an omission always depends on the existence of a positive primary obligation to act.[20] An omission is committed by a failure to act in accordance with the obligation, either by remaining inactive at all or by taking only partial or insufficient action.

The issue of breaches committed by omissions is particularly relevant in the context of responsibility for transboundary harm, because most hazardous activities are not carried out by state organs but by private persons or entities. As shown below, the conduct of private actors is not generally attributable to a state.[21] Hence, although the ultimate cause of transboundary harm is usually an action, namely the conduct of carrying out the hazardous activity, state responsibility commonly arises from a failure to take appropriate measures to prevent harm, and thus from an

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18 *Ibid.*, Commentary to Article 2, para. 4, fn. 64.

19 *Crawford* (n. 4), 218; cf. 'omission', in: *Bryan A. Garner* (ed.), Black's Law Dictionary (11th ed. 2019), 1311.

20 *Crawford* (n. 4), 218; *Franck Latty*, Actions and Omissions, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 355, 357–358.

21 ARSIWA (n. 5), Commentary to Chapter II, para. 3; see *infra* section A.II.2.

omission. But responsibility may also result from a combination of actions and omissions, for instance, when a state *authorizes* the release of an LMO but *omits* to impose and enforce appropriate preventive measures. Similar situations may arise when the hazardous activity itself is attributable to the state.

II. Attribution

In the previous section it was shown that a distinction must be drawn between the actual conduct of developing, importing or releasing an LMO (either by state or non-state actors) on the one hand, and acts undertaken (or omitted) by the authorities of a state to authorize and regulate such conduct on the other. This raises the question under which circumstances a particular conduct or omission is considered to be that 'of' the state.

Article 2(a) ARSIWA stipulates that a state can only be held responsible for conduct that is 'attributable' to it under international law. The purpose of attribution is to determine whether a certain conduct is considered to be an 'act of state' and thus capable of giving rise to state responsibility.[22] Thus, attribution reflects the principle that a state is not generally responsible for the conduct of all human beings, organizations or corporations that are linked by nationality, habitual residence or incorporation.[23] Instead, the responsibility of a state under international law only extends to organs of its government organs and those who act under the direction, instigation or control of these organs.[24] The conduct of non-state actors is not generally or automatically attributable to the state.[25] Hence, the doctrine of attribution serves to draw the line between the private realm and those acts or omissions which are considered 'acts of the state' and

22 *Ibid.*, Commentary to Chapter II, para. 2; *Crawford* (n. 4), 113; *Joanna Kulesza*, Due Diligence in International Law (2016), 93.

23 ARSIWA (n. 5), Commentary to Chapter II, para. 2; see *Lucas Bergkamp*, Liability and Environment (2001), 158; *Olivier* de *Frouville*, Attribution of Conduct to the State: Private Individuals, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 257.

24 ARSIWA (n. 5), Commentary to Chapter II, para. 2; see *Malcolm N. Shaw*, International Law (8th ed. 2017), 595.

25 ARSIWA (n. 5), Ch. II, para. 3; see *Roberto Ago*, Fourth Report on State Responsibility, YBILC 1972, Vol. II, 126 (1972), paras. 145–146; *Cedric Ryngaert*, State Responsibility and Non-State Actors, in: Math Noortmann/August Reinisch/Cedric Ryngaert (eds.), Non-State Actors in International Law (2015) 163, 163.

can thus give rise to international responsibility.[26] Notably, a state may nevertheless be responsible for the result of the conduct of private actors when it fails to take necessary measures to prevent those effects despite being obliged to do so.[27] However, this concerns the scope of respective preventive obligations, not attribution.[28]

Whether certain conduct is attributable to a state primarily depends on the relationship between the acting person or entity and the state in question.[29] In principle, only conduct by the organs of a state and persons or entities exercising governmental authority is attributable (1.). Additionally, a state is responsible for the conduct of non-state actors to the extent that it directs or controls such conduct (2.). Moreover, the conduct of non-state actors can become attributable *ex post* when a state adopts and acknowledges such conduct as its own (3.). Attribution may also follow from *lex specialis* norms (4.) or, according to international jurisprudence, from international human rights law (5.).

1. Conduct by State Organs and Persons Exercising Governmental Authority

The most straightforward type of attribution applies to the conduct of the *organs* of a state. The ARSIWA do not give an abstract definition of the term 'organ', but only provide that it includes 'any person or entity which has that status in accordance with the internal law of that State'.[30] It is not relevant for attribution what particular functions the organ exercises or what position it holds in the internal organisation of the state.[31] Moreover, attribution extends to the conduct of persons or entities empowered by the law of the state to exercise 'elements of governmental authority',[32] as well as state organs placed at the disposal of another state.[33]

Hence, whether a particular actor's conduct is attributable under one of these categories largely depends on the domestic constitutional and legal

26 *Hanqin Xue*, Transboundary Damage in International Law (2003), 74.
27 Cf. ARSIWA (n. 5), Commentary to Chapter II, para. 4.
28 See chapter 4, in particular section E.
29 See generally *Edwin M. Borchard*, Theoretical Aspects of the International Responsibility of States, 1 (1929) ZaöRV 223, 228–231.
30 ARSIWA (n. 5), Article 4(2); see *Borchard* (n. 29), 231–239.
31 ARSIWA (n. 5), Article 4(1).
32 *Ibid.*, Article 5.
33 *Ibid.*, Article 6.

rules of the state in question.[34] At the same time, the conduct of such actors is attributed even when they exceed their authority or contravene instructions.[35] This shows that the *legal authority* to act on behalf of the state is the primary factor for the first category of attribution.[36] At the same time, a state cannot escape its international responsibility by declaring certain institutions to be 'autonomous' or 'independent' from the executive government.[37] Moreover, it is irrelevant whether the conduct of a state organ may be classified as 'industrial or commercial' or *acta iure gestionis.*[38]

The identification of organs and *de facto* organs of a state is the most direct form of attribution as the conduct in question can immediately be assessed against the relevant obligations under international law. In other words, there is a legal presumption that the state's government is exercising *actual ultimate control* over the persons acting on its behalf.[39] Possible examples could be nuclear activities or genetic engineering conducted by a state's military.[40]

The conduct of a state's regulatory agencies is always directly attributable under Article 4 or 5 ARSIWA.[41] The same applies when a state fails to live up to its obligations under international law, regardless of whether this failure is caused by omissions by the legislature or regulatory agencies.[42] Consequently, a state may be internationally responsible for its failure to appropriately regulate the conduct of private or public actors under its jurisdiction that enables these actors to impose transboundary environmental interference.[43] For instance, when a state party to the Cartagena Protocol fails to apply the *Advance Informed Agreement* (AIA) procedure for

34 *Ibid.*, Commentary to Chapter II, para. 4; cf. *Crawford* (n. 4), 115.
35 ARSIWA (n. 5), Article 7; cf. *Crawford* (n. 4), 136–140.
36 Cf. *Xue* (n. 26), 76; ARSIWA (n. 5), Commentary to Article 7, para. 7. This is also confirmed by Article 4(2) ARSIWA, cf. ARSIWA (n. 5), Commentary to Article 4, para. 11. Also see *Ryngaert* (n. 25), 167.
37 ARSIWA (n. 5), Commentary to Chapter II, para. 6.
38 *Ibid.*, Commentary to Article 4, para. 6; see 'Actum iure gestionis', in: *Aaron X. Fellmeth/Maurice Horwitz*, Guide to Latin in International Law (2011), 14.
39 *Xue* (n. 26), 76; cf. ICJ, Difference Relating to Immunity from Legal Process of a Special Rapporteur of the Commission on Human Rights, Advisory Opinion of 29 April 1999, ICJ Rep. 62, para. 62.
40 Cf. *Xue* (n. 26), 77.
41 *Rebecca M. Bratspies*, State Responsibility for Human-Induced Environmental Disasters, 55 (2012) German YBIL 175, 203; *Crawford* (n. 4), 127–128.
42 Cf. *Latty* (n. 20), 361; *Bratspies* (n. 41), 203–204.
43 Cf. *Bratspies* (n. 41), 204–205, who observes that the 'notion that the failure to regulate adequately can breach international legal obligations, thereby triggering State responsibility is gaining traction across a wide range of international fora'.

transboundary movements of LMOs,[44] such failure is always attributed to the state, regardless of which governmental organ or agency would have been responsible for implementing the AIA procedure according to the internal division of powers in that state.

2. Conduct by Persons Instructed or Controlled by the State

The second type of attribution concerns the conduct of private or non-state actors. The central provision on this matter in the ILC's Articles on State Responsibility is Article 8, which reads:

> *'The conduct of a person or group of persons shall be considered an act of a State under international law if the person or group of persons is in fact acting on the instructions of, or under the direction or control of, that State in carrying out the conduct.'*

Hence, whether conduct is attributable under Article 8 ARSIWA depends on whether a particular act is carried out 'under the instructions of, or under the direction or control' of a state. In contrast to Articles 4 to 7 ARSIWA, the decisive factor here is not the legal status of the actor, but whether the conduct in question is *in fact* influenced by the state.[45] Article 8 ARSIWA codifies customary international law, as held by the *International Court of Justice* (ICJ) in the *Bosnian Genocide* case.[46]

The following section analyses the different criteria for attribution under Article 8 ARSIWA (a)). Subsequently, these criteria are tested in different scenarios of activities relating to biotechnology carried out by non-state actors (b)).

a) The Criteria for Attribution Under Article 8 ARSIWA

According to the wording of Article 8 ARSIWA, the decisive criterion for attributing conduct of non-state actors is whether such conduct is carried out 'under the instructions of, or under the direction or control' of a state. According to the ILC's commentary to Article 8, the terms 'instructions', 'direction' and 'control' are used disjunctively, and it shall

44 See chapter 3, section A.II.1.
45 Cf. ARSIWA (n. 5), Commentary to Article 8, para. 2.
46 ICJ, Bosnian Genocide (n. 8), para. 398.

suffice to establish any one of them.[47] However, the commentary does not provide definitions of these terms and seems to treat the terms 'direction' and 'control' as synonyms.[48] In scholarly literature, there is a tendency to conflate all or some of the criteria; most commonly, the terms 'direction and control' are regarded as denoting a single standard of attribution.[49] This is supported by a strictly grammatical interpretation of Article 8 ARSIWA – as there is no comma before for the 'or', 'direction or control' could be seen as a single category.[50] At the same time, the genesis of Article 8 rather supports the assumption that the ILC intended to include three separate criteria.[51]

aa) Instruction

The first criterion for attribution is that the non-state person or entity acts 'on the instructions of' the state. The term 'instruction' denotes an 'authoritative order to be obeyed'.[52] Hence, an instruction can be assumed when a state decides to engage in particular conduct and instructs a non-state entity to do so on its behalf.[53] Moreover, the non-state actors must be 'factually subordinate' to the state at the moment when the acts in question

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47 ARSIWA (n. 5), Commentary to Article 8, para. 7.

48 *Kubo Mačák*, Decoding Article 8 of the International Law Commission's Articles on State Responsibility: Attribution of Cyber Operations by Non-State Actors, 21 (2016) Journal of Conflict and Security Law 405, 411; cf. ARSIWA (n. 5), Commentary to Article 8, para. 1, which refers to 'two such circumstances', the first involving private persons acting on the instructions of the State, the second dealing 'with a more general situation were private persons act under the State's direction or control'.

49 *Crawford* (n. 4), 146; *Shaw* (n. 24), 598; *André J.* de *Hoogh*, Articles 4 and 8 of the 2001 ILC Articles on State Responsibility, the Tadić Case and Attribution of Acts of Bosnian Serb Authorities to the Federal Republic of Yugoslavia, 72 (2002) BYIL 255, 277–278. A different stand is taken by *Cassese*, who assumes that the first and second criteria are similar, while the third test is, in his view, 'rather loose', cf. *Antonio Cassese*, The Nicaragua and Tadic Tests Revisited in Light of the ICJ Judgment on Genocide in Bosnia, 18 (2007) EJIL 649, 663.

50 Cf. *Robert Heinsch*, Conflict Classification in Ukraine: The Return of the "Proxy War"?, 91 (2015) International Law Studies 323, 348.

51 *Mačák* (n. 48), 412–414.

52 Cf. 'instructions, n.', in *James Murray* et al., Oxford English Dictionary, Online Edition, available at: http://www.oed.com/ (last accessed 28 May 2022).

53 *Mačák* (n. 48), 414.

are committed.[54] While it may be sufficient that the non-state actor simply accepts the instructions given by the state and acts on them, attribution is not established when a state merely instigates, encourages or incites non-state actors to commit certain actions.[55] Furthermore, the instructions must order a specific, identifiable conduct.[56] As the ICJ held in the *Bosnian Genocide* case, the relevant instructions must be given 'in respect of each operation in which the alleged violations occurred, not generally in respect of the overall actions taken by the person or groups of persons having committed the violation'.[57] Although the case concerned the attribution of war crimes, particularly the massacre at *Srebrenica* committed in the *Bosnian War*, the ICJ expressly noted that it applied the general rules of attribution under the law of state responsibility.[58] Consequently, the Court's assessment of the law of attribution is widely perceived to be relevant beyond the specific context in which they were made.[59]

As the wording of Article 8 ARSIWA indicates, attribution is only possible as long as the private person acts 'on' the instructions of the state. A state will not incur responsibility if the non-state actors exceed the specific instructions given to them, thus going beyond what was incidental to the course of action authorized by the state.[60] Indeed, under Article 8 ARSIWA a factual relationship between the state and the non-state actor is required, which no longer exists when the latter acts on its own.[61]

54 *Ibid.*, 415; *Crawford* (n. 4), 146.
55 *Mačák* (n. 48), 415–416, who points to specific rules prohibiting incitement to genocide or discrimination.
56 *Ibid.*, 416.
57 ICJ, Bosnian Genocide (n. 8), para. 400.
58 *Ibid.*, para. 401, noting that '[t]he rules for attributing alleged internationally wrongful conduct to a State do not vary with the nature of the wrongful act in question in the absence of a clearly expressed lex specialis'.
59 Cf. *Frouville* (n. 23), 266–267; *Mačák* (n. 48), 414–415; *Crawford* (n. 4), 156; see *infra* n. 85 and accompanying text.
60 ARSIWA (n. 5), Commentary to Article 8, para. 8; cf. *Mačák* (n. 48), 417. In this regard, there is a systematic difference to the attribution of conduct by state organs or agents, for which Article 7 ARISWA provides that such conduct is attributable even when the organ or agents exceeds its authority or contravenes instructions; see ARSIWA (n. 5), Commentary to Article 7, para. 7.
61 *Ibid.*, Commentary to Article 8, para. 8.

bb) Direction

The second criterion for attribution under Article 8 ARSIWA is that a person or entity acts under the 'direction' of the state. This criterion has received comparably little attention in scholarly literature and, as noted above, is often conflated with one of the other two.[62] For instance, the ICJ held in the *Bosnian Genocide* case that an act is attributable

> *'where an organ of the State gave the instructions or provided the direction pursuant to which the perpetrators of the wrongful act acted'.*[63]

Hence, the question arises of how to distinguish between 'instructions' and 'direction' of a state, particularly since the natural meaning of both terms appears to be quite synonymous.[64] According to *Crawford*,

> *'"Direction" implies a continuing period of instruction, or a relationship between the state and a non-state entity such that suggestion or innuendo may give rise to responsibility.'*[65]

Consequently, the criterion of 'direction' provides a lowered threshold of causality for the particular act in question but requires an underlying continued relationship between the state and the non-state actor. In other words, when a state 'nurtures a relationship of subordination' with a non-state person or entity and continuously guides the conduct of these actors, it may incur responsibility for an act even when it did not give an express instruction to commit that act.[66]

cc) Control

According to the final criterion of Article 8 ARSIWA, the conduct of non-state actors is attributable to a state when they act under the 'control' of that state in carrying out the conduct. This criterion is not only the most relevant but, arguably, also the most controversial of the three bases of

62 Cf. *Mačák* (n. 48), 417; see *supra* n. 49 and corresponding text.
63 ICJ, Bosnian Genocide (n. 8), para. 406.
64 Cf. 'direction, n.', in Oxford English Dictionary (n. 52), Sect. 1c, where the term is defined as '[t]he action [...] of instructing how to proceed or act aright; authoritative guidance, instruction'.
65 *Crawford* (n. 4), 146 fn. 28.
66 *Mačák* (n. 48), 418.

attribution. The reason for this controversy is that the element of 'control' operates between two thresholds.

On the *upper* end, the scope of Article 8 is exceeded when a non-state actor is in 'complete dependence' and, ultimately, nothing more than an 'instrument' of the state.[67] In these situations, the non-state actor is regarded as a 'de facto organ' of the state which is responsible for the relevant conduct under Article 4 ARSIWA.[68] Delimiting this upper threshold of Article 8 is relatively straightforward and a rather theoretical exercise, as it concerns merely the legal basis on which the conduct is attributed.

Determining the *lower* threshold of Article 8 ARSIWA, i.e. the minimum level of control required for attribution, is more difficult. This is because it lies in the very nature of states to exercise a certain degree of control over the conduct of private persons and entities in their territory.[69] At the same time, it is also well recognized that a state does not bear a general responsibility for all unlawful acts perpetrated within its territory.[70] The central problem of Article 8 ARSIWA thus concerns the degree of control that the state must exercise for the conduct to be attributable.[71]

It is controversial under which circumstances a state is deemed to have 'control' over the conduct of non-state actors in the sense of Article 8 ARSIWA. As far as it is known, all international case law relevant to this issue relates to armed activities.[72] In the case concerning *Military and Paramilitary Activities in and against Nicaragua*, the ICJ held in 1986 that the conduct of non-state actors was only attributable to a state when the latter has 'effective control' over the activities during which the alleged violations of international law occurred.[73] Essentially, this required the state to be involved in planning the operations, choosing the targets and providing operational support.[74]

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67 ICJ, Bosnian Genocide (n. 8), para. 392; cf. *Paolo Palchetti*, De Facto Organs of a State, in: Wolfrum/Peters (ed.), MPEPIL, MN. 7–13; *Ryngaert* (n. 25), 171–172.

68 ICJ, Bosnian Genocide (n. 8), para. 406; see *Stefan Talmon*, The Responsibility of Outside Powers for Acts of Secessionist Entities, 58 (2009) ICLQ 493, 498–502.

69 *Mačák* (n. 48), 420.

70 ICJ, Corfu Channel Case (United Kingdom v. Albania), Merits Judgment of 09 April 1949, ICJ Rep. 4, 18.

71 Cf. ARSIWA (n. 5), Commentary to Article 8, paras. 4 et seq.

72 Cf. *Ryngaert* (n. 25), 169.

73 ICJ, Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States of America), Merits Judgment of 27 June 1986, ICJ Rep. 14, para. 115.

74 *Ibid.*, para. 112; see *Mačák* (n. 48), 421.

In its judgment in the *Tadić* case of 1999, the *International Criminal Tribunal for Former Yugoslavia* (ICTY) held that the required degree of control 'may vary according to the factual circumstances of each case'.[75] It confirmed that 'effective control' is required for attributing acts carried out by private individuals engaged by a state to perform specific actions.[76] At the same time, it assumed that the degree of control could be lower with regard to actions by organized and hierarchically structured groups, such as military or paramilitary units. In these instances, the ICTY deemed it sufficient that the state has 'overall control' over the group concerned.[77]

In its 2007 judgment in the *Bosnian Genocide* case, the ICJ refused to adopt the 'overall control' test developed by the ICTY. First, it noted that the ICTY's *Tadić* judgment did not concern questions of state responsibility but individual criminal responsibility.[78] Moreover, it held that the 'overall control' test broadened the scope of state responsibility far beyond the fundamental principle that a state is only responsible for its 'own' conduct, i.e. the conduct of persons acting, on whatever basis, on its behalf.[79] Instead, the ICJ considered it to be 'settled jurisprudence' that a state may only be responsible for the conduct of private actors when it has 'effective control' over these activities.[80]

As a result, it is sometimes assumed that there are two competing 'control tests' for attribution under Article 8 ARSIWA.[81] At the same time, it seems reasonable to lower the threshold for attribution in situations where states delegate power to semi-autonomous groups or organizations,[82] including so-called private military contractors.[83] Otherwise, states would be

75 ICTY, Prosecutor v. Duško Tadić, Judgment of the Appeals Chamber of 15 July 1999, IT-94–1, 38 ILM 1518, para. 118.
76 *Ibid.*, paras. 118–119.
77 *Ibid.*, para. 145; see *Talmon* (n. 68), 504–507.
78 ICJ, Bosnian Genocide (n. 8), para. 403; see ICTY, Tadić (n. 75), Separate Opinion of Judge Shahabuddeen, paras. 17–18; but see *Cassese* (n. 49), 655–664, arguing that the ICTY indeed addressed a question concerning the law of state responsibility, albeit in order to solve an issue of international humanitarian law.
79 ICJ, Bosnian Genocide (n. 8), para. 406.
80 *Ibid.*, paras. 402–406; see *Crawford* (n. 4), 156, noting that 'this determination effectively ends the debate as to the correct standard of control to be applied under Article 8'.
81 See e.g. *Kristen E. Boon*, Are Control Tests Fit for the Future? The Slippage Problem in Attribution Doctrines, 15 (2015) Melb. J. Int'l L. 1, 10; *Shaw* (n. 24), 598–599.
82 Cf. *Cassese* (n. 49), 665–667.
83 Cf. *Boon* (n. 81), 22.

able to evade their international responsibility by deliberately relinquishing control. The tests of 'effective control' and 'effective overall control' should thus not be seen as competing but as complementing each other depending on the situation to be assessed.

Considering that all of the above case law is placed in the context of armed activities, it could be questioned whether the standards developed in this context also apply outside this specific context,[84] such as in relation to the development and use of biotechnology products and LMOs. However, case law from other areas does not indicate any fundamental differences. For instance, in investor-state disputes concerning alleged breaches of international investment law, arbitral tribunals have repeatedly recognized that:

> *'International jurisprudence is very demanding in order to attribute the act of a person or entity to a State, as it requires both a general control of the State over the person or entity and a specific control of the State over the act the attribution of which is at stake; this is known as the "effective control" test.'*[85]

Consequently, it can be concluded that the 'effective control' test as formulated by the ICJ reflects general international law. Since there are no *lex specialis* rules providing for different standards of attribution in the present context, the 'effective control' test also applies to conduct that gives rise to transboundary harm, including in the context of biotechnology.

In any event, neither international jurisprudence nor legal scholarship has so far offered much guidance on when control is indeed 'effective' or 'overall effective'.[86] The ILC merely acknowledged that 'it is a matter for

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84 *Ibid.*, 19–21.

85 ICSID, Jan de Nul NV and Dredging Intemational NV v. Egypt, Award of 06 November 2008, ICSID Case No. ARB/04/13, para. 173; confirmed in ICSID, Gustav F Hamester GmbH and Co KG v. Ghana, Award of 18 June 2010, ICSID Case No. ARB/07124, para. 179; UNCITRAL Arbitral Tribunal, White Industries Australia Limited v. Republic of India, Final Award of 30 November 2011, para. 8.1.18; but see ICSID, Bayindir Insaat Turizm Ticaret Ve Sanayi A.Ş. v. Islamic Republic of Pakistan, Award of 27 August 2009, ICSID Case No. ARB/03/29, noting that 'that the approach developed in […] areas of international law [concerning foreign armed intervention or international criminal responsibility] is not always adapted to the realities of international economic law and that they should not prevent a finding of attribution if the specific facts of an investment dispute so warrant.' See generally *Simon Olleson*, Attribution in Investment Treaty Arbitration, 31 (2016) ICSID Review 457.

86 Cf., e.g., *Crawford* (n. 4), 146–156; *Ryngaert* (n. 25), 165–168.

appreciation in each case' whether the degree of control calls for attribution of the relevant conduct or not.[87] As a general rule, it can be assumed that the law of state responsibility is 'conservative in nature' and 'tends to err on the side of non-attribution of responsibility for the conduct of private parties'.[88] However, it appears not to be inconceivable that unsolicited actions by non-state actors, such as laboratory research on or unauthorized releases of self-spreading LMOs, are in fact directed or controlled by a state and thus attributable to the latter.

Finally, it is important to note that the notion of 'control' over acts of non-state actors in the sense of Article 8 ARSIWA should not be confused with concepts of 'control' used in other areas.[89] As shown earlier, if a state exercises control (in the sense of *de facto* jurisdiction) over a territory, it must ensure that activities carried out in that territory do not cause significant transboundary harm.[90] Similarly, in the human rights context, the notion of control is used to determine the extraterritorial application of international human rights obligations.[91] However, whether a state exercises control over a territory or individuals and is thus responsible for human rights violations is not necessarily the same as whether it is responsible for the conduct of private actors under Article 8 ARSIWA.[92]

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87 ARSIWA (n. 5), Commentary to Article 8, para. 5.

88 *Mačák* (n. 48), 426; also see *Jacqueline Peel*, Unpacking the Elements of a State Responsibility Claim for Transboundary Pollution, in: S. Jayakumar/Tommy Koh et al. (eds.), Transboundary Pollution (2015) 51, 59.

89 *Boon* (n. 81), 4–6 notes that the concept of 'control' plays a role in at least ten different fields of international law.

90 See chapter 4, section B.II.

91 Cf. ICJ, Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory, Advisory Opinion of 09 July 2004, ICJ Rep. 136, paras. 107–111; ECtHR, Al-Skeini et al. v. the United Kingdom, Judgment of 07 July 2011, Application no. 55721/07, paras. 130–150; see *Ralph Wilde*, The Extraterritorial Application of International Human Rights Law on Civil and Political Rights, in: Scott Sheeran/Nigel Rodley (eds.), Routledge Handbook of International Human Rights Law (2014) 635, 640–649.

92 *Marko Milanović*, Extraterritorial Application of Human Rights Treaties (2011), 41–53, notes that 'state jurisdiction is not state responsibility'. Even so, this does not mean that both issues may not arise in combination. For instance, a state may be responsible when it entertains unrecognized militias that exercise de facto control in a foreign territory and commit potential human rights violations there, see *Marko Milanović/Tatjana Papić*, The Applicability of the ECHR in Contested Territories, 67 (2018) ICLQ 779, 283–284; but see *infra* section A.II.5.

b) Attribution of Private Activities Causing Transboundary Harm

In the following, the criteria for attributing private conduct to a state under Article 8 ARSIWA analysed above are applied to different scenarios in which activities are carried out by private actors but under the guidance or governance of a state cause transboundary harm. These cases include activities regulated by a state (aa)), state-owned and controlled enterprises (bb)), research and development activities by public institutions (cc)) and state-funded research activities by non-state actors (dd)).

aa) Regulatory Oversight

A literal understanding of the notion of 'control' in Article 8 ARSIWA could lead to the assumption that a state's regulatory oversight of a hazardous activity carried out by private actors justified attribution. This appears to be assumed by the ICJ judge *Xue*, who argues that activities conducted by private entities, 'but under the direct authorization and supervision of the state government' should be attributable under Article 5 or 8 ARISIWA.[93] In her view, this could include the nuclear industry, the space industry, some public transportation such as civil aviation and railways, and certain strictly controlled import and export activities.[94] *Xue* notes that

> *'an overly strict interpretation of the classical rules would result in a simplistic and unresponsive approach to the growing problems of transboundary activities conducted by the private sector'.*[95]

However, this understanding overstretches the scope of Articles 5 and 8 ARSIWA as laid out above and thus cannot be sustained.[96] Attributing each conduct to a state solely because there is a high degree of regulatory oversight would blur the lines between primary obligations (such as those to regulate private activities to avoid transboundary interference) and secondary obligations (such as to make reparation for harm resulting from a failure to appropriately regulate private activities). After all, there is no evidence that the threshold for attribution under Article 8 ARISWA is

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93 *Xue* (n. 26), 77.
94 *Ibid.*
95 *Ibid.*, 78.
96 See *supra* sections A.II.1 and A.II.2.

lower than for the other bases of attribution. Instead, the decisive question is whether a state exercises control over a private activity to a degree similar to that of activities directly carried out by state organs.

For hazardous activities not attributable to the state under these standards, the obligation of states not to allow their territory to be used to the detriment of other states and corresponding preventive duties come into play.[97] Therefore, neither mere knowledge of a specific private activity nor its authorization by the administrative authorities of a state automatically renders this activity attributable to that state.[98] For instance, a permit allowing the release of a certain LMO into the environment does not make the *release* itself attributable to the relevant state. At the same time, the act of *issuing the permit* is attributable to the state, as is any other conduct of the regulatory agencies of a state.[99] This shows that careful distinction is required between the hazardous conduct itself and acts undertaken by the authorities of a state to authorize and regulate such conduct.

bb) Enterprises Owned and Controlled by a State

A different problem is posed by companies or enterprises owned and controlled by a state. If such companies act contrary to the international obligation of the state, the question arises of whether such conduct is attributable to the state in question.

In principle, international law accepts the distinct legal personality of corporations of which the state is the principal, or even the sole, shareholder.[100] Consequently, the mere fact that a state owns a corporate entity is not a sufficient basis for attributing the conduct of that entity to the state.[101] Instead, attribution is adjudged according to the general principles

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97 See chapters 3 to 5.
98 ARSIWA (n. 5), Commentary to Article 11, para. 6; see *Barbara Saxler* et al., International Liability for Transboundary Damage Arising from Stratospheric Aerosol Injections, 7 (2015) Law, Innovation and Technology 112, 118–119.
99 See *supra* section A.II.1; cf. *Bratspies* (n. 41), 203–204.
100 See ICJ, Case Concerning the Barcelona Traction, Light and Power Company, Limited (New Application 1962, Second Phase), Judgment of 05 February 1970, ICJ Rep. 3, paras. 56–58; ARSIWA (n. 5), Commentary to Article 8, para. 6.
101 ARSIWA (n. 5), Commentary to Article 8, para. 6; cf. Judicial Committee of the UK Privy Council, La Générale des Carrières et des Mines v. FG Hemisphere Associates LLC (Gécamines), 17 July 2012, Appeal No 0061 of 2011, 2012 UKPC 27, paras. 15–29; see *Crawford* (n. 4), 162–163.

laid down in the ILC's Articles on State Responsibility. When a corporation is empowered to exercise elements of governmental authority, the conduct carried out in the exercise of such authority will be attributable to the state under Article 5 ARSIWA.[102] Moreover, when a state uses its ownership of or control over a corporation to direct it towards particular actions, the resulting conduct is attributable to the state in accordance with the standards formulated in Article 8 ARSIWA.[103]

It has been suggested that the 1986 nuclear accident at *Chernobyl* was an example of environmental harm caused by a state-owned enterprise in which neither Article 5 nor Article 8 ARSIWA were fulfilled.[104] The nuclear power plant at Chernobyl was not constructed and operated by the Soviet Union itself but by a state enterprise that possessed a legal personality distinct from that of the state.[105] At the same time, other authors assessing the potential international responsibility of the Soviet Union for the Chernobyl accident assumed that the Soviet Union was indeed the operator of the nuclear plant[106] but, in any event, had effective control over both the construction of the plant and the tests which had caused

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102 ARSIWA (n. 5), Commentary to Article 5, para. 2, and Commentary to Article 8, para. 6; see IUSCT, Phillips Petroleum Company Iran v. The Islamic Republic of Iran et al., 29 June 1989, Award No. 425–39–2, 21 Iran–US CTR 79, paras. 88–120.

103 ARSIWA (n. 5), Commentary to Article 8, paras. 6–7; see ICSID, EDF (Services) Ltd. v. Romania, Award of 08 October 2009, ICSID Case No. ARB/05/13, paras. 209–213.

104 *Kirsten Schmalenbach*, Verantwortlichkeit und Haftung, in: Alexander Proelß (ed.), Internationales Umweltrecht (2017) 211, 217; also see *Sayed M. M. Zeidan*, State Responsibility and Liability for Environmental Damage Caused by Nuclear Accidents (2012), 307.

105 *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 245. This was confirmed by German civil courts in an action for damages brought against the Soviet Union, see Amtsgericht Bonn, Schadensersatzklage gegen UdSSR wegen Tschernobyl-Kernreaktorunfalls (Action for damages against USSR for Chernobyl nuclear accident), Order of 29 September 1987, 9 C 362/86, 41 NJW 1393. The court dismissed the claims on the grounds that 'a third institution, AES Chernobyl, is the addressee of both the contract for the construction and the supervisory measures. This is an independent legal entity, which is endowed with its own property and is liable with it for damages caused' (own translation). Also see *B. A. Semenov*, Nuclear Power in the Soviet Union, 25 (1983) IAEA Bulletin 47.

106 *Linda A. Malone*, The Chernobyl Accident: A Case Study in International Law Regulating State Responsibility for Transboundary Nuclear Pollution, 12 (1987) Colum. J. Envt'l. L. 203, 238–240.

the disaster.[107] Although a number of states had expressly reserved their right to hold the Soviet Union accountable for damage resulting from the radioactive fallout caused by the incident, no state ever made any formal claims.[108] However, the reasons for this are probably less to be found in matters of attribution than in evidentiary issues, legal uncertainties (as there were no binding international nuclear safety standards[109]) and, of course, political considerations.[110]

No comparable issues of attribution were raised by the nuclear accident of 2007 at *Fukushima*, as the operator of the nuclear plant involved in the accident had already been privatized in the 1950s.[111] In any event, there have been no reports about adverse transboundary effects, apart from marine pollution resulting from the discharge of contaminated water into the sea.[112]

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107 *Victoria R. Hartke*, The International Fallout from Chernobyl, 5 (1987) Dickinson Journal of International Law 319, 329–330; *Lefeber* (n. 105), 243.

108 Cf. *Philippe Sands* (ed.), Chernobyl: Law and Communication (1988), 26–30; *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 752–753.

109 *Lefeber* (n. 105), 344.

110 *Sands* et al. (n. 108), 753–754.

111 See *Eri Osaka*, Corporate Liability, Government Liability, and the Fukushima Nuclear Disaster, 21 (2012) Pacific Rim Law & Policy Journal 433; *Julius Weitzdörfer*, Die Haftung für Nuklearschäden nach japanischem Atomrecht – Rechtsprobleme der Reaktorkatastrophe von Fukushima I, 16 (2011) Zeitschrift für Japanisches Recht 61. A different view is taken, by *Bratspies* (n. 41), 206, who argues that 'the intertwined relationship of TEPCO [the company operating the Fukushima plant] and the Japanese government might also raise the possibility of a de facto agency relationship sufficient to establish direct State responsibility'.

112 See *Yen-Chiang Chang/Yue Zhao*, The Fukushima Nuclear Power Station Incident and Marine Pollution, 64 (2012) Marine Pollution Bulletin 897; also see *Kirsten Haupt/Thomas Mützelburg*, Global Radiation Monitoring in the Wake of the Fukushima Disaster, 16 (2011) CTBTO Spectrum 18, reporting that the monitoring system of the *Preparatory Commission for the Comprehensive Nuclear-Test-Ban Treaty Organization* (CTBTO) detected a global spread of radioactive particles and noble gases from Fukushima, although the radioactivity levels outside Japan were 'far below levels that could cause harm to humans and the environment'.

cc) Research and Development Activities by Public and Governmental Institutions

Attribution is also questionable with regard to research and development activities conducted by public research institutions, such as universities or governmental agencies.[113] These could be regarded as state organs because Article 4 ARSIWA provides that the status of a person or entity as a state organ does not depend on the exercise of legislative, executive or judicial functions but may also arise from the exercise of 'any other functions'. Moreover, attribution under Article 4 ARSIWA is not limited to sovereign or authoritative acts (*acta iure imperii*[114]) but also includes non-authoritative and commercial acts (*acta iure gestionis*[115]).[116] Consequently, research carried out by public research institutions or civil servants, such as professors and their staff, could be regarded as being attributable to the respective state.[117]

This finding is challenged by the fact that universities and other public research institutions often enjoy a high degree of independence from the government and commonly pursue their research free of instructions.[118] Moreover, as shown above, the conduct of commercial enterprises incorporated under private law but (predominantly) owned by the state is not generally attributable.[119] This would lead to the paradoxical situation that the same conduct would be attributed when performed by an entity established under the public law of a state, but not when carried out by a state-owned entity incorporated under private law.[120]

To resolve this discrepancy, it is necessary to distinguish between the different bases of attribution. Only Article 4 ARSIWA relies on the legal status of the acting person or entity. In contrast, all other bases for attribution rely on whether the actor in fact exercises (elements of) governmental

113 See *Constantin Teetzmann*, Schutz vor Wissen? (2020), 150–152.
114 Cf. *Fellmeth/Horwitz* (n. 38), 14.
115 Cf. *ibid.*
116 ARSIWA (n. 5), Commentary to Article 4, para. 6.
117 This appears to be assumed by the German Ethics Council, Biosecurity – Freedom and Responsibility of Research: Opinion (2014) at page 268 (fn. 581) of the German language version (the respective part is not included in the English translation).
118 *Teetzmann* (n. 113), 152.
119 See *supra* section A.II.2.a)bb).
120 Cf. *Teetzmann* (n. 113), 152.

authority[121] or acts under the instruction, direction, or control of the state.[122] As argued before, there is a legal presumption that persons or entities who qualify as *state organs* under the internal law of the state in the sense of Article 4(2) ARSIWA are acting on behalf, and under the control, of the state.[123] At the same time, there appears to be no state practice justifying the assumption that conduct can be attributed solely based on the actor's legal status, regardless of whether that actor is in fact exercising governmental powers.[124] Hence, the presumption that a person or entity bearing the status of a state organ always acts in that capacity should be regarded as refutable. If the relevant conduct does not constitute an exercise of governmental authority (i.e. constitutes *acta iure gestionis*) and would not be attributable under any of the other bases of attribution set out in Articles 5–8 ARSIWA, the mere legal status of the actor as a state organ will most likely not suffice to justify attribution.[125] Consequently, research and development activities conducted by public institutions are not attributable as long as these institutions are independent of the respective government and not acting on its instructions.[126]

However, it should be noted that academic freedom, despite being a fundamental human right,[127] is not guaranteed in many states around the

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121 ARSIWA (n. 5), Articles 5–7.

122 *Ibid.*, Article 8; cf. *Ryngaert* (n. 25), 164.

123 See *supra* section A.II.1.

124 *Teetzmann* (n. 113), 141, points out that in both cases cited by the ILC in support of attributing acts of 'independent' State organs, attribution was ultimately justified by the fact that governmental authority was exercised. Moreover, both cases did not concern attribution, but sovereign immunity of State organs, and the ILC assumed that 'the same principle applies in the field of State responsibility', cf. ARSIWA (n. 5), Commentary to Article 11, para. 11 and n. 122.

125 Cf. *ibid.*, Commentary to Article 4, para. 13. Also see *Crawford* (n. 4), 129–130.

126 *Teetzmann* (n. 113), 152. On the contrary, *Mačák* (n. 48), 415, points out that 'if a State specifically instructed an IT department within a university to carry out a Distributed Denial of Service (DDoS) attack against a designated target, the resulting operation would be attributable to the State in question.'

127 Cf. Article 15(3) of the International Covenant on Economic, Social and Cultural Rights (16 December 1966; effective 03 January 1976), 993 UNTS 3, which reads: 'The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.' Also see CESCR, General Comment No. 25 (2020) On Science and Economic, Social and Cultural Rights, UN Doc. E/C.12/GC/25 (2020), para. 13, noting that this includes *inter alia*, 'protection of researchers from undue influence on their independent judgment; the possibility for researchers to set up autonomous research institutions and to define the aims and objectives of the research and the methods to be adopted.'

world. As pointed out by the *UN Special Rapporteur on the Right to Freedom of Opinion and Expression*, governments often interfere with the autonomy of academic institutions by exerting, among other things, political, financial, ideological, and/or social and cultural pressure.[128] At the same time, the realities of academic freedom do not yet seem to be a thoroughly studied field.[129] Researchers developed an *Academic Freedom Index* ranking countries for their overall academic freedom by relying on standardized *de iure* and *de facto* indicators.[130] But whether a particular research or development undertaking is in fact carried out free of instructions and control by the respective government may be difficult to determine. In any event, if a government exercises partial or full control over research and development activities, such activities become attributable to the state even when no governmental authority is imposed on third parties.[131]

dd) State-Funded Research and Development Activities

Finally, problems may arise regarding research and development activities conducted by non-state actors but funded by the state. Commonly, the state – like any other donor – has a certain degree of influence on the objective and conduct of the research it funds. Whether the research is attributable to the state depends on whether the relevant conduct is carried out 'under the instructions of, or under the direction or control' of the state in the sense of Article 8 ARSIWA.[132] Accordingly, research may be attributable when the state instructs the researchers to use particular methods or pursue certain goals or when the state can order the activities to cease at any time.[133] Furthermore, attribution may be assumed when a research objective permitted, commissioned, or ordered by a state constitutes

128 *David Kaye*, Report of the Special Rapporteur on the Promotion and Protection of the Right to Freedom of Opinion and Expression, UN Doc. A/75/261 (2020), para. 31.

129 *Katrin Kinzelbach* et al., Free Universities: Putting the Academic Freedom Index into Action (2020).

130 *Katrin Kinzelbach*, Introduction to the Study of Academic Freedom, in: Katrin Kinzelbach (ed.), Researching Academic Freedom (2020) 1–10.

131 *Teetzmann* (n. 113), 152.

132 See *supra* section A.II.2.a).

133 *Teetzmann* (n. 113), 153–154.

a breach of international law or even of *ius cogens*, such as the development of biological or chemical weapons.[134]

3. Attribution of Conduct Acknowledged and Adopted by the State as Its Own

Article 11 ARSIWA addresses the special case of *ex post facto* attribution.[135] Conduct which was not attributable at the time of its commission shall nevertheless be attributed 'if and to the extent that the State acknowledges and adopts the conduct in question as its own'.[136] The prime example of attribution under this rule is the *Tehran Hostages* case, in which the Iranian government issued a decree approving and maintaining the occupation of the embassy of the United States in Tehran and the taking as hostages of its diplomatic and consular staff by militant Iranian revolutionists.[137] In the context of environmental disputes, a further example of *ex post facto* attribution is the *Gabčíkovo-Nagymaros* case, where the ICJ concluded that Slovakia adopted the sole responsibility for the construction project after the dissolution of Czechoslovakia, and thus was liable to pay compensation not only for its own wrongful conduct but also for that of Czechoslovakia.[138]

4. Attribution by Lex Specialis Norms

Besides the rules of attribution set out in the ARSIWA, the conduct of non-state actors may also be attributed on the grounds of other norms of international law. Article 55 ARSIWA expressly recognizes the prevalence of *lex specialis* norms over the general law of state responsibility.[139] For instance, Article 139 of the *UN Convention on the Law of the Sea* (UNC-

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134 See chapter 3, section J.I.
135 *Crawford* (n. 4), 181.
136 See ARSIWA (n. 5), Commentary to Article 11, para. 1.
137 Cf. *ibid.*, Commentary to Article 11, para. 4; see ICJ, United States Diplomatic and Consular Staff in Tehran, Judgment of 24 May 1980, ICJ Rep. 3, para. 74; *Crawford* (n. 4), 183–186.
138 ICJ, Gabčíkovo-Nagymaros Project (Hungary v. Slovakia), Judgment of 25 September 1997, ICJ Rep. 7, para. 151; see *Crawford* (n. 4), 186–187.
139 *Ibid.*, 114.

LOS)[140] provides that states are responsible for the conduct of private actors engaging in seabed mining activities, provided that these actors are nationals of that state or have been 'sponsored' by it.[141] Moreover, Article 263(3) UNCLOS provides, *inter alia*, that states shall be responsible and liable for damage caused by pollution of the marine environment arising out of marine scientific research undertaken on their behalf.[142] Another example can be found in Article VI of the *Outer Space Treaty*,[143] according to which states parties shall bear international responsibility for national activities in outer space, including when such activities are carried out by non-governmental entities.

5. Attribution of Transboundary Harm Through Human Rights Law?

A special form of attribution could also result from the interplay of international environmental law and international human rights law. In its 2018 advisory opinion on *Human Rights and the Environment*,[144] the *Inter-American Court of Human Rights* addressed the question of whether

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140 United Nations Convention on the Law of the Sea (10 December 1982; effective 16 November 1994), 1833 UNTS 3 (hereinafter 'UNCLOS').

141 For details, see *Silja Vöneky/Anja Höfelmeier*, Article 139 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017) 968. In the terminology of UNCLOS, the notion of sponsorship refers to a formal endorsement which is required for private undertaking to engage in seabed exploration or mining activities, cf. Article 153(3)(b) UNCLOS. In this context, also see ITLOS, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, Advisory Opinion of 01 November 2011, Case No. 17, ITLOS Rep. 10; *David Freestone*, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, 105 (2011) AJIL 755.

142 Note that Article 263(3) UNCLOS refers to Article 235, which makes additional provisions on responsibility and liability. By 'liability', UNCLOS refers to state responsibility, cf. *Tim Stephens*, Article 235 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017), MN. 8.

143 Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies (27 January 1967; effective 10 October 1967), 610 UNTS 205.

144 IACtHR, The Environment and Human Rights (State Obligations in Relation to the Environment in the Context of the Protection and Guarantee of the Rights to Life and to Personal Integrity – Interpretation and Scope of Articles 4(1) and 5(1) of the American Convention on Human Rights), Advisory Opinion OC-23/18 of 15 November 2017, IACtHR Ser. A, No. 23.

the *American Convention on Human Rights* (ACHR)[145] applies to persons residing outside a state's territory who are affected by transboundary harm originating from that state. This depends on whether such persons are subject to the 'jurisdiction' of a state sense of Article 1(1) ACHR.

The Court first reiterated the established principles for the extraterritorial application of the Convention, namely that a person residing outside the territory of a state is nevertheless subject to the 'jurisdiction' of that state when the latter is exercising authority over the person or when the person is under the effective control of the said state.[146] Subsequently, it held:

> *'For the purposes of the American Convention, when transboundary damage occurs that effects treaty-based rights, it is understood that the persons whose rights have been violated are under the jurisdiction of the State of origin, if there is a causal link between the act that originated in its territory and the infringement of the human rights of persons outside its territory.'*[147]

In the Court's view, the exercise of jurisdiction is based on the understanding that the state in whose territory the activities are carried out has effective control over these activities and is in a position to prevent them from causing transboundary harm.[148] Consequently, the Court held that the potential victims of transboundary harm were 'under the jurisdiction of the state of origin for the purposes of the possible responsibility of that state for failing to comply with its obligation to prevent transboundary damage'.[149]

It has been criticized that the Court 'effectively conflate[d] the extraterritoriality threshold with the obligation to prevent transboundary damage'.[150] Indeed, the Court's approach is questionable because it ignores the 'effective control' test usually required for the extraterritorial application

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145 American Convention on Human Rights (22 November 1969; effective 18 July 1978), 1144 UNTS 123.

146 IACtHR, Advisory Opinion on Human Rights and the Environment (n. 144), para. 81.

147 *Ibid.*, para. 101.

148 *Ibid.*, para. 102.

149 *Ibid.*

150 *Giovanny Vega-Barbosa/Lorraine Aboagye*, Human Rights and the Protection of the Environment: The Advisory Opinion of the Inter-American Court of Human Rights, EJIL: Talk!, 26 February 2018, available at: https://www.ejiltalk.org/human-rights-and-the-protection-of-the-environment-the-advisory-opinion-of-the-inter-american-court-of-human-rights/ (last accessed 28 May 2022).

of human rights treaties.[151] However, as noted earlier, the question of whether conduct is *attributable* to a state under the law of state responsibility is not the same as whether a state has *jurisdiction* in the sense of human rights law.[152] The mere fact that there is a causal link between an activity and adverse effects on the enjoyment of human rights abroad does neither automatically give rise to attribution nor effective control.[153] Consequently, the position of the Inter-American Court represents at best *progressive development* but does certainly not reflect the current rules of general international law.[154]

6. Conclusions

The preceding analysis has shown that, on the one hand, the conduct of the organs of a state and persons exercising governmental authority is generally attributable to that state. On the other hand, there is no general responsibility of a state for the conduct of private persons or entities. Neither mere knowledge of such conduct nor its authorization by a state's administrative authorities, such as a permit for releasing LMOs into the environment, automatically renders the activity itself attributable to the state in question.[155] The conduct of private actors is only attributable when the state exercises *effective control* over such conduct or *acknowledges and*

151 Notably, the Court itself noted that 'the situations in which the extraterritorial conduct of a State constitutes the exercise of its jurisdiction are exceptional and, as such, should be interpreted restrictively', IACtHR, Advisory Opinion on Human Rights and the Environment (n. 144), para. 81.

152 See *supra* section A.II.2.a)cc); see *Milanović* (n. 92), 41–52.

153 See *ibid.*, 126–127.

154 But see *Angeliki Papantoniou*, Advisory Opinion on the Environment and Human Rights, 112 (2018) AJIL 460–466, 465, who considers the Court's linking of extraterritorial jurisdiction with the obligation to prevent transboundary harm to be 'an important step toward bringing environmental claims with a transboundary element before human rights tribunals'. Also see *Maria L. Banda*, Regime Congruence: Rethinking the Scope of State Responsibility for Transboundary Environmental Harm, 103 (2019) Minnesota Law Review 1879–1690, 1932, arguing that transboundary harm could be covered by the 'direct effects' test developed by human rights tribunals, and that 'interpreting a State's duties under human rights law congruently with its obligations under international environmental law can further the goals of both regimes at their points of intersection' (*ibid.*, 1946).

155 ARSIWA (n. 5), Commentary to Article 11, para. 6; see *Saxler* et al. (n. 98), 118–119.

adopts it as its own. Both of these bases for attribution are subject to high thresholds.

At the same time, the conduct of state organs – consisting of actions or omissions – will mostly be *in relation* to the activities of non-state actors. The act of authorizing a private activity through administrative authorities constitutes attributable conduct, as does a state's failure to take action to prevent hazardous or harmful private activities. However, this does not render the activity *itself* attributable. Hence, it is crucial to clearly distinguish between the actual activity and the conduct of state organs in the realm of that activity. In most cases, only the latter can give rise to the responsibility of the state concerned.

III. Breach of an International Obligation

The second requirement of an internationally wrongful act is that the attributable conduct must constitute a breach of an international obligation. Article 12 ARSIWA provides that:

> *'There is a breach of an international obligation by a State when an act of that State is not in conformity with what is required of it by that obligation, regardless of its origin or character.'*

Hence, state responsibility arises when a relevant international obligation binds the state in question (1.) and when the state's conduct is 'not in conformity' with what is required from it by that obligation (2.). This also entails the question of whether the existence of fault is relevant (3.).

1. International Obligation of Any Origin or Character

The ILC has recognized that international obligations may be established by rules of customary international law, international treaties, and general principles of law which are applicable within the international legal order.[156] This corresponds with Article 38 of the Statute of the ICJ, which is commonly considered to contain an authoritative list of the sources

156 ARSIWA (n. 5), Commentary to Article 12, para. 3.

of international law.[157] In addition, states may also assume international obligations by unilateral acts.[158] In any case, the obligation must be in force for the state at the time when the relevant act occurs.[159]

As set out earlier in this study, the pertinent legal obligations can be distinguished into obligations to prevent adverse transboundary effects of LMOs on the one hand and obligations pertaining to liability and redress for such effects on the other.

Regarding the former type of obligations, it is generally recognized that a state may incur international responsibility for failing to comply with its obligations to prevent the causation of transboundary harm.[160] The pertinent treaty obligations, including from the *Convention on Biological Diversity* and its *Cartagena Protocol on Biosafety*, are assessed in chapter 3. Besides, the obligation to prevent significant transboundary harm, and ensuing procedural duties, is also part of universal customary international law, as discussed in chapter 4. The specific obligations regarding engineered gene drives are addressed in chapter 5.

Besides, a breach of international law may also occur when a state fails to comply with its international obligations to provide for liability and redress in case harm occurs.[161] The principal instrument in the present

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157 Statute of the International Court of Justice (18 April 1946), 33 UNTS 993 (hereinafter 'ICJ Statute'), Article 38(1); cf. *James Crawford*, Brownlie's Principles of Public International Law (9th ed. 2019), 18.

158 ARSIWA (n. 5), Commentary to Article 12, para. 3.

159 *Ibid.*, Article 13.

160 See, e.g., *Lefeber* (n. 105), 60–98; *Crawford* (n. 4), 226–232; *Leslie-Anne Duvic-Paoli*, The Prevention Principle in International Environmental Law (2018), 331–339; ICJ, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) and Construction of a Road in Costa Rica along the San Juan River (Nicaragua v. Costa Rica), Merits Judgment of 16 December 2015, ICJ Rep. 665, Separate Opinion of Judge Donoghue, para. 9; in conventional law, see Convention on the Regulation of Antarctic Mineral Resource Activities (02 June 1988; not in force), 27 ILM 868, Article 8(3)(a), which reads: 'Damage […] which would not have occurred or continued if the Sponsoring State had carried out its obligations under this Convention with respect to its Operator shall, in accordance with international law, entail liability of that Sponsoring State.' Also see UNCLOS (n. 140), Article 139(2), which provides that 'damage caused by the failure of a State Party or international organization to carry out its responsibilities under this Part shall entail liability'. On breaches of preventive obligations, see chapter 4, section E.

161 Institut de Droit International, Responsibility and Liability Under International Law for Environmental Damage: Resolution Adopted on September 4, 1997, 37 ILM 1474, Article 6(2).

context is the *Nagoya – Kuala Lumpur Supplementary Protocol*, which is assessed in chapter 6. Apart from treaty law, states arguably bear a customary obligation to ensure that victims of transboundary damage have access to prompt and adequate compensation as well as non-discriminatory remedies in their domestic legal system, as shown in chapter 8.

2. Conduct in Breach of the Obligation

To determine whether there is a breach of an international obligation, the conduct of the state must be compared with the conduct prescribed by the relevant obligation.[162] Unlike some domestic legal systems, international law does not distinguish between the contractual, tortious or criminal responsibility of states. Moreover, the severity of the breach is not relevant to the question of whether state responsibility arises, although it may affect the legal consequences of state responsibility.[163]

In some cases, the conduct expected from the state is precisely defined, while in others, the obligation only sets a minimum standard above which the state is free to act.[164] As shown earlier, determining breaches of *due diligence* obligations can be particularly difficult, as it requires an inquiry into what knowledge was available to the state at the time when action should have been taken and a determination whether, in light of this knowledge, a state had taken all measures which it could be reasonably expected to take in order to prevent the apprehended event from occurring.[165]

3. No Requirement of Fault

There is no general requirement of *fault* – such as intent or negligence – for state responsibility to arise.[166] Whether such a requirement exists depends solely on the pertinent primary obligation.[167] Where the primary

162 ARSIWA (n. 5), Commentary to Article 12, para. 2; *Crawford* (n. 4), 217.
163 ARSIWA (n. 5), Commentary to Article 12, para. 6; Article 40(2); also see *Giuseppe Palmisano*, Fault, in: Wolfrum/Peters (ed.), MPEPIL, MN. 37–38.
164 ARSIWA (n. 5), Commentary to Article 12, para. 2.
165 See chapter 4, sections C and E; see *Crawford* (n. 4), 226–232.
166 *Borchard* (n. 29), 225; ARSIWA (n. 5), Article 2, para. 10; *Christian J. Tams*, All's Well that Ends Well, 62 (2002) ZaöRV 759, 766; *Crawford* (n. 4), 60–62.
167 Cf. *N.L.J.T. Horbach*, The Confusion About State Responsibility and International Liability, 4 (1991) Leiden J. Int'l L. 47, 51.

obligation does not involve such a requirement, it is only the state's objective conduct that matters for establishing a breach of the obligation.[168] Similarly, there is no distinction between 'objective' and 'subjective' elements of a breach.[169] Arguably, the concept of due diligence encompasses a subjective dimension, as a breach of due diligence always depends on individual circumstances, including the knowledge and capabilities of the state concerned.[170] Hence, due diligence will often be breached by negligent conduct by organs of the state concerned.[171] But the concept of *negligence* is not well established in international law,[172] and any failure of the state to act appropriately would rather be assessed in terms of a breach of due diligence than in terms of fault.

IV. Circumstances Precluding Wrongfulness

Although the responsibility of a state for a breach of international law does not depend on a requirement of fault, the responsibility is still precluded under certain exceptional circumstances. This applies when the affected state has given valid consent (1.), or where the state alleged to have breached its obligations has acted in lawful self-defence (2.) or applied lawful countermeasures (3.), the act occurred as a result of force majeure (4.), distress, or due to a state of necessity (5.). When a state lawfully invokes such a defence, the question arises of whether it has to make reparation for any damage suffered by the act in question (6.). Notably, no defence can be invoked for breaches of peremptory norms (or *ius cogens*), such as the prohibitions of aggression, genocide, and torture.[173]

168 ARSIWA (n. 5), Article 2, para. 10; *Crawford* (n. 4), 61.
169 ARSIWA (n. 5), Commentary to Article 2, para. 3; see *Palmisano* (n. 163), MN. 16–17.
170 Cf. *Borchard* (n. 29), 226, see chapter 4, section C.
171 Cf. *Horbach* (n. 167), 51; *Palmisano* (n. 163), MN. 16.
172 *Neil McDonald*, The Role of Due Diligence in International Law, 68 (2019) ICLQ 1041, 1044 n. 13.
173 ARSIWA (n. 5), Article 26 and commentary thereto, paras. 5–6.

1. Consent

According to Article 20 ARSIWA, the ‘valid consent’ of the affected state precludes the wrongfulness of an act that would otherwise constitute an internationally wrongful act.

The concept of valid consent needs to be distinguished from treaty-based *prior consent* mechanisms such as the Cartagena Protocol’s AIA mechanism, where the prior agreement of the affected state not only precludes the wrongfulness of the conduct in question but renders the conduct (positively) lawful.[174] Moreover, an importing state cannot validly consent to the non-observance of the AIA mechanism, e.g. by agreeing to all imports of LMOs from a particular exporting state.[175] Because Article 14 of the Protocol provides that derogations must not result in a lower level of protection than that provided for by the Protocol, this would constitute an unlawful downward derogation from the Cartagena Protocol.[176] As discussed below, the Cartagena Protocol also does not establish a ‘self-contained regime’ providing its own rules on the consequences of non-compliance.[177]

2. Self-Defence

Article 21 ARSIWA provides that the wrongfulness of certain conduct is precluded if the act constitutes a lawful measure of self-defence taken in conformity with the *Charter of the United Nations*.[178] This relates to Article 51 of the Charter, which provides that every UN Member State has the right to self-defence if it faces an armed attack.[179] While this primarily refers to the prohibition of the use of force enshrined in Article 2(4) of the UN Charter, it may also justify the non-performance of certain other obligations.[180] Hence, it could be questioned whether the intentional release

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174 See *Crawford* (n. 4), 288.

175 *Susanne Förster*, Internationale Haftungsregeln für schädliche Folgewirkungen gentechnisch veränderter Organismen (2007), 210–211.

176 Cf. *ibid.*

177 See *infra* section C.III.3.b).

178 Charter of the United Nations (26 June 1945; effective 21 October 1945), 1 UNTS XVI (hereinafter ‘UN Charter’).

179 See generally *Crawford* (n. 157), 720–725.

180 ARSIWA (n. 5), Commentary to Article 21, para. 2; *Crawford* (n. 4), 290.

and transboundary movement of self-spreading LMOs could be permitted as a lawful measure of self-defence.

However, self-defence does not justify conduct in all cases and with respect to all obligations, especially those arising from international humanitarian law or human rights.[181] As shown earlier, international law prohibits the development and use of biological weapons as well as any military use of techniques of modern biotechnology that cause widespread, long-lasting or severe effects.[182] With regard to treaties relating to the protection of the environment, the ICJ held in its *Nuclear Weapons* advisory opinion that these treaties did not intend to 'deprive a State of the exercise of its right of self-defence under international law'.[183] But the Court also pointed out that respect for the environment was one of the elements to be taken into account when assessing whether military actions adhered to the principles of necessity and proportion.[184] As these obligations specifically concern the conduct of military activities in armed conflict (*ius in bello*), their non-observance cannot be justified by the legitimate exercise of self-defence.[185]

3. Countermeasures

Article 22 ARSIWA provides that the wrongfulness of an act is precluded if and to the extent that it constitutes a countermeasure lawfully taken against another state. Countermeasures are measures that would normally contravene international obligations but are taken in response to the internationally wrongful act of another state to induce the latter to cease the wrongful act and make reparation.[186] To be justifiable, a countermeasure must meet several conditions,[187] including that it is commensurate to the injury suffered, the gravity of the breach and the rights in question.[188]

181 ARSIWA (n. 5), Commentary to Article 21, para. 3.
182 See chapter 3, section J.
183 ICJ, Legality of the Threat or Use of Nuclear Weapons, Advisory Opinion of 08 July 1996, ICJ Rep. 226, para. 30.
184 *Ibid.*
185 Cf. *Crawford* (n. 4), 292.
186 ARSIWA (n. 5), Article 49(1) and commentary to Part Three, chapter II, para. 1; see *infra* section B.III.
187 Cf. ICJ, Military and Paramilitary Activities in and against Nicaragua (n. 73), para. 249; ICJ, Gabčíkovo-Nagymaros (n. 138), para. 83.
188 ARSIWA (n. 5), Article 51.

Moreover, the countermeasure may only be applied as long as the other state acts in violation of international law. As soon as the responsible state has complied with the legal requirements under the law of state responsibility (i.e., cessation, non-repetition, and reparation), the countermeasure must be terminated.[189] Moreover, a countermeasure can only preclude wrongfulness in the relations between the injured state and the state which has committed the internationally wrongful act.[190]

4. Force Majeure

According to Article 23(1) ARSIWA, the wrongfulness of an otherwise wrongful act is precluded if the act is due to *force majeure*, which means an irresistible force or an unforeseen event beyond the control of the state that makes it materially impossible to perform the obligation.[191] Article 23(2) ARSIWA provides that this justification does not apply if the state invoking it caused the situation or has assumed the risk of it occurring.[192] According to the ILC's commentary to this provision, *force majeure* should not excuse performance if the state is legally required to prevent the given situation.[193] This applies to preventive obligations assumed by way of a treaty and under customary international law, such as the general obligation to prevent significant transboundary harm. Since the foreseeability of a certain risk is already taken into account when determining whether a state has breached its due diligence obligation to prevent harm, it cannot also serve as a possible justification once a breach of due diligence has been established.[194]

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189 Cf. *ibid.*, Article 53; see *infra* section B.

190 Cf. *ibid.*, Commentary to Article 22, para. 5; ICJ, Gabčíkovo-Nagymaros (n. 138), para. 48.

191 Also cf. 'force majeure' in: Black's Law Dictionary (n. 19), 788.

192 Cf. ARSIWA (n. 5), Article 23(2).

193 *Ibid.*, Commentary to Article 23, para. 10.

194 See *ibid.* It has been suggested that *force majeure* could be assumed in the context of the nuclear disaster of 2011 at *Fukushima*, where an earthquake and consequent tsunami caused a failure of the plant's cooling system, which resulted in a nuclear meltdown (see *Peel* (n. 88), 56 fn. 23). But as the risk of tsunamis was known beforehand, the disaster was not caused by an unforeseen event but rather by a 'cascade of industrial, regulatory and engineering failures' and could have been prevented if the Japanese government had followed international best practices and standards (see *Costas Synolakis/Utku Kânoğlu*, The Fukushima Accident Was Preventable, 373 (2015) Philos. Trans. R. Soc. A 20140379).

5. Necessity

Article 25 ARSIWA provides that the wrongfulness of an otherwise wrongful act can be precluded by 'necessity', which refers to situations where the only means by which a state can protect an essential interest from a grave and imminent peril is by not complying with an international obligation that protects a less important interest.[195] Unlike *force majeure*, where there is 'no element of free choice',[196] necessity involves a choice by the state to act inconsistently with an international obligation in order to protect another interest.[197] According to Article 25(1) ARSIWA, a plea of necessity is contingent upon four requirements: There must be (1) an 'essential interest' which is (2) threatened by a 'grave and imminent peril', and the act in question must be (3) the 'only way' to safeguard this interest. Moreover, (4) the act must not seriously impair an essential interest of the state(s) towards the obligation is owed.

As to the *first* requirement, the extent to which a certain interest is 'essential' depends on all relevant circumstances.[198] Besides the economic survival of the state and the safety of civilians, one of the interests most frequently invoked by states is the preservation of the environment.[199] In 1980, the ILC suggested that 'safeguarding the ecological balance has come to be considered an "essential interest" of all States'.[200] This was confirmed in 1997 in the case of the *Gabčíkovo-Nagymaros Project*, which concerned the suspension and subsequent abandonment of a joint barrage project in the river *Danube* between Hungary and Czechoslovakia (later Slovakia).[201] In this case, the ICJ ruled that a state's concern for its natural environment can constitute an essential interest within the meaning of what is now codified in Article 25 ARSIWA.[202] This also extends to the protection of

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195 *Sarah Heathcote*, Circumstances Precluding Wrongfulness in the ILC Articles on State Responsibility: Necessity, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 491, 491.

196 ARSIWA (n. 5), Commentary to Article 23, para. 1.

197 *Ibid.*, Commentary to Article 25, para. 2; *Crawford* (n. 4), 307.

198 ARSIWA (n. 5), Commentary to Article 25, para. 15; *Crawford* (n. 4), 308.

199 *Heathcote* (n. 195), 496–497; *Crawford* (n. 4), 308–309; also see the cases discussed in ARSIWA (n. 5), Commentary to Article 25, paras. 6, 9, 11, and 12; and, more recently ICJ, Certain Activities/Construction of a Road (Merits) (n. 160), paras. 158–159.

200 ILC, Report of the Commission to the General Assembly on the Work of Its Thirty-Second Session, YBILC 1980, vol. II(2) (1981), p. 39, para. 14.

201 For the background of the case, see *Sands* et al. (n. 108), 345–347.

202 ICJ, Gabčíkovo-Nagymaros (n. 138), para. 53.

species threatened with extinction.[203] For instance, the *Fisheries Jurisdiction* case of 1998 concerned the seizure of a Spanish fishing ship by Canada, which argued that its conduct was 'necessary' to prevent overfishing of the Greenland halibut.[204] This could also apply to LMO techniques used to control invasive or protect endangered species.

The *second* element of necessity is that the essential interest must be threatened by a 'grave and imminent peril'.[205] The term 'peril' implies that the essential interest must be at risk and has not already perished.[206] In the view of the ILC, the peril has to be objectively established and not merely apprehended as possible.[207] Besides being grave, the peril must also be 'imminent' in the sense of 'proximate'.[208] But in *Gabčíkovo-Nagymaros*, the ICJ held that

> *'a "peril" appearing in the long term might be held to be "imminent" as soon as it is established […] that the realization of that peril, however far off it might be, is not thereby any less certain and inevitable'.*[209]

Hence, the criterion of imminence does not require that the damage occur immediately but that immediate action is required to break the causal chain that would otherwise lead to damage to the interest in question.[210] At the same time, the peril must be 'objectively established and not merely apprehended as possible'.[211] This could be interpreted as excluding situations in which the risk cannot be established without doubt due to scientific uncertainties.[212] But the ILC stated in its commentary that a degree of uncertainty about the future does not necessarily disqualify a state from invoking necessity if the peril is 'clearly established on the basis of the evidence reasonably available at the time'.[213] Hence, it does not seem to be

203 Cf. *Crawford* (n. 4), 308–309.
204 ICJ, Fisheries Jurisdiction (Spain v. Canada), Jurisdiction of the Court, Judgment of 04 December 1998, ICJ Rep. 432, para. 20; cf. ARSIWA (n. 5), Commentary to Article 25, para. 12.
205 *Ibid.*, Article 25(1)(a).
206 *Heathcote* (n. 195), 497; ARSIWA (n. 5), Commentary to Article 25, para. 16; see ICJ, Gabčíkovo-Nagymaros (n. 138), para. 54.
207 ARSIWA (n. 5), Article 25, para. 15.
208 *Ibid.*, Commentary to Article 25, para. 15.
209 ICJ, Gabčíkovo-Nagymaros (n. 138), para. 54.
210 Cf. *Heathcote* (n. 195), 497.
211 ICJ, Gabčíkovo-Nagymaros (n. 138), para. 54; ARSIWA (n. 5), Commentary to Article 25, para. 15.
212 Cf. *Heathcote* (n. 195), 497.
213 ARSIWA (n. 5), Commentary to Article 25, para. 16.

generally impossible to rely on the precautionary principle when invoking necessity,[214] although the ICJ's jurisprudence indicates that the judicial scrutiny in such a case would be more rigid than in other situations.[215]

The *third* element of necessity requires that the course of action implemented by the state is the 'only way' to safeguard the interest at stake.[216] The plea of necessity is excluded whenever there are other (otherwise lawful) means available, even if they are more costly or less convenient or require cooperation with other states.[217] The question of available alternative means could be particularly controversial in the context of self-spreading LMOs, especially when their deployment is proposed as a more efficient way to address an issue for which conventional means already exist. Moreover, any conduct going beyond what is strictly necessary for safeguarding the threatened interest is not covered by the plea of necessity.[218]

The *fourth* condition for a plea of necessity is that the act in question must not seriously impair an essential interest of the state(s) towards which the obligation exists or the international community as a whole.[219] This implies that the interest sought to be safeguarded must, from an objective point of view, outweigh all other interests of the state(s) affected by the measure.[220]

While the conditions for necessity discussed until now require a balancing of interests, there are two exceptions in which necessity may in no case be invoked. According to Article 25(2)(a) ARSIWA, the justification cannot be invoked when the international obligation in question excludes the possibility of invoking necessity. Such an exclusion can be made explicitly or implicitly, either because the primary norm leaves no room for the invoking necessity or because it provides a *lex specialis* rule on derogation in abnormal situations like most human rights instruments do.[221]

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214 *Heathcote* (n. 195), 497–498; *Crawford* (n. 4), 311; on the precautionary principle in general, see chapter 4, section B.VI.
215 Cf. ICJ, Gabčíkovo-Nagymaros (n. 138), para. 54; ICJ, Certain Activities/Construction of a Road (Merits) (n. 160), paras. 158–159.
216 ARSIWA (n. 5), Article 25(1)(a).
217 *Ibid.*, Commentary to Article 25, para. 15; *Crawford* (n. 4), 311; see ICJ, Gabčíkovo-Nagymaros (n. 138), para. 55; ICJ, Construction of a Wall (n. 91), para. 142.
218 ARSIWA (n. 5), Commentary to Article 25, para. 15.
219 *Ibid.*, Article 25(1)(b).
220 *Ibid.*, Commentary to Article 25, para. 17; *Heathcote* (n. 195), 498.
221 *Heathcote* (n. 195), 498; see ARSIWA (n. 5), Commentary to Article 25, para. 19; ICJ, Construction of a Wall (n. 91), paras. 136–137.

Moreover, Article 25(2)(b) ARSIWA provides that necessity may not be relied upon if the responsible state has contributed to the situation of necessity. According to the ILC's commentary, such a contribution must be 'sufficiently substantial and not merely incidental or peripheral'.[222] In the *Gabčíkovo-Nagymaros* case, the ICJ held that even if Hungary had been able to establish a state of necessity (which it was not), it could not have relied on necessity as a justification since it had contributed to the situation which now threatened its interests.[223] Similar scenarios are conceivable in the context of the present study. If, for example, a state has approved the release of a gene drive that spreads uncontrollably across borders, it may be barred from invoking necessity for releasing a second gene drive in an attempt to 'reverse' the former. But against this background, it is questionable whether it is reasonable to generally exclude the plea of necessity because it runs the risk of producing 'absurd results' by barring action that could help mitigate the situation.[224]

6. Reparation in the Event of a Circumstance Precluding Wrongfulness

Article 27(b) ARSIWA provides that the invocation of a circumstance precluding wrongfulness shall be without prejudice to 'the question of compensation for any material loss caused by the act in question'. The term 'material loss' is narrower than the concept of damage applied elsewhere in the ARSIWA[225] and seems to exclude moral damage.[226] Moreover, the ILC's commentary notes that 'compensation' is not limited to monetary compensation in the sense of the ARSIWA's framework for reparation.[227] The commentary also emphasizes that Article 27(b) ARSIWA 'is a proper condition, in certain cases, for allowing a State to rely on a circumstance precluding wrongfulness'.[228] This suggests that there is indeed a legal obli-

222 ARSIWA (n. 5), Commentary to Article 25, para. 20.
223 ICJ, Gabčíkovo-Nagymaros (n. 138), para. 57.
224 Cf. *Heathcote* (n. 195), 499.
225 ARSIWA (n. 5), Commentary to Article 27, para. 4.
226 *Crawford* (n. 4), 318.
227 ARSIWA (n. 5), Commentary to Article 27, para. 4; see *Crawford* (n. 4), 318 and *infra* section B.II.
228 ARSIWA (n. 5), Commentary to Article 257, para. 5; also see ICJ, Gabčíkovo-Nagymaros (n. 138), para. 48, noting that Hungary had expressly acknowledged that its invocation of a state of necessity would not exempt it from its duty to compensate its partner.

gation to make reparation for damage suffered from an act the wrongfulness of which is precluded – a finding which is not self-evident considering that, under the law of state responsibility, the obligation to make reparation follows from the wrongfulness of the act.[229] However, the ARSIWA do neither specify the legal grounds for such compensation nor in which cases compensation is required.[230]

With regard to the legal basis of an obligation to make reparation for damage caused by acts of which the wrongfulness is precluded, two possible approaches have been discussed. The first approach is to assume the existence of responsibility without any wrongful act, which has been discussed intermittently by the ILC as 'liability for lawful acts'.[231] However, as shown below, there is no (strict) liability of states for harm caused by activities not prohibited by international law.[232] Another approach is to apply the normal rules on reparation contained in the ARSIWA.[233] According to this view, reparation in these cases falls within the scope of the secondary rules of responsibility because it concerns situations where state responsibility arises *prima facie* and is excluded only subsequently due to a circumstance precluding the wrongfulness.[234] This appears to be in line with the ICJ's position in *Gabčíkovo-Nagymaros,* where the court assumed that the existence of a circumstance precluding wrongfulness did not mean that a state had acted in accordance with its obligations or that these obligations had ceased to be binding upon it.[235] As indicated by Article 27(b) ARSIWA, the regime on circumstances precluding wrongfulness is premised on the understanding that a preclusion of wrongfulness does not release the state from its obligation to make reparation. In any event, whether this obligation is seen as a substitute for the primary obligation that cannot be met, or attached as a legal consequence to the preclusion of wrongfulness,[236] appears to be a rather theoretical question.

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229 Cf. *Mathias Forteau*, Reparation in the Event of a Circumstance Precluding Wrongfulness, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 887, 888–889.
230 Cf. ARSIWA (n. 5), para. 5; *Forteau* (n. 229), 888.
231 Cf. *S. P. Jagota*, State Responsibility: Circumstances Precluding Wrongfulness, 16 (1985) NYL 249, 274; *Horbach* (n. 167), 59; *Forteau* (n. 229), 890.
232 See chapter 10.
233 *Forteau* (n. 229), 890–891.
234 *James Crawford*, Second Report on State Responsibility, UN Doc. A/CN. 4/498 (1999), para. 341.
235 ICJ, Gabčíkovo-Nagymaros (n. 138), para. 48.
236 Cf. the discussion by *Forteau* (n. 229), 891–892.

A more relevant question relates to which categories of circumstances precluding wrongfulness give rise to an obligation to make reparation. In the case of *necessity*, which leaves the acting state a choice (in theory at least) as to whether to act inconsistently with its international obligation, the duty to compensate is widely recognized.[237] Conversely, reparation is not owed for lawful *countermeasures* or *self-defence*, because those circumstances depend on a prior wrongful conduct of the 'target' state.[238] *Consent* by the affected state(s) equates to a waiver of the respective right and thus can be made contingent upon an agreement on any question of compensation that may arise.

However, it is doubtful whether reparation is due in cases of *force majeure*, since the state relying on this justification has, by definition, not contributed to the situation and therefore is 'no more responsible for any material loss than the state suffering it'.[239] Situations of self-defence and countermeasures when the victim is a third party raise similar issues. However, since the acting state is still the ultimate perpetrator of the injury, it appears justifiable to assume that it shall bear the consequences of its conduct suffered by other states.[240] In any event, the commentary to Article 27 ARSIWA indicates that it would be for the state invoking a circumstance precluding wrongfulness to agree with any affected states on the possibility and extent of compensation payable in a given case.[241]

B. Legal Consequences of International Responsibility

The previous section has shown that the international responsibility of a state arises for conduct that is attributable to the state and that is not in conformity with its international obligations, provided that no valid defence can be invoked. Once a state's international responsibility is established under these conditions, the question about the content of that responsibility arises.

It is generally assumed that a breach of a 'primary' obligation of international law leads to the emergence of 'secondary' obligations, which denote

237 Cf. *Crawford* (n. 4), 318–319; *Forteau* (n. 229), 892; ICJ, Gabčíkovo-Nagymaros (n. 138), para. 48.
238 *Crawford* (n. 4), 319.
239 *Ibid.*
240 Cf. *Forteau* (n. 229), 893.
241 *Crawford* (n. 4), Commentary to Article 27, para. 6.

the legal consequences of breaches of primary obligations.[242] In particular, the responsible state is under an obligation to cease the wrongful conduct and to offer appropriate assurances and guarantees of non-repetitions, where appropriate (I.), and obliged to make full reparation for any caused by the internationally wrongful act (II.). Moreover, state responsibility offers the injured state the right to take countermeasures (III.).

I. Obligations of Cessation and Non-Repetition

Article 29 ARSIWA stipulates that the occurrence of a breach does not relieve the responsible state from its continuing duty to perform the obligation breached. This is mirrored by Article 60 of the *Vienna Convention on the Law of Treaties* (VCLT),[243] which provides that a material breach of a treaty does not void the treaty, but rather entitles the injured state(s) to suspend or terminate the treaty.[244]

As a corollary of the continued duty of performance, Article 30(a) ARSIWA provides that the responsible state is required to cease that act if it is continuing.[245] In the context of the present study, this means that whenever an activity that causes transboundary harm (such as an ongoing unlawful release of LMOs) is attributable to a state,[246] the state is required to immediately terminate that activity.[247] However, in situations where the harmful activity is not directly attributable to the state, the legal consequences may be more difficult to identify. In these situations, the breach consists of the state's failure to adequately regulate and control the hazardous activity in question. Hence, the state cannot terminate the activity itself but must require the private operator to do so. However, that private actor may possess a valid authorization for his activity, which cannot be

242 ARSIWA (n. 5), General commentary, para. 1; *Tams* (n. 166), 764.
243 Vienna Convention on the Law of Treaties (23 May 1969; effective 27 January 1980), 1155 UNTS 331 (hereinafter 'VCLT').
244 Cf. ARSIWA (n. 5), Article 29, para. 3.
245 Cf. ICJ, Construction of a Wall (n. 91), paras. 150–151; ICJ, Jurisdictional Immunities of the State (Germany v. Italy: Greece intervening), Judgment of 03 February 2012, ICJ Rep. 99, para. 137. On the (rather academic) question of the distinction between cessation and the continued duty of performance, see *Crawford* (n. 4), 464–465.
246 See *supra* section A.II.
247 *Lefeber* (n. 105), 129.

repealed without taking due account of the actor's legal rights.[248] In these instances, it may be justified to allow the responsible state a reasonable amount of time to arrange for the relevant activity to be terminated or modified.[249] However, such a 'grace period' is without prejudice to the obligation of the responsible state to make reparation for any harm caused during this transitional period.[250] Moreover, although injured states have sometimes offered to share the financial burden of modifying or terminating a harmful activity with the source state, there is no legal obligation to do so.[251]

According to Article 30(b) ARSIWA, the responsible state must offer 'appropriate assurances and guarantees of non-repetition, if circumstances so require'. Assurances and guarantees of non-repetition are commonly sought when the injured state has reasons to believe that merely returning to the pre-existing situation by cessation and reparation of the injury does not satisfactorily protect it from future infringements.[252] They may be required, for example, when there are indications that deliberate unlawful releases of LMOs by the responsible state or actors under its jurisdiction are likely to occur again in the future.

II. Obligation to Make Full Reparation

The most important and far-reaching consequence of state responsibility is the responsible state's obligation to make reparation for the injury caused by the wrongful act. The most prominent statement of this principle was made in 1927 by the *Permanent Court of International Justice* (PCIJ) in the *Chorzów Factory* case, where the Court held that it was 'a principle of international law that the breach of an engagement involves an obligation to make reparation in an adequate form'.[253] Addressing the content of this obligation, the PCIJ held in a subsequent judgment on the same dispute that

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248 *Ibid.*, 130; cf. Trail Smelter Case (United States v. Canada), Decision of 11 March 1941, III RIAA 1938, 1966.
249 *Lefeber* (n. 105), 130.
250 *Ibid.*; see *infra* section B.II.
251 *Lefeber* (n. 105), 130–132.
252 ARSIWA (n. 5), Commentary to Article 30, para. 9; see *Crawford* (n. 4), 469–479.
253 PCIJ, Factory at Chorzów (Germany v. Poland), Judgment on Jurisdiction of 26 July 1927, PCIJ Rep. Ser. A, No. 9, 21.

> *'reparation must, as far as possible, wipe out all the consequences of the illegal act and reestablish the situation which would, in all probability, have existed if that act had not been committed'.*[254]

This definition emphasizes two core principles of reparation, namely that of 'full reparation', which provides that all consequences of the unlawful act shall be wiped out, and the principle that reparation shall aim at re-establishing the *status quo ante*. The customary status of this obligation has been confirmed in international case law on numerous occasions.[255]

The ILC's Articles on State Responsibility provide that the state responsible for an internationally wrongful act is under an obligation to make 'full reparation for the injury caused by the internally wrongful act'.[256] Reparation includes both material and moral damage (1.), provided that there is a causal link between the wrongful conduct and the injury (2.). Depending on the circumstances, full reparation shall take the form of reparation, compensation, satisfaction, or a combination of these forms (3.). However, the obligation to make reparation may be reduced in situations where the injured state has contributed to the injury or failed to mitigate damage after it occurred (4.).

1. Recoverable Injury

Article 31(2) ARSIWA provides that the notion of injury for which full reparation shall be made 'includes any damage, whether material or moral, caused by the internationally wrongful act of a State'. In its commentary, the ILC explained that this formulation was to be understood 'both as inclusive, covering both material and moral damage broadly understood, and limitative, excluding merely abstract concerns or general interests of a State which is individually unaffected by the breach'.[257]

254 PCIJ, Factory at Chorzów (Germany v. Poland), Merits Judgment of 13 September 1928, PCJI Rep. Ser. A, No. 17, 47.

255 See, e.g., ICJ, Bosnian Genocide (n. 8), para. 460; ICJ, Construction of a Wall (n. 91), para. 152; ICJ, Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo), Merits Judgment of 30 November 2010, ICJ Rep. 639, para. 161; ICJ, United States Diplomatic and Consular Staff in Tehran (n. 137); for further references, see *Crawford* (n. 4), 481.

256 ARSIWA (n. 5), Article 31(1).

257 *Ibid.*, Commentary to Article 31, para. 5.

The notion of 'material' damage refers to damage to property or other interests which is assessable in financial terms. In contrast, 'moral' damage embodies two distinct concepts: On the one hand, it refers to moral damage *to individuals*, which includes things such as individual pain and suffering, loss of loved ones or intrusion in one's home or private life.[258] Like material damage, moral damage suffered by individuals is often repaired by the payment of monetary compensation.[259] On the other hand, moral damage *to a state* is the 'non-material injury' caused by a violation of rights of that state, such as its territorial integrity.[260] In some cases, this may also include the 'legal injury' arising from the mere fact that an international obligation has been breached.[261]

2. Causation

In order to be subject to reparation, damage must be 'caused' by the wrongful act, which means that there must be a causal link between the wrongful conduct and the injury.[262] For the causal link to be properly established, the wrongful act must be a necessary condition (or *conditio sine qua non*) of the harm, without which the harm would not have occurred.[263]

However, the sole reliance on a factual link can lead to liability being too wide.[264] For this reason, it is generally accepted that factual causality is a necessary but insufficient condition for reparation.[265] In addition, there must be a degree of proximity between the wrongful act and the injury.[266] According to the ICJ's settled case law, establishing a causal link requires to determine

> *'whether there is a sufficiently direct and certain causal nexus between the wrongful act […] and the injury suffered by the Applicant'.*[267]

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258 *Ibid.*, Commentary to Article 31, para. 5.
259 See *infra* section B.II.3.b)aa).
260 ARSIWA (n. 5), Commentary to Article 37, para. 3–4.
261 See *Crawford* (n. 4), 487–491.
262 ARSIWA (n. 5), Article 31(2) and commentary thereto, para. 9.
263 *Lefeber* (n. 105), 89.
264 *Ibid.*, 92.
265 ARSIWA (n. 5), Commentary to Article 31, para. 10, see *Crawford* (n. 4), 492.
266 *Lefeber* (n. 105), 92.
267 Cf. ICJ, Bosnian Genocide (n. 8), para. 462; ICJ, Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo), Judgment on Compensa-

In the view of the ILC, the establishment of a causal link requires that the injury is not 'too remote' or 'consequential' from the wrongful act.[268] In other words, the wrongful act must be a 'proximate cause' of the resulting injury.[269] However, the ILC noted that there is no 'single verbal formula' to describe the link which must exist between the wrongful act and the injury.[270] Instead, the ILC held that several factors could be relevant, including the foreseeability or proximity of the damage and whether the harm caused was 'within the ambit of the rule which was breached',[271] i.e. whether the purpose of the rule was to avoid the harm that occurred. Moreover, there must be no supervening acts that broke the chain of causation.[272] On the other hand, it has been argued that the chain of causation shall not be considered interrupted by lawful intervening measures if these measures are reasonable in light of the circumstances of the case.[273]

After all, the acceptable length of a causal chain can only be determined on a case-by-case basis.[274] Yet, special questions arise about the causation of environmental damage (a)). Moreover, there is a general requirement that the harm must be within the ambit of the rules breached (b)). The attribution of responsibility may also entail difficulties when concurrent causes or multiple actors contributed to the damage (c)).

a) Proof of Causality for Environmental Damage

Proving a causal link may be prone to particular difficulties in cases of environmental damage, especially when LMOs are involved.[275] These diffi-

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tion of 19 June 2012, ICJ Rep. 324, para. 14; ICJ, Certain Activities Carried out by Nicaragua in the Border Area (Costa Rica v. Nicaragua), Compensation Owed by Nicaragua to Costa Rica, Judgment of 02 February 2018, ICJ Rep. 15, para. 32.

268 ARSIWA (n. 5), Commentary to Article 31, para. 10.

269 *Lefeber* (n. 105), 92; *Bergkamp* (n. 23), 285–286.

270 ARSIWA (n. 5), Commentary to Article 31, para. 10.

271 *Ibid.*

272 UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning Part One of the Fourth Instalment of "F4" Claims, UN Doc. S/AC.26/2004/16 (2004), para. 48; similarly UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the Fifth Instalment of "F4" Claims, UN Doc. S/AC.26/2005/10 (2005), para. 56.

273 *Lefeber* (n. 105), 97–98; see chapter 11, section A.II.1.

274 *Lefeber* (n. 105), 98.

275 Cf. *ibid.*, 32–33.

culties may result, for instance, from the fact that there is no scientific evidence that a certain activity or LMO is in fact capable of causing the damage in question[276] or when the damage cannot be attributed to one of several possible causes.[277] Lapse of time may also be a factor causing difficulties in establishing causation, as the adverse effects of an LMO may appear only months or even years after being released.[278] For these reasons, it is questionable whether the criteria for proving causation should be modified in cases involving damage to the environment.

In legal scholarship, some authors have proposed to lower the evidentiary threshold for the proof of causation for environmental damage.[279] In its resolution on liability for environmental damage of 1997, the *Institut de Droit International* proposed to establish 'presumptions of causality' in relation to hazardous activities and cumulative or long-standing damages that are not attributable to a single entity but a certain sector or type of activity.[280] However, such presumptions of causality appear not yet to be established in international case law. With regard to Article 139(2) UNCLOS,[281] which provides for liability of states sponsoring mining activities in the international seabed area, the *Seabed Disputes Chamber* of the *International Tribunal for the Law of the Sea* held that liability requires a causal link between the sponsoring state's failure to adequately regulate

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276 Cf. ICJ, Certain Activities (Compensation) (n. 267), para. 34.

277 Cf. *Ruth Mackenzie*, Environmental Damage and Genetically Modified Organisms, in: Michael Bowman/Alan E. Boyle (eds.), Environmental Damage in International and Comparative Law (2002) 63, 71; *Förster* (n. 175), 274–275; *Gurdial S. Nijar* et al., Liability & Redress Under the Cartagena Protocol on Biosafety (2008), 144–145; *Odile J. Lim Tung*, Genetically Modified Organisms and Transboundary Damage, 38 (2013) SAYIL 67, 81–82; *Daniela M. Schmitt*, Staatenverantwortlichkeit für Schäden an der biologischen Vielfalt (2018), 399.

278 Cf. *Reynaldo A. Alvarez-Morales*, A Scientific Perspective on the Supplementary Protocol, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 105, 107.

279 Cf. generally *Bergkamp* (n. 23), 287–291 with further references. In the context of transboundary air pollution, see *Phoebe N. Okowa*, State Responsibility for Transboundary Air Pollution in International Law (2000), 187; on climate change, see *Roda Verheyen*, Climate Change Damage and International Law (2005), 257–263; with respect to damage resulting from LMOs, see *Förster* (n. 175), 275–280; on damage to biodiversity, see *Schmitt* (n. 277), 403.

280 IDI, Resolution on Responsibility and Liability for Environmental Damage (n. 161), Article 7.

281 Article 139(2) UNCLOS provides, *inter alia*, that 'damage caused by the failure of a State Party or international organization to carry out its responsibilities under this Part shall entail liability'.

the activity and the occurrence of damage, and that such a link cannot be presumed.[282] Similarly, in the *Pulp Mills* case, the ICJ required 'clear evidence' to establish a link between the damage and its alleged cause.[283] In the view of the ICJ, the risk of environmental harm did not lead to a lowered standard of proof for the establishment of a causal link.[284]

The *Pulp Mills* case also shows that the problems involved in establishing causation cannot be overcome by relying on the precautionary principle. As shown above, the precautionary principle provides that lack of full scientific certainty shall not be used as a reason not to take action to avoid serious or irreversible damage to the environment.[285] While the precautionary principle mandates preventive action in situations of scientific uncertainty about the cause-and-effect relationship, it cannot be relied upon to establish liability for harm that has already occurred.[286] Thus, although non-observance of the precautionary principle might give rise to international responsibility, it cannot be relied upon to overcome evidentiary issues in establishing that damage has been caused by a particular conduct. This was also confirmed by the ICJ, which concluded that the precautionary principle does not operate as a reversal of the burden of proof in situations where the claimant state is unable to bring scientific proof of the damage and its cause.[287]

A closely related issue concerns the foreseeability of the damage. According to an older doctrine in scholarship and international case law, the establishment of a causal link requires that the source state foresaw – or could have foreseen – the occurrence and extent of harm at the time when it engaged in the relevant unlawful conduct.[288] Consequently, liability

282 ITLOS, Responsibilities and Obligations of States (n. 141), paras. 182–184. See *Vöneky/Höfelmeier*, Article 139 UNCLOS (n. 141), MN. 15.

283 ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment of 20 April 2010, ICJ Rep. 14, para. 257.

284 *Daniel Kazhdan*, Precautionary Pulp: Pulp Mills and the Evolving Dispute Between International Tribunals over the Reach of the Precautionary Principle, 38 (2011) ELQ 527, 546.

285 Rio Declaration on Environment and Development (14 June 1992), UN Doc. A/CONF.151/26/Rev.1 (Vol. I), Principle 15; see chapter 4, section B.VI.

286 *Lefeber* (n. 105), 91.

287 ICJ, Pulp Mills (n. 283), para. 164.

288 Cf. *Gaetano Arangio-Ruiz*, Second Report on State Responsibility, YBILC 1989 Vol. II Pt. 1, 1, paras. 38–40; *Bergkamp* (n. 23), 292–294; in international case law, see e.g., Lighthouses Arbitration between France and Greece, Claims 19 and 21, 23 ILR 353, 353; Samoan Claims (Germany, Great Britain, United States), Decision Given by Oscar II, King of Sweden and Norway of 14 October

would be limited to the extent that harm was objectively foreseeable.[289] However, all cases in which the element of foreseeability was relied upon occurred at a time when fault was still considered a necessary element of an internationally wrongful act.[290] Today, the aspect of foreseeability is incorporated in the obligation to exercise *due diligence* to avoid transboundary damage, and the foreseeability and extent of harm are elements in establishing a violation of this obligation.[291] In this vein, the precautionary principle might require action even when damage is not objectively foreseeable. However, the foreseeability of harm no longer affects the establishment of a causal link.[292]

In its judgment on compensation in the *Certain Activities* case between Costa Rica and Nicaragua, the ICJ expressly recognized that '[i]n cases of alleged environmental damage, particular issues may arise with respect to the existence of damage and causation'.[293] In the Court's view, these issues may result from the damage being caused by several concurrent causes or scientific uncertainties about the alleged cause-and-effect relationship.[294] However, the Court refused to formulate general principles on how these challenges shall be dealt with. Instead, it held that they 'must be addressed as and when they arise in light of the facts of the case at hand and the evidence presented to the Court'.[295] In the view of the Court, problems in establishing a causal link in cases of environmental damage should be taken into account in the judicial appreciation of the facts:

> *'Ultimately, it is for the Court to decide whether there is a sufficient causal nexus between the wrongful act and the injury suffered.'*[296]

1902, IX RIAA 15, 26; Anglo-Italian Conciliation Commission, Currie Case – Decision No. 21, 13 March 1954, XIV RIAA 19, 24; see *Lefeber* (n. 105), 95–96.

289 Cf. Naulilaa Arbitration (Portugal v. Germany), Responsabilité de l'Allemagne à raison des dommages causés dans les colonies portugaises du sud de l'Afrique (sentence sur le principe de la responsabilité) of 31 July 1928, II RIAA 1011, 1031; see *Johan G. Lammers*, Pollution of International Watercourses (1984), 602 (providing a translation of the relevant passages).

290 *Lefeber* (n. 105), 96. Note that foreseeability is still named as a possible criterion in ARSIWA (n. 5), Article 31, para. 10.

291 *Lefeber* (n. 105), 96; see *supra* section A.III.3, and chapter 4, sections B.IV. and B.VI.

292 *Ibid.*

293 ICJ, Certain Activities (Compensation) (n. 267), para. 34.

294 *Ibid.*

295 *Ibid.*

296 *Ibid.*

In sum, the requirements for proving a causal link between an internationally wrongful act and the occurrence of environmental damage are not different to those that apply to other types of damage. Under current international law, a mere probable cause is not a sufficient basis to require a responsible state to make reparation. Lowering the evidentiary threshold for establishing causal links in cases of environmental damage remains a proposal that is yet to be adopted by international legal practice.[297] However, the recent case law of the ICJ suggests that evidentiary problems should be duly considered by the judges when determining whether there is a sufficient causal link between the wrongful act and the damage.

b) Harm Within the Ambit of the Rule Breached

According to the ILC, another factor for determining whether a sufficient causal link exists between the breach of an international obligation and the occurrence of harm is whether the harm caused was 'within the ambit of the rule which was breached, having regard to the purpose of that rule'.[298] In other words, the purpose of the obligation breached must – at least indirectly – cover the avoidance of the type of harm in question.

In the context of the present study, this means that a breach of an obligation that serves to protect biological diversity – namely, the CBD and the Cartagena Protocol – does not necessarily entail the responsibility to make reparation for damage that is not related to biodiversity, such as property damage or economic losses, unless it is a direct consequence of damage to biodiversity caused by the wrongful act. This appears to be in line with the general rule that the establishment of causation not only requires a factual link, but also that the breach is a 'proximate cause' for the damage sustained.[299]

c) Concurrent Causes of Damage and 'Shared Responsibility'

Another issue relating to causation concerns cases in which damage is caused by a combination of two or more factors referred to as 'concurrent'

297 See chapter 6, section C.III.
298 ARSIWA (n. 5), Commentary to Article 31, para. 10.
299 See *supra* section B.II.2.

or 'concomitant' causes of damage.[300] There may also be cases in which damage is not caused by a single actor, but where multiple actors contribute to a single harmful outcome. In legal scholarship, this problem is discussed as cases of 'shared responsibility'.[301]

Scenarios of shared responsibility can be broadly divided into two categories: 'Horizontal' shared responsibility denotes situations in which a plurality of states are jointly responsible for the same instance of harm.[302] The second category, which is called 'vertical' shared responsibility, refers to situations in which not only states but also private actors or international organizations contributed to the damage.[303] In all of these situations, it is questionable whether – and to what extent – an individual state can be held liable.

According to the ILC's commentary to the ARSIWA, unless some part of the injury can be distinguished as not being caused by the responsible state, the latter shall be held responsible for all the consequences of its wrongful conduct, provided they are not 'too remote'.[304] The environmental panel of the *United Nations Compensation Commission* (UNCC)[305] did not follow this approach but awarded partial compensation where the evidence allowed it to determine the portion of the damage directly caused by Iraq's actions.[306] Where the data submitted by the claimants did not allow to determine the proportion of the loss attributable to Iraq, the

300 *Philippe Gautier*, Environmental Damage and the United Nations Claims Commission: New Directions for Future International Environmental Cases?, in: Tafsir M. Ndiaye/Rüdiger Wolfrum (eds.), Law of the Sea, Environmental Law, and Settlement of Disputes (2010) 177, 196.

301 *André Nollkaemper/Dov Jacobs*, Shared Responsibility in International Law: A Conceptual Framework, 34 (2013) Mich. J. Int'l L. 359.

302 *Ilias Plakokefalos*, Liability for Transboundary Harm, in: André Nollkaemper/Ilias Plakokefalos et al. (eds.), The Practice of Shared Responsibility in International Law (2017) 1051, 1052.

303 *Ibid.*, 1053.

304 ARSIWA (n. 5), Commentary to Article 31, para. 13.

305 The United Nations Compensation was established by the United Nations Security Council to implement the liability of Iraq for its unlawful invasion and occupation of Kuwait in 1990 and 1991. The environmental panel was a dedicated panel of commissioners tasked with assessing claims for compensation for damage to the environment. For details, see chapter 11, section B.I.3.

306 UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the Third Instalment of "F4" Claims, UN Doc. S/AC.26/2003/31 (2003), para. 39.

claims were rejected.[307] Nevertheless, the UNCC granted compensation when Iraq's actions were the 'predominant cause' of the damage.[308]

It appears that there has never been a case in which a shared responsibility of multiple states was invoked before an international court or tribunal. Such a claim would raise not only difficult legal and evidentiary questions but also jurisdictional problems if not all states involved can be brought before a single international adjudicator.[309] In any event, shared claims against states and private actors are likely to be brought in different fora.[310]

3. Forms of Reparation

In the *Chorzów Factory* case mentioned before, the PCIJ specified the content of the obligation to make reparation for an internationally wrongful act. It stated that

> *'reparation must, as far as possible, wipe out all the consequences of the illegal act and reestablish the situation which would, in all probability, have existed if that act had not been committed'.*[311]

In order to achieve full reparation, international law has come to distinguish three forms of reparation, namely restitution (a)), compensation (b)), and satisfaction (c)).[312] Depending on the type and extent of the injury, wiping out the consequences of a wrongful act may require some or all forms of reparation.[313]

a) Restitution

The primary form of reparation is *restitution*, which denotes the re-establishment of the situation that existed before the wrongful act was commit-

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307 UNCC Panel Report F4/4.1 (2004) (n. 272), para. 40. Cf., e.g., UNCC Panel Report F4/5 (2005) (n. 272), para. 322, where the panel rejected a claim for salinization of groundwater due to insufficient evidence of causation.

308 *Ibid.*, para. 629; see *Gautier* (n. 300), 197–198.

309 *Peel* (n. 88), 62.

310 See *André Nollkaemper*, Procedural Aspects of Shared Responsibility in International Adjudication, 4 (2013) Journal of International Dispute Settlement 277.

311 PCIJ, Factory at Chorzów (Germany v. Poland) (n. 254), 47.

312 See ARSIWA (n. 5), Article 34–37; *Crawford* (n. 4), 507–508.

313 ARSIWA (n. 5), Commentary to Article 34, para. 2.

ted.[314] This encompasses any action that needs to be taken by the responsible state in order to restore the situation resulting from its internationally wrongful act.[315] Usually, restoration takes place either in the form of *legal restitution*, e.g. by revoking an LMO release permit granted in violation of international law, or in the form of *material restitution*, such as the restitution of property[316] or clean-up and restoration measures taken in response to environmental harm.[317]

aa) Objective of Restitution

An important conceptual question is whether restitution is aimed at restoring the situation that existed before the wrongful act was committed (i.e. the *status quo ante*[318]) or at establishing the situation that would have, had the wrongful act not been committed, most probably existed at the time when restitution is served.

The latter approach, which was followed by the PCIJ in *Chorzów Factory*,[319] appears to indemnify the victim more comprehensively.[320] However, this approach is also more complex as it requires a hypothetical inquiry into what the situation would likely be if the wrongful act had not been committed.[321] For this reason, the ILC adopted the former, narrower concept.[322] In the view of the ILC, any remaining injury, such as loss of the use of goods wrongfully detained, shall be repaired by compensation.[323]

In the *Certain Activities* case, the ICJ partly refused claims for environmental damage because the affected area had already been revegetated at the time of the verdict.[324] At the same time, it awarded compensation for the impairment of environmental services until they had recovered.[325]

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314 *Ibid.*, Article 35.
315 *Ibid.*, Commentary to Article 35, para. 5.
316 See ICJ, Temple of Preah Vihear (Cambodia v. Thailand), Merits Judgment of 16 June 1962, ICJ Rep. 6.
317 Cf. *Lefeber* (n. 105), 133.
318 See ‘Status quo ante’, in: *Fellmeth/Horwitz* (n. 38), 267.
319 PCIJ, Factory at Chorzów (Germany v. Poland) (n. 254), 47; also see *Lefeber* (n. 105), 132–133.
320 Cf. *ibid.*, 132–133.
321 ARSIWA (n. 5), Commentary to Article 35, para. 2.
322 *Ibid.*
323 *Ibid.*; cf. *Crawford* (n. 4), 510–511.
324 ICJ, Certain Activities (Compensation) (n. 267), para. 74.
325 *Ibid.*, para. 78; see chapter 11, section B.III.

bb) Restitution Not Materially Impossible

Restitution is not required when it is 'materially impossible'.[326] According to the ILC, this encompasses situations where the property to be restored has been permanently lost or destroyed.[327]

In the context of environmental damage, restitution may be impossible when there is no way to restore the affected environmental components, such as in the case of an extinct species or the irreparable destruction of an ecosystem.[328] Moreover, the injury suffered between the commission of the wrongful act and the full recovery of the affected environment, namely the impairment or loss of the ability of the environment to provide goods and services in the meantime,[329] is usually not recoverable by restitution. Restitution may also be impossible when there have been other changes to the affected environment, such as changes in ownership or deforestation.[330]

Furthermore, restitution is impossible when the adverse environmental effects occur within the territory of the injured state. In such a situation, the responsible state will not be allowed to unilaterally take response measures without the permission of the injured state, as this would constitute a violation of the latter's territorial integrity.[331] Instead, the restoration measures will usually be implemented by the government of the injured state, which is normally in the best position to take immediate action to prevent and mitigate damage to its own land.[332] The responsible state will be required to reimburse the costs and expenses incurred by the injured state in taking such measures, which is usually included in the injured state's claim for compensation.[333]

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326 ARSIWA (n. 5), Article 35(a).
327 *Ibid.*, Commentary to Article 35, para. 8.
328 *Lefeber* (n. 105), 133; cf. *Crawford* (n. 4), 513.
329 Cf. ICJ, Certain Activities (Compensation) (n. 267), para. 42; also see ARSIWA (n. 5), Commentary to Article 35, para. 2.
330 Cf. Affaire des forêts du Rhodope central (fond) (Greece v. Bulgaria), Award of 19 March 1933, III RIAA 1405, 1432, see *Crawford* (n. 4), 513.
331 *Xue* (n. 26), 95; see Article 2(4) and (7) UN Charter (n. 178); *Shaw* (n. 24), 387–391; also see *Lefeber* (n. 105), 139.
332 *Xue* (n. 26), 95.
333 *Ibid.*; cf. ICJ, Certain Activities (Compensation) (n. 267), para. 41; but see *Lefeber* (n. 105), 139, who seems to assume that reimbursement of the costs of restoration measures is owed as a form of restitution. On the reimbursement of expenses incurred in taking response measures, see chapter 11, section A.

On the other hand, when the internationally wrongful act has caused damage to areas beyond the limits of national jurisdictions, it appears conceivable to require the responsible state to provide restitution in kind by implementing reasonable clean-up and restoration measures.[334] This approach caters best for the fact that damage to the environment in areas beyond the limits of national jurisdiction does not constitute an injury to individual states but rather to the international community as a whole.[335]

cc) Disproportionality of Restitution

Finally, restitution is ruled out when it involves a 'burden out of all proportion to the benefit deriving from restitution instead of compensation'.[336] In the view of the ILC, this only applies when there is a

> *'grave disproportionality between the burden which restitution would impose on the responsible State and the benefit which would be gained, either by the injured State or by any victim of the breach'.*[337]

The disproportionality of restitution is often raised in cases that concern the breach of procedural obligations. For example, in the *Pulp Mills* case, the ICJ refused to order the demolition of a pulp mill on the border river between Uruguay and Argentina because by building the mill, Uruguay had violated only procedural and not substantial obligations.[338] Hence, where the same substantive result could – and probably would – have occurred had the relevant procedures been followed, it may well be that restitution is disproportionate.[339] In other words, restitution 'should not give the injured State more than it would have been entitled to if the relevant obligation had been performed'.[340]

334 *Lefeber* (n. 105), 139.
335 But see *Xue* (n. 26), 255–257, who argues that clean-up and restoration actions in the common areas can prove difficult and complicated, and that any measurement of loss should therefore extend also to monetary compensation. However, *Xue* does not indicate who should be the recipient of such payments.
336 ARSIWA (n. 5), Article 35(b).
337 *Ibid.*, Commentary to Article 35, para. 11.
338 ICJ, Pulp Mills (n. 283), para. 275.
339 *Crawford* (n. 4), 514–515.
340 ARSIWA (n. 5), Commentary to Article 35, para. 3.

b) Compensation

In many cases, particularly those involving damage to the environment, it will be impossible to fully repair the damage resulting from an internationally wrongful act.[341] Article 36(1) ARSIWA provides that the responsible state is obliged to *compensate* for the damage caused by the wrongful act insofar as such damage is not made good by *restitution*.[342] The notion of 'compensation' refers to the payment of a sum that corresponds to the value that restitution in kind would bear.[343]

Like restitution, the award of compensation requires proof of actual harm as well as a causal link between the internationally wrongful act and the harm.[344] When these requirements are met, compensation shall cover any 'financially assessable damage including loss of profits insofar as it is established'.[345] In the view of the ILC, the obligation to serve compensation encompasses damage suffered both by the state itself and its nationals on whose behalf the state claims compensation by way of exercising diplomatic protection.[346]

The heads of compensable damage, as well as the principles of how such damage is quantified, largely depend on the content of the primary obligation breached.[347] The categories of damage frequently invoked include loss of life and personal injury (aa)), property damage (bb)), economic loss (cc)), and damage to the environment (dd)). Other issues include punitive damages (ee)) and the payment of interest (ff)).

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341 *Lefeber* (n. 105), 133.

342 Cf. ICJ, Gabčíkovo-Nagymaros (n. 138), para. 152; ICJ, Construction of a Wall (n. 91), paras. 152–153; ICJ, Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo) (n. 255), para. 161.

343 PCIJ, Factory at Chorzów (Germany v. Poland) (n. 254), 47.

344 *Lefeber* (n. 105), 133.

345 ARSIWA (n. 5), Article 36(2).

346 *Ibid.*, Commentary to Article 36, para. 5. Diplomatic protection refers to the process by which a State invokes the responsibility of another State injury caused by an international wrongful act of the latter State to nationals of the former State, see *infra* section C.II.

347 ARSIWA (n. 5), Commentary to Article 36, para. 7; *Crawford* (n. 4), 519; *Stephan Wittich*, Compensation, in: Wolfrum/Peters (ed.), MPEPIL, MN. 12–13.

aa) Loss of Life and Personal Injury

It is generally recognized that a state may seek compensation for the death or personal injury suffered by its officials or nationals as a consequence of an internationally wrongful act.[348] Such compensation encompasses material losses such as medical expenses and the loss of earnings as well as non-material damage suffered by the affected individuals.[349] For instance, in the case concerning damages for the death of United States nationals in the sinking of the British ocean liner *Lusitania* by a German torpedo in 1915, the arbitrator held that compensation should encompass the losses of the surviving heirs, including financial sustenance, 'the pecuniary value […] of the deceased's personal services in claimant's care, education, or supervision' as well as reasonable compensation for mental suffering or shock caused by the death of their relatives.[350] Similarly, in the *Corfu Channel* case, the ICJ awarded compensation for the cost of pensions and other grants made by the United Kingdom to victims of the incident or their dependants, besides the costs incurred for medical treatment, administration and the like.[351] The *United Nations Claims Commission* awarded compensation for health damage not only to individuals for their injury or suffering[352] but also to states for their expenses incurred in combating public health problems caused by environmental damage that resulted directly from Iraq's invasion and occupation of Kuwait.[353]

Compensation for personal injury may also cover non-material damage, such as mental suffering or humiliation.[354] In the *Lusitania* case, the arbitrator held that 'such damages are very real, and the mere fact that they are

348 ARSIWA (n. 5), Commentary to Article 36, para. 16; *Xue* (n. 26), 87; *Wittich* (n. 347), MN. 27–29.

349 ARSIWA (n. 5), Commentary to Article 36, para. 16.

350 Opinion in the Lusitania Cases, 01 November 1923, VII RIAA 32, 35.

351 ICJ, Corfu Channel Case (United Kingdom v. Albania), Judgment on Compensation of 15 December 1949, ICJ Rep. 244, 249–250.

352 Cf. UNCC, Governing Council Decision 3. Personal Injury and Mental Pain and Anguish (23 October 1991), UN Doc. S/AC.26/1991/3; see *John J. Chung*, The United Nations Compensation Commission and the Balancing of Rights Between Individual Claimants and the Government of Iraq, 10 (2005) UCLA Journal of International Law & Foreign Affairs 141.

353 UNCC Panel Report F4/5 (2005) (n. 272), para. 68; see *Peter H. Sand/James K. Hammitt*, Public Health Claims, in: Cymie R. Payne/Peter H. Sand (eds.), Gulf War Reparations and the UN Compensation Commission (2011) 193; *Gautier* (n. 300), 204–205.

354 ARSIWA (n. 5), Commentary to Article 36, para. 16.

difficult to measure or estimate by money standards makes them none the less real and affords no reason why the injured person should not be compensated'.[355] Compensation for non-material damage was also awarded by the ICJ in the *Diallo* case, in which it relied on 'equitable considerations' to quantify the compensation due for the unlawful arrest, detention and expulsion of a Guinean national from the Democratic Republic of the Congo.[356]

bb) Property Damage

The second category of compensable damage is property damage or material injury. The scope of this category is broad and not necessarily confined to physical damage.[357] When claiming property damage, the claimant must establish a direct causal link between the damage and the loss of or reduction in the value of his property.[358] Compensation for the capital value of property damaged or destroyed due to an internationally wrongful act is generally determined based on the *fair market value* of the property,[359] which is defined as

> *'[t]he price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's-length transaction'.*[360]

Determining compensation by referring to the market value of property encounters problems when the injured property is not regularly traded or when the property's actual value is not of a commercial nature but rather intangible or sentimental.[361] In these situations, it may be necessary to resort to estimates made by independent experts to assign a monetary value to the injured property.[362] Similar difficulties arise concerning envi-

355 Opinion in the Lusitania Cases (n. 350), 40.
356 ICJ, Diallo (Compensation) (n. 267), para. 24.
357 *Xue* (n. 26), 92.
358 *Lefeber* (n. 105), 133; *Xue* (n. 26), 89.
359 ARSIWA (n. 5), Commentary to Article 36, para. 22.
360 'Fair market value', in: Black's Law Dictionary (n. 19), 1865; cf. IUSCT, Starrett Housing Corporation v. Government of the Islamic Public of Iran et al., 14 August 1987, Award No. 314–24–1, 16 Iran–US CTR 112, para. 227.
361 Cf. ARSIWA (n. 5), Commentary to Article 36, para. 22.
362 Cf. UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning Part Two of the First Instalment of Individual Claims for Damages Above US$100,000 (Category "D" Claims), UN Doc. S/AC.26/1998/3 (1998), paras. 44–50.

ronmental goods. For instance, the commercial value of standing timber can be assessed by referring to the average price of standing timber of the relevant species, reduced by the costs that would be incurred by harvesting the timber and transporting it to the market. However, this assessment presupposes that the injured party was willing to commercially utilize the timber rather than conserving it for ecological purposes.[363] Moreover, it should be taken into account that sustainable forestry would probably not allow harvesting all of the affected timber at once, but rather require limiting harvesting to a rate not exceeding the re-growth.[364]

In the *Certain Activities* case, the difficulties related to attributing monetary values to individual categories of impaired environmental goods, including timber, led the ICJ to adopt an 'overall assessment' approach, which in essence resulted in the award of a lump sum to the injured state.[365] Notably, in most past cases of large-scale damage by hazardous activities, the question of compensation was settled by negotiations rather than by adjudication; an important reason for this might be the difficulties involved in precisely determining the monetary value of the damage in question.[366]

cc) Loss of Profits or Income

Article 36(2) ARSIWA recognizes that compensable damage may include 'loss of profits insofar as it is established'. Loss of profits can be caused by injury to persons or property (or their unlawful taking),[367] but also by harm to the environment, in particular when businesses rely on certain environmental goods or services, such as beaches, forests or certain species.[368] However, loss of profits is only compensable when it is 'established', which means that the injured party must prove a causal relationship between the internationally wrongful act and the eventual loss of

363 On the valuation of environmental damage, see chapter 11, section B.II.2.

364 Cf. ICJ, Certain Activities (Compensation) (n. 267), paras. 60–61.

365 *Ibid.*, para. 78; see chapter 11, section B.III.4.

366 Cf. *Julio Barboza*, The Environment, Risk and Liability in International Law (2011), 46–64; *Xue* (n. 26), 90–92.

367 Cf. PCIJ, Factory at Chorzów (Germany v. Poland) (n. 254), 50–53; ICJ, Diallo (Compensation) (n. 267), para. 40.

368 Cf. *Lefeber* (n. 105).

(potential) income.[369] In the words of the ILC, this requires that 'an anticipated income stream has attained sufficient attributes to be considered a legally protected interest of sufficient certainty'.[370] This can be indicated by the existence of contractual arrangements or a well-established history of dealings.[371] On the other hand, profits that are merely prospective or even speculative will usually not be compensable.[372]

As far as evident, there has been no international arbitral or judicial decision expressly dealing with compensation for lost profits resulting from unlawful environmental interference, which is arguably due to the difficulties in establishing the extent and causality of losses in line with the aforementioned requirements.[373] However, some settlements reached by negotiations seem to include compensation for lost income, including the cases of the 1976 *Seveso* disaster and the 1986 *Sandoz* disaster.[374] Loss of income or profit is also expressly recognized as compensable damage in some civil liability conventions.[375]

369 *Xue* (n. 26), 90; see ARSIWA (n. 5), Commentary to Article 36, para. 32, where the ILC argued that claims for lost profits are 'subject to the usual range of limitations on the recovery of damages, such as causation, remoteness, evidentiary requirements and accounting principles, which seek to discount speculative elements from projected figures'.

370 *Ibid.*, Commentary to Article 36, para. 27. See *Marjorie M. Whiteman*, Damages in International Law, Vol. III (1943), 1837, who argued that 'in order to be allowable, prospective profits must not be too speculative, contingent, uncertain, and the like. There must be proof that they were reasonably anticipated; and that the profits anticipated were probable and not merely possible'. This view was adopted in ICSID, Asian Agricultural Products Ltd. v. Republic of Sri Lanka, Award of 27 June 1990, ICSID Case No. ARB/87/3, para. 104.

371 ARSIWA (n. 5), Commentary to Article 36, para. 27; *Whiteman* (n. 370), 1837.

372 *Whiteman* (n. 370), 1837; *Crawford* (n. 4), 523; cf. ICSID, Asian Agricultural Products Ltd. v. Republic of Sri Lanka (n. 370), para. 107.

373 *Xue* (n. 26), 90.

374 *Ibid.*, 91.

375 See Vienna Convention on Civil Liability for Nuclear Damage (25 May 1963; effective 12 September 1997), 1063 UNTS 358, as amended by the Protocol of 12 September 1997 (effective 4 October 2003), IAEA Doc. INFCIRC/566 (hereinafter '1997 Vienna Convention on Civil Liability for Nuclear Damage'), Article 1(k); Convention on Civil Liability for Damage Caused During Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels (10 October 1989; not yet in force), UN Doc. ECE/TRANS/79, Article 1(10)(c); International Convention on Civil Liability for Bunker Oil Pollution Damage (23 March 2001; effective 21 November 2008), IMO Doc. LEG/CONF.12/19 (hereinafter 'Bunker Oil Convention'), Article 1(9); Kiev Protocol on Civil Liability and Compensation for Damage Caused by the Transboundary Effects of Industrial

dd) Damage to the Environment

Besides the 'traditional' types of damage discussed in the preceding sections, an internationally wrongful act may also cause damage to the environment that does not (only) materialize in individual injury. This poses the question of whether – and to what extent – environmental damage caused by an internationally wrongful act is subject to compensation.

On the one hand, it appears to be generally recognized that the costs of implementing response and reinstatement measures are compensable under international law. In its commentary to the ARSIWA, the ILC expressly mentioned 'the costs incurred in responding to pollution damage' as an example of damage subject to compensation under Article 36 ARSIWA.[376] Similarly, in its claim against the former Soviet Union for damage resulting from the crash of the Soviet nuclear-powered satellite *Cosmos 954*, Canada included 'only those costs that are reasonable, proximately caused by the intrusion of the satellite […] and capable of being calculated with a reasonable degree of certainty'.[377] This approach is also reflected in the vast majority of international treaties on operator liability, which recognize that the costs of 'preventive measures' as well as of 'reasonable measures of reinstatement actually undertaken or to be undertaken' are part of the damage for which the responsible operator shall be liable.[378]

On the other hand, compensation for damage to the environment *per se* is more controversial. Damage to the environment *per se*, or 'pure' environmental damage, refers to such injury that cannot be restored through remediation measures. This includes both a temporary impairment of the environment until its recovery, such as a reduction in the abundance of

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Accidents on Transboundary Waters (21 May 2003; not yet in force), UN Doc. ECE/MP.WAT/11-ECE/CP.TEIA/9, Article II(2)(d)(iii).

376 ARSIWA (n. 5), Commentary to Article 36, para. 8.

377 Canada, Department of External Affairs, Claim Against the Union of Soviet Socialist Republics for Damage Caused by Soviet Cosmos 954 (23 January 1979), 18 ILM 889, para. 23.

378 Cf. International Convention on Civil Liability for Oil Pollution Damage (29 November 1969; effective 19 June 1975), 973 UNTS 3, as amended by the Protocol of 27 November 1992 (effective 30 May 1996), 1956 UNTS 255, Article I(6) and (7); also see, e.g., Bunker Oil Convention (n. 375), Article I(9); 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 375), Article I(1)(k) and (m-o); Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty: Liability Arising from Environmental Emergencies (14 June 2005; not yet in force), ATCM Measure 1 (2005) (hereinafter 'Antarctic Liability Annex'), Article VI(1); Supplementary Protocol (n. 12), Article 5(5).

a species, and permanent losses that cannot be restored, such as the complete loss of a species. However, it is often difficult to attribute a financial value to such losses, especially when they do not impair natural resources that have a market value because they are used economically. Since Article 36(2) ARSIWA provides that compensation shall cover 'financially assessable damage', it is sometimes argued that damage to the environment *per se* was not compensable under international law.[379] The same stance is taken by most of the aforementioned liability treaties, which usually limit compensation to the reimbursement of preventive and reinstatement measures.[380] However, the ILC also noted that environmental damage 'will extend beyond that which can be readily quantified in terms of clean-up costs or property devaluation', but that such damage 'is, as a matter of principle no less real and compensable than damage to property, though it may be difficult to quantify'.[381] This was recently confirmed by the ICJ in its judgment on compensation in the *Certain Activities* case, where it held that 'compensation is due for damage caused to the environment, in and of itself, in addition to the expenses incurred by an injured State as a consequence of such damage'.[382]

Nevertheless, compensation for environmental damage remains a highly complex topic prone to many uncertainties and controversies, which relate not only to the conditions under which expenses for response measures are subject to compensation but also to the question of whether, and if so, how damage to the environment *per se* shall be compensated. These issues, including a detailed assessment of the ICJ's judgment on environmental compensation in the *Certain Activities* case, are addressed in chapter 11 below.

ee) Punitive Damages

In cases of intentional and serious violations of international law, the idea of *punitive* or *exemplary damages* is sometimes put forward. The concept of punitive damages derives from common law and denotes the payment of damages in addition to those covering actual loss when the defendant

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379 See, e.g., the statement of by Iran before the UN Compensation Commission, UNCC Panel Report F4/5 (2005) (n. 272), para. 46.
380 See *supra* n. 378.
381 ARSIWA (n. 5), Article 36, para. 15.
382 ICJ, Certain Activities (Compensation) (n. 267), para. 41.

acted with recklessness, malice, deceit, or other reprehensible conduct.[383] They are intended to punish the wrongdoer and thereby deter similar misconduct in the future.[384] The inclusion of punitive damages was discussed in the ILC during the drafting of the ARSIWA but ultimately rejected.[385] The ILC's final commentary clearly states that compensation 'is not concerned to punish the responsible State, nor does compensation have an expressive or exemplary character'.[386] This appears to reflect a wide consensus in international law.[387]

Nevertheless, the idea of awarding punitive damages resurrects from time to time.[388] For instance, in the *Certain Activities* case before the ICJ, a minority of judges argued that punitive damages should be considered in extraordinary cases 'where it is proven that a State has caused serious harm to the environment',[389] or that the award of damages should at least have regard to the gravity of the responsible state's actions.[390] However, the majority maintained that compensation should not have a punitive or exemplary character.[391]

ff) Interest

Article 38 ARSIWA provides that reparation may include the payment of interest 'when necessary in order to achieve full reparation'. According to the ILC's commentary, interest is not a necessary component of compensation in every case but might nevertheless be required 'in some

383 *Nina H. B. Jorgensen*, A Reappraisal of Punitive Damages in International Law, 68 (1998) BYIL 247; *Stephan Wittich*, Punitive Damages, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 667, 667.

384 *Wittich* (n. 383), 667.

385 See *Crawford* (n. 4), 524–525; *Wittich* (n. 383), 672–674.

386 ARSIWA (n. 5), Commentary to Article 36, para. 4.

387 *Jorgensen* (n. 383), 266; *Crawford* (n. 4), 526; *Wittich* (n. 347), 674.

388 Cf. *Jefferi H. Sendut*, The International Court of Justice and Compensation for Environmental Harm: A Missed Opportunity?, 1 (2018) De Lege Ferenda 17, 25–27.

389 Cf. ICJ, Certain Activities (Compensation) (n. 267), Separate Opinion of Judge Bhandary, para. 18; Separate Opinion of Judge Cançado Trindade, para. 19.

390 Cf. *ibid.*, Dissenting Opinion of Judge ad hoc Dugard, para. 41–43.

391 Cf. *ibid.*, Judgment, para. 31; Declaration of Judge Gevorgian, para. 9; see *Kévine Kindji/Michael G. Faure*, Assessing Reparation of Environmental Damage by the ICJ: A Lost Opportunity?, 57 (2019) QIL 5, 12.

cases' to achieve full reparation for the injury caused by an internationally wrongful act.[392] However, the commentary provides no guidance as to the circumstances in which interest shall be paid. There also appears to be no uniform practice in international case law with regard to the situations in which interest is owed, the rate of interest and the time period during which interest accrues.[393] Nevertheless, when compensation is awarded in the form of a lump sum, interest is usually not awarded separately.[394] This is also reflected in the ICJ's recent judgment on compensation in the *Certain Activities* case. While the Court awarded pre-judgment interest on costs and expenses, it held that the claimant was not entitled to interest on the compensation for environmental damage, which the Court had determined by applying an 'overall valuation'.[395] At the same time, post-judgment interest appears to be broadly recognized in international case law.[396]

c) Satisfaction

Article 37 ARSIWA provides that when the injury cannot be made good by restitution or compensation, the state responsible for an internationally wrongful act is under an obligation to give satisfaction. Satisfaction is the appropriate remedy for non-material or 'moral' damage, which, although not financially assessable, nevertheless constitutes an 'affront to the State'.[397] Hence, possible forms of satisfaction include 'an acknowledgement of the breach, an expression of regret, a formal apology or an-

392 ARSIWA (n. 5), Commentary to Article 38, para. 1; also see *Crawford* (n. 4), 531–533.

393 Cf. PCIJ, Case of the S.S. "Wimbledon" (United Kingdom et al. v. Germany), Merits Judgment of 17 August 1923, PCIJ Rep. Ser. A, No. 1, 32; IUSCT, Iran v. United States, Decision of 30 September 1987, Case A19, Decision No. DEC 65-A19-FT, 16 Iran–US CTR 285, 289–290; ICJ, Diallo (Compensation) (n. 267), para. 56; ICJ, Certain Activities (Compensation) (n. 267), paras. 152–154; see ARSIWA (n. 5), Commentary to Article 38, para. 10; *Elihu Lauterpacht/Penelope Nevill*, The Different Forms of Reparation: Interest, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 613.

394 ARSIWA (n. 5), Commentary to Article 38, para. 11.

395 Cf. ICJ, Certain Activities (Compensation) (n. 267), paras. 152–153; see chapter 11, section B.III.4.

396 Cf. PCIJ, Wimbledon (n. 393), 32; ICJ, Diallo (Compensation) (n. 267), para. 56; ICJ, Certain Activities (Compensation) (n. 267), para. 154.

397 ARSIWA (n. 5), Commentary to Article 37, para. 3.

other appropriate modality'.[398] Satisfaction may also consist of a monetary payment,[399] especially when a moral injury is suffered by individuals.[400] However, in disputes not involving individuals, the ICJ has repeatedly held that a judicial declaration of wrongfulness already constitutes an appropriate form of satisfaction.[401]

4. Contribution to the Injury and Failure to Mitigate Damage

In some situations, the state that has acted in contravention of international law may not be exclusively responsible for the resulting damage. Instead, the injured state may have contributed to the damage either intentionally or negligently. This is reflected in Article 39 ARSIWA, which provides that any wilful or negligent contribution to the damage by the injured state shall be taken into account when determining the reparation owed. By 'wilful or negligent', the Article refers to a 'lack of due care on the part of the victim of the breach for his or her own property or rights'.[402] The same applies when not the injured state but a person or entity for whom reparation is sought has contributed to the injury.[403]

Even when the injured state has not contributed to the damage, it must take all available steps to mitigate the damage.[404] Although the obligation to mitigate is not a legal obligation that gives itself rise to responsibility, a failure by the injured party to mitigate damage may preclude recovery to that extent.[405] In the *Gabčíkovo-Nagymaros* case, the ICJ recognized that

> '*an injured State which has failed to take the necessary measures to limit the damage sustained would not be entitled to claim compensation for that damage which could have been avoided*'.[406]

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398 *Ibid.*, Article 37(2).
399 *Ibid.*, Commentary to Article 37, para. 5.
400 *Wittich* (n. 347), para. 31; see *supra* section B.II.1.
401 See, e.g., ICJ, Corfu Channel (Merits) (n. 70), 35; ICJ, Bosnian Genocide (n. 8), para. 464; ICJ, Pulp Mills (n. 283), para. 269; cf. *Crawford* (n. 4), 529–530.
402 ARSIWA (n. 5), Commentary to Article 39, para. 5.
403 Cf. *ibid.*, Commentary to Article 39, para. 6.
404 *Crawford* (n. 4), 494–495.
405 ARSIWA (n. 5), Commentary to Article 31, para. 11; see *Wittich* (n. 347), MN. 20–21.
406 ICJ, Gabčíkovo-Nagymaros (n. 138), para. 80.

This principle was also applied by the environmental panel of the UNCC, which repeatedly stressed that claimant states were obliged to mitigate and contain environmental damage to the extent possible and reasonable in the circumstances. It held that this duty was 'a necessary consequence of the common concern for the protection and conservation of the environment, and entails obligations towards the international community and future generations'.[407] Where claimant governments had failed to take the necessary measures to prevent aggravation of environmental damage, compensation was either denied or reduced to take account of the fact that some of the damage was caused by factors not attributable to the responsible state.[408]

The concept of contribution to injury and the duty to mitigate damage are closely related and can at times be difficult to distinguish.[409] Both concern situations in which an injured state suffers (greater) damage due to its own conduct or omission.[410] However, while the duty to mitigate damage arises only after the damage has occurred, contributory negligence occurs at the time of the breach or the original infliction of damage.[411] For instance, a party to the Cartagena Protocol that has knowingly allowed transboundary movements of LMOs into its territory without applying the *Advance Informed Agreement* procedure may be barred from claiming reparation for damage subsequently resulting from these LMOs. However, even when it has followed all applicable norms and taken due care to avoid damage, a state's claim for reparation may be reduced when it has not taken all available steps to contain an LMO after it has proven harmful.

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407 UNCC Panel Report F4/3 (2003) (n. 306), paras. 42–43; UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning Part Two of the Fourth Instalment of "F4" Claims, UN Doc. S/AC.26/2004/17 (2004), para. 38; UNCC Panel Report F4/5 (2005) (n. 272), paras. 40–41.

408 See *Peter H. Sand*, Compensation for Environmental Damage from the 1991 Gulf War, 35 (2005) Environmental Policy and Law 244, 246; *Sands* et al. (n. 108), 758 with further references.

409 *Wittich* (n. 347), para. 40.

410 *Crawford* (n. 4), 501; *Wittich* (n. 347), para. 40.

411 *Wittich* (n. 347), para. 40; *Crawford* (n. 4), 501.

III. Right to Take Countermeasures

Countermeasures are measures that would normally contravene international obligations but are taken in response to a breach of international law by another state in order to induce the latter to cease the wrongful act and to make reparation.[412] Countermeasures are independent of international compliance control and dispute settlement mechanisms[413] and have therefore been described as a 'unilateral self-help measure'.[414]

As mentioned before, the international wrongfulness of a countermeasure is precluded under certain conditions.[415] A countermeasure may only be applied as long as the breach persists and shall be taken in a way that allows the other state to resume compliance with the obligations in question.[416] Moreover, countermeasures may not be taken while the dispute is pending before a court or tribunal with the authority to make decisions binding on the parties.[417]

When countermeasures are taken, they must be commensurate with the injury suffered, taking into account the gravity of the breach and the rights in question.[418] They must be terminated as soon as the responsible state has complied with its obligations under the law of state responsibility, i.e. that it ceased to act inconsistently with its primary obligations, has given assurances of non-repetition (where required), and has made full reparation for the injury caused by the breach.[419]

In any event, a countermeasure can only preclude wrongfulness in the relations between the injured state and the state which has committed the internationally wrongful act.[420] In the *Gabčíkovo-Nagymaros* case, the ICJ stressed that the measure in question must be 'directed against' the responsible state.[421] Similarly, the ILC underlined that in situations where the obligation breached by a lawful countermeasure is also owed to a third state, the wrongfulness of the measure is not precluded vis-à-vis that third

412 ARSIWA (n. 5), Article 49(1) and commentary to Part Three, chapter II, para. 1.
413 See *Duvic-Paoli* (n. 160), 343–354.
414 *Crawford* (n. 4), 676.
415 Cf. ARSIWA (n. 5), Article 22; ICJ, Gabčíkovo-Nagymaros (n. 138), paras. 83–87 and *supra* section A.IV.3.
416 ARSIWA (n. 5), Article 49 (2) and (3).
417 *Ibid.*, Article 52(3)(b).
418 *Ibid.*, Article 51.
419 *Ibid.*, Article 53.
420 Cf. *ibid.*, Commentary to Article 22, para. 5.
421 ICJ, Gabčíkovo-Nagymaros (n. 138), para. 83.

state.[422] Consequently, countermeasures cannot justify breaches of obligations owed *erga omnes (partes)* which serve the protection of common interests.[423] This is true for a vast number of obligations in international environmental law, especially those relating to the protection of global commons. When such obligations are breached, an injured state could only suspend compliance with a different obligation owed bilaterally.[424]

A closely related question is whether international law allows for 'collective countermeasures' taken by non-injured states in response to breaches of obligations owed *erga omnes (partes)*. Article 49 ARSIWA specifically refers to 'injured states' as those entitled to take countermeasures, which seemingly excludes non-injured states defending collective interests from taking countermeasures.[425] The ILC found 'no clearly recognized entitlement of States referred to in article 48 to take countermeasures in the collective interest'.[426] For this reason, Article 54 ARSIWA merely provides that the ARSIWA 'do not prejudice' the right of states to take lawful countermeasures when defending *erga omnes (partes)* obligations.[427] However, it has been argued more recently that collective countermeasures have received 'increasingly strong support' in state practice since the adoption of the ARSIWA in 2001.[428] Besides, sanctions imposed by non-compliance

422 ARSIWA (n. 5), Commentary to Article 49, para. 4.
423 *Lefeber* (n. 105), 143; see *infra* section C.I.2.a).
424 *Ibid.*, 143–144.
425 *Alan E. Boyle/Catherine Redgwell*, Birnie, Boyle, and Redgwell's International Law and the Environment (4th ed. 2021), 245.
426 ARSIWA (n. 5), Commentary to Article 55, para. 6; see *Linos-Alexander Sicilianos*, The Classification of Obligations and the Multilateral Dimension of the Relations of International Responsibility, 13 (2002) EJIL 1127, 1141–1144.
427 Cf. *Crawford* (n. 4), 703–706.
428 Cf. *Martin Dawidowicz*, Third-Party Countermeasures: A Progressive Development of International Law?, 29 (2016) QIL 3. Also see *Jonathan I. Charney*, Third State Remedies for Environmental Damage to the World's Common Spaces, in: Francesco Francioni/Tullio Scovazzi (eds.), International Responsibility for Environmental Harm (1991) 149, 161; *Jacqueline Peel*, New State Responsibility Rules and Compliance with Multilateral Environmental Obligations: Some Case Studies of How the New Rules Might Apply in the International Environmental Context, 10 (2001) RECIEL 82, 87. Also see ICJ, Construction of a Wall (n. 91), para. 159, where the Court implied that states were obliged to take lawful measures to bring to an end the ongoing violation of the right to self-determination of the Palestine people it had found. In any event, in cases involving direct injury to one or several states lawful countermeasures taken by third states would depend on the consent of the injured state(s), cf. *James Crawford*, Third Report on State Responsibility, UN Doc. A/CN.4/507 and Add. 1–4 (2000), para. 400.

procedures under multilateral environmental agreements could be seen as collective countermeasures, although they only are ‘countermeasures’ *stricto sensu* when their implementation is otherwise inconsistent with the international obligation of the states engaging in it.[429]

C. Implementation of State Responsibility

The previous sections have dealt with the requirements and legal consequences of state responsibility for harm resulting from modern biotechnology. The present section addresses the practical issues involved in implementing such responsibility. First of all, the right to invoke responsibility is generally limited to states *injured* by the breach, which raises problems in the context of obligations serving community interests such as the environment (I.). Secondly, injured nationals need to be represented by the affected state through *diplomatic protection*, which raises the question of whether these nationals must first exhaust any local remedies available to them in the responsible state (II.). The final subsection briefly touches upon the invocation and judicial enforcement of state responsibility (III.).

I. Standing to Invoke State Responsibility

It is generally recognized that a state is only entitled to invoke the international responsibility of another state when it has a legal interest in the matter.[430] Traditionally, only states whose subjective rights had been *injured* could invoke responsibility.[431] As held by the ICJ in the *Reparations* case of 1949, ‘only the party to whom an international obligation is due can bring a claim in respect of its breach.’[432] In many cases, identifying the party whose rights have been violated by a breach does not entail particular diffi-

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429 ARSIWA (n. 5), Commentary to Chapter II, para. 4; *Peter H. Sand*, Enforcing CITES: The Rise and Fall of Trade Sanctions, 22 (2013) RECIEL 251; see *infra* section C.III.3.a)aa).

430 *Okowa* (n. 279), 209.

431 *K. Sachariew*, State Responsibility for Multilateral Treaty Violations: Identifying the ‘Injured State’ and Its Legal Status, 35 (1988) NLR 273, 274; *Crawford* (n. 4), 542.

432 ICJ, Reparation for Injuries Suffered in the Service of the United Nations, Advisory Opinion of 11 April 1949, ICJ Rep. 174, 181–182; reaffirmed in ICJ, Barcelona Traction (n. 100), 82.

culties; for instance, a state affected by significant transboundary harm will be entitled to invoke the international responsibility of the source state.[433] But the question of standing is more difficult with regard to obligations that are not owed to a particular state but serve the protection of collective interests such as global biodiversity, because breaches of these obligations do not necessarily cause injury to individual states.[434]

Previously, there was a prevalent view both in legal scholarship and within the ILC that breaches of obligations owed to the international community as a whole (or the commission of 'international crimes') would result in all other states qualifying as 'injured states' and thus being individually entitled to invoke the international responsibility of the responsible state.[435] This was later given up in favour of a more narrow concept of 'injured states', while at the same time it was recognized that also non-injured states could have standing to invoke the responsibility of another state in certain cases.[436] Consequently, the final ARSIWA strictly distinguish between injured states, which are always entitled to invoke responsibility (1.), and non-injured states, which may only invoke responsibility under certain conditions (2.).[437]

1. Invocation of Responsibility by Injured States

Article 42 ARSIWA addresses the invocation of responsibility by injured states.[438] According to Article 42(a) ARSIWA, a state is entitled to invoke the responsibility as an injured state if the obligation breached is owed individually to the state concerned.[439] This applies to obligations resulting

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433 *Okowa* (n. 279), 210; *Boyle/Redgwell* (n. 425), 243.
434 *Xue* (n. 26), 237.
435 Cf. *Sachariew* (n. 431), p. 279, 282; *Lefeber* (n. 105), 113–120; *Crawford* (n. 4), 542–544. It was recognized that some states among those injured could be 'especially affected', e.g. because they suffered material damage from a breach of a communitarian obligation, see *Sachariew* (n. 431), 287–289.
436 For a critical view, see *Tams* (n. 166), 770–775.
437 Cf. ARSIWA (n. 5), Commentary to Article 42, para. 1; *Giorgio Gaja*, The Concept of an Injured State, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 941, 941–942; *Crawford* (n. 4), 542.
438 As clarified by Article 46 ARSIWA, there may also be a plurality of injured states, as several states may be injured by one and the same internationally wrongful act.
439 ARSIWA (n. 5), Article 42(a).

from a bilateral treaty concluded between the states concerned as well as obligations arising from bilateral custom or a unilateral undertaking made by one state to another.[440]

However, an obligation owed to another state individually may also arise from a multilateral undertaking. Although a multilateral treaty (or regional custom) establishes an engagement among all contracting parties, its performance in certain cases creates bilateral relationships between two parties.[441] In these situations, the performance of an obligation derived from a multilateral undertaking is owed to a specific state, regardless of whether the obligation is also owed to other states either simultaneously or under different circumstances.[442]

For this reason, multilateral treaties have been characterized as creating 'bundles' of interwoven bilateral obligations.[443] For example, the requirement to obtain the *Advance Informed Agreement* of the receiving state prior to the transboundary movement of an LMOs under the Cartagena Protocol[444] stipulates an obligation that only applies in the bilateral relationship between an exporting and an importing party. Similarly, the obligation to prevent unintentional transboundary movements of LMOs[445] is owed to all states parties to the Cartagena Protocol, but only those states actually affected by an unintentional transboundary movement can claim to be injured by a breach of this obligation.[446] If a breach of the obligation can be established, the affected state would be entitled to the full range of legal consequences following from the international responsibility of the source state, including reparation and the right to take countermeasures.

Article 42(b) ARSIWA provides for two scenarios involving breaches of collective obligations, i.e. obligations whose performance is not owed to a state individually, but to a group of states (such as the parties to a multilateral treaty) or the international community as a whole.[447] This

440 *Ibid.*, Commentary to Article 42, paras. 6–7; *Sicilianos* (n. 426), 1133; *Crawford* (n. 4), 545.

441 ARSIWA (n. 5), Commentary to Article 42, para. 8; *Tams* (n. 166), 776; *Gaja* (n. 437), 943–944.

442 *Crawford* (n. 4), 546.

443 *Sachariew* (n. 431), 277–278; *Sicilianos* (n. 426), 1133; see ARSIWA (n. 5), Commentary to Article 42, para. 8, pointing out that in this regard, the scope of Article 42(a) ARSIWA is different from that of Article 60(1) VCLT, which only applies to bilateral treaties.

444 Cf. Article 7(1) Cartagena Protocol; see chapter 3, section A.II.1.

445 Cf. Article 16(3) Cartagena Protocol; see chapter 3, section A.II.2.a)cc).

446 *Förster* (n. 175), 178.

447 ARSIWA (n. 5), Commentary to Article 42, para. 11.

refers to obligations that serve collective purposes rather than individual interests of the participating states and thus cannot be characterized as creating 'bundles' of bilateral obligations. In these situations, a state is only considered to be *injured* by a breach of the obligation when additional requirements are met.

According to the first scenario, set out in Article 42(b)(i) ARSIWA, a state is injured if it is 'specially affected' by the breach of a collective obligation. An example given in the ILC's commentary is a case of pollution of the high seas in breach of Article 194 UNCLOS that particularly affects one or several coastal states. Although the obligation serves the collective interest of all UNCLOS parties in the preservation of the marine environment in general, a coastal state whose beaches are polluted as a consequence of the breach would be regarded as specially affected, and thus injured by the breach.[448] A similar example within the scope of the present study is the obligation to regulate and control LMOs laid down in Article 8(g) CBD. While the obligation serves the protection of biodiversity globally,[449] an uncontrolled release or spread of an LMO could cause particular harm to the biodiversity of one or several states parties. In this case, the latter would be considered injured by the breach as a specially affected state in the sense of Article 42(b)(i) ARSIWA.

The second scenario in which breaches of collective obligations are equated to breaches of bilateral obligations, set out in Article 42(b)(ii) ARSIWA, concerns breaches that are 'of such a character as radically to change the position of all other states to which the obligation is owed'. This refers to so-called *integral obligations* which are conditioned upon their scrupulous performance by all states involved and breaches of which put in jeopardy the entire collective undertaking.[450] Examples of this 'relatively rare'[451] type of obligation are disarmament and non-proliferation undertakings,[452] such as the obligation not to acquire biological weapons under the *Biological Weapons Convention*.[453] Another example would be the obligation to refrain from territorial claims over parts of Antarctica

448 *Ibid.*, Commentary to Article 42, para. 12; also see *Xue* (n. 26), 245; *Gaja* (n. 437), 946–947; *Boyle/Redgwell* (n. 425), 243.

449 See chapter 3, section B.III.

450 ARSIWA (n. 5), Commentary to Article 42, para. 13; *Sicilianos* (n. 426), 1134; *Crawford* (n. 4), 547.

451 *Gaja* (n. 437), 945.

452 ARSIWA (n. 5), Commentary to Article 42, para. 13; *Crawford* (n. 4), 547.

453 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) And Toxin Weapons and on Their Destruc-

enshrined in the *Antarctic Treaty*.[454] A breach of either obligation would affect all parties to the respective instruments, which would entitle them to the full range of legal consequences, including cessation and non-repetition, restitution, and the right to take countermeasures against the responsible state.[455]

Some authors have argued that integral obligations could also be found in the sphere of international environmental law.[456] However, the performance of environmental obligations is usually not conditioned upon their simultaneous performance by all other states parties in the sense that non-compliance by one state would void the whole purpose of the obligation.[457] Thus, obligations of an integral nature are not common in international environmental law. A possible exception could be seen in the proposed global moratorium on environmental releases of engineered gene drives,[458] as states could argue that their acceptance of such a moratorium was premised on the understanding that all other states would also refrain from conducting such releases in order to prevent a 'global race' for gene drive technology.

2. Invocation of Responsibility by Non-Injured States

In many cases, breaches of obligations that serve purely collective interests will not cause injury to individual states in the sense of Article 42 ARSIWA. This is particularly true for obligations concerned with the protection of global environmental goods, such as the global biodiversity, or of areas of common concern, such as the high seas beyond national jurisdiction.

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tion (10 April 1972; effective 26 March 1975), 1015 UNTS 163, Article I(1); see chapter 3, section J.I.

454 Antarctic Treaty (01 December 1959; effective 23 June 1961), 402 UNTS 71, Article 4; cf. ARSIWA (n. 5), Commentary to Article 42, para. 14; *Gaja* (n. 437), 945; *Crawford* (n. 4), 547.

455 ARSIWA (n. 5), Commentary to Article 42, para. 14.

456 Cf. *Sachariew* (n. 431), 281; *Peel* (n. 428), 89–91; *Crawford* (n. 4), 547.

457 *Sicilianos* (n. 426), 1135. But see *Peel* (n. 428), 89–91, who argues that fishery conservation agreements could be seen as establishing integral obligations by setting catch quotas for particularly vulnerable or over-fished species, and that by exceeding its allocated quota one state affects the enjoyment of fishing rights by all other state parties. But this overlooks that the compliance by other states with their respective quotas will remain unaffected by a breach; it is rather the joint conservation effort to prevent overfishing that is jeopardized.

458 See chapter 5, section A.

Violations of these obligations will not necessarily cause injury to any particular state (at least when no state is specially affected by the breach).[459] However, it is recognized that in case of breaches of obligations that serve collective interests, states may invoke the responsibility for a breach even when they are not themselves injured in the sense of Article 42 ARSIWA.[460] In the *Barcelona Traction* case, the ICJ distinguished obligations owed *vis-à-vis* individual states and obligations owed towards the international community as a whole.[461] With regard to the latter, the Court held that 'all States can be held to have a legal interest in their protection; they are obligations *erga omnes*'.[462] Thus, in some situations, states are entitled to invoke the international responsibility of another state even if they have not been injured by the internationally wrongful act (a)). But there are certain limitations to the remedies a non-injured state may seek (b)).

a) Right of Non-Injured States to Invoke Responsibility

The right of non-injured states to invoke the responsibility of another state for breaches of collective obligations is set out in Article 48 ARSIWA, which distinguishes between two types of collective obligations.

Article 48(1)(a) ARSIWA refers to obligations owed to a group of states, which are established to protect a collective interest of that group. These obligations are commonly referred to as obligations *erga omnes partes* because their performance is owed to all other states of the relevant group, i.e. the parties to a multilateral treaty or those states bound by a non-universal rule of customary international law.[463] The right of non-injured states to invoke breaches of obligations *erga omnes partes* appears to be

459 *Peel* (n. 428), 86. But see *James Crawford*, Fourth Report on State Responsibility, UN Doc. A/CN.4/517 and Add.1 (2001), para. 40, who suggests that also rules which primarily establish bilateral obligations could, at the same time, also serve a collective interest. This is also indirectly acknowledged in Article 48(2)(b) ARSIWA, which provides that a non-injured state can claim from the responsible state to perform its obligation of reparation, inter alia, 'in the interest of the injured State'. See infra, section C.I.2.b).

460 ARSIWA (n. 5), Commentary to Article 48, para. 2.

461 ICJ, Barcelona Traction (n. 100), para. 33.

462 *Ibid.*

463 ARSIWA (n. 5), Commentary to Article 48, para. 6; *Giorgio Gaja*, States Having an Interest in Compliance with the Obligation Breached, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 957, 959.

generally accepted[464] and was also recognized by the ICJ in the case of *Belgium v. Senegal*.[465]

Many of the obligations analysed in the preceding chapters can be characterized as obligations *erga omnes partes*, including the obligation to establish appropriate risk management measures for LMOs[466] and the obligations to share relevant information on LMOs through the Biosafety Clearing-House.[467] These obligations serve the collective interest of all parties to improve the safety in handling LMOs, including by exchanging information. The same applies to most of the obligations contained in the *Nagoya–Kuala Lumpur Supplementary Protocol*. As shown above, the Protocol serves the collective interest in providing appropriate response measures to biodiversity damage caused by LMOs. However, it does not stipulate clear obligations that would apply in the bilateral relationship between a state of origin of a harmful LMO and a state affected by damage caused by it.[468]

The second type of collective obligations, addressed in Article 48(1)(b) ARSIWA, is obligations owed to the international community *as a whole*. This refers to obligations *erga omnes*, in respect of which all states are entitled to invoke the responsibility of any other state for an alleged breach. Traditional examples of obligations *erga omnes* are basic human rights such as the protection from slavery and racial discrimination,[469] the prohibition of aggression and genocide,[470] and the right of peoples to self-determination.[471] Besides, it is widely recognized in legal scholarship that certain environmental obligations, including the obligation to protect the marine environment and the environment in areas beyond national jurisdiction,

464 Cf. *Okowa* (n. 279), 210–212; *Duvic-Paoli* (n. 160), 341.
465 ICJ, Questions relating to the Obligation to Prosecute or Extradite (Belgium v. Senegal), Judgment of 20 July 2012, ICJ Rep. 422, paras. 68–69.
466 Cf. Article 16(1) Cartagena Protocol; see chapter 3, section A.II.2.a)aa).
467 Cf. Article 20 Cartagena Protocol; see chapter 3, section A.II.3.
468 See chapter 6.
469 Cf. ICJ, Barcelona Traction (n. 100), para. 34.
470 Cf. *ibid.;* ICJ, Reservations to the Convention on the Prevention and Punishment of the Crime of Genocide, Advisory Opinion of 28 May 1951, ICJ Rep. 15, 23; ICJ, Application of the Convention on the Prevention and Punishment of the Crime of Genocide (Bosnia and Herzegovina v. Yugoslavia), Preliminary Objections, Judgment of 11 July 1996, ICJ Rep. 595, para. 31.
471 ICJ, Case Concerning East Timor (Portugal v. Australia), Judgment of 30 June 1995, ICJ Rep. 90, para. 29; ICJ, Construction of a Wall (n. 91), para. 156; ICJ, Legal Consequences of the Separation of the Chagos Archipelago from Mauritius in 1965, Advisory Opinion of 25 February 2019, ICJ Rep. 95, para. 180.

also apply *erga omnes*.[472] Arguably, this also applies to the conservation of the global biological diversity, which is recognized as a 'common concern of mankind' in the preamble to the CBD.[473]

While it was previously controversial whether states can invoke breaches of obligations *erga omnes* even when they are not injured themselves,[474] the existence of such a right to an *actio popularis* now appears to be no longer contested.[475] For instance, the *Seabed Disputes Chamber* of ITLOS held that each state party to the UNCLOS was entitled to invoke the responsibility of another state for environmental damage caused by deep sea-bed mining

472 Cf. *Frederic L. Kirgis*, Standing to Challenge Human Endeavors that Could Change the Climate, 84 (1990) AJIL 525, 527–528; *Charney* (n. 428), 161–162; *Lefeber* (n. 105), 124–128; *Okowa* (n. 279), 212–213; *Maurizio Ragazzi*, The Concept of International Obligations Erga Omnes (2000), 154–163; *Peel* (n. 428), 94–95; *Silja Vöneky*, Die Fortgeltung des Umweltvölkerrechts in internationalen bewaffneten Konflikten (2001), 332–335; *Sicilianos* (n. 426), 1135; *Xue* (n. 26), 246; *Boyle/Redgwell* (n. 425), 244. Moreover, *Okowa* (n. 279), 216, suggests that in cases of transboundary harm causing injury to individual states, the interests of other states in the protection of the environment should be treated as subordinate where other states have a better interest to protect. Also see ICJ, Nuclear Tests (Australia v. France), Judgment of 20 December 1974, ICJ Rep. 253, para. 50, where the Court considered France's announcement not to conduct any further atmospheric tests as a unilateral undertaking *erga omnes*. The issue of standing was not addressed in ICJ, Whaling in the Antarctic (Australia v. Japan: New Zealand intervening), Merits Judgment of 31 January 2014, ICJ Rep. 226, because Japan had not challenged Australia's standing to invoke a violation of the International Convention for the Regulation of Whaling of 1946.

473 Cf. CBD, Preambular para. 3; see *Malgosia A. Fitzmaurice*, Liability for Environmental Damage Caused to the Global Commons, 5 (1996) RECIEL 305, 308–310; *Lefeber* (n. 105), 126–127; *Förster* (n. 175), 184–187; *Schmitt* (n. 277), 419–422.

474 Cf. ICJ, South West Africa (Ethopia v. South Africa; Liberia v. South Africa), Judgment of 18 July 1966, ICJ Rep. 6, para. 88; ICJ, Nuclear Tests (Australia v. France) (n. 472), Dissenting Opinion of Judge Petren, p. 303; Dissenting Opinion of Judge de Castro, p. 387; Joint Dissenting Opinion of Judges Onyeama, Dillard, Jiménez de Aréchaga and Sir Humphrey Waldock, para. 117; see *Okowa* (n. 279), 212–215; *Peel* (n. 428), 95; *Edith Brown Weiss*, Invoking State Responsibility in the Twenty-First Century, 96 (2002) AJIL 798, 803–805; *Crawford* (n. 4), 552.

475 ALI, Restatement of the Law Third: Foreign Relations of the United States, Volume 2 (1987), § 902(1) and Comment a; *Charney* (n. 428), 175–176; *Fitzmaurice* (n. 473), 306–307; IDI, Resolution on Responsibility and Liability for Environmental Damage (n. 161), Article 27; *Peel* (n. 428), 95; ITLOS, Responsibilities and Obligations of States (n. 141), para. 180; *Duvic-Paoli* (n. 160), 342; *Boyle/Redgwell* (n. 425), 244; but see *Xue* (n. 26), 246–250.

due to the *erga omnes* character of the obligations relating to the preservation of the environment of the high seas and in the international seabed area.[476]

b) Remedies Available to Non-Injured States

A corollary question to the right of non-injured states to invoke breaches of obligations *erga omnes (partes)* is which remedies these states can seek. As the breached obligation is owed toward these states, it is beyond doubt that they can demand the responsible state to cease the wrongful act and, where required, to give appropriate assurances and guarantees of non-repetition.[477] This is also recognized in Article 48(2)(a) ARSIWA. However, a more complex issue is whether – and to what extent – non-injured states can also claim reparation.

As shown above, non-injured states that invoke the responsibility for breaches do so in the exercise of a collective interest in compliance with the obligation, but they will usually not have sustained damage affecting them individually. Hence, there is no reason to allow those states to claim reparation in their own name.[478] However, if reparation for damage to collective interests could not be claimed by any state, such damage would likely remain unrepaired. Even more, the unavailability of reparation for damage not affecting individual states could endanger the effectiveness of obligations *erga omnes (partes)*, as the remedies available to non-injured states would be limited to diplomatic protest, resort to non-compliance procedures and dispute settlement mechanisms (where available) and, arguably, the implementation of countermeasures.[479]

Article 48(2)(b) ARSIWA provides that a non-injured state can claim 'performance of the obligation of reparation in the interest of the injured state or of the beneficiaries of the obligation breached'. The ILC acknowledged that this provision involved 'a measure of progressive development', which in the view of the ILC was justified since it provided a means of protecting the community or collective interests at stake.[480] However, the

476 ITLOS, Responsibilities and Obligations of States (n. 141), para. 180.
477 Cf. *Duvic-Paoli* (n. 160), 343; *Gaja* (n. 463), 960–961.
478 *Johan G. Lammers*, International Responsibility and Liability for Damage Caused by Environmental Interferences, 31 (2001) Environmental Policy and Law 42–50 and 94–105, 46; *Gaja* (n. 463), 961.
479 *Gaja* (n. 463), 959; see *supra* section B.III.
480 ARSIWA (n. 5), Commentary to Article 48, para. 12.

question remains as to who should be the beneficiary of such reparation and what form such reparation should take. This is particularly difficult in the context of damage to 'global commons' such as global biodiversity and the environment in areas beyond the limits of national jurisdiction. Still, there are no apparent reasons why non-injured states could not claim the performance of reparation from the responsible state under Article 48(2)(b) ARSIWA. In particular, the requirement that reparation must be performed 'in the interest […] of the beneficiaries of the obligation breached' should not be construed too restrictively. This does not exclude the possibility that obligations aimed at protecting global commons may have no ultimate beneficiaries apart from the environment as such and the international community as a whole.[481] In these cases, non-injured states should not be barred from seeking reparation in pursuance of the collective interest, although account should be taken of the risk of parallel claims by multiple claimants.[482] Collective action, including through competent international organizations, would therefore be preferable but appears not to be legally required.

As to the available remedies, restitution *ad integrum* remains the primary means of reparation. In cases where damage can be repaired by clean-up or reinstatement measures, the responsible state can be required to implement such measures even if the injury does not affect individual states but common interests. Moreover, where non-injured states take such measures instead of the responsible state, they should be entitled to reimbursement of any reasonable expenses thereby incurred, in line with the established principles on such reimbursements.[483] Arguably, this includes compensatory restoration measures that seek to offset the damage by improving the environment in locations or forms other than those harmed.[484]

In situations in which restoration of the *status quo ante* is impossible, state responsibility provides for monetary compensation.[485] However, unlike restoration measures, monetary compensation requires a beneficiary to whom the payment shall be made. This could be resolved by resorting to funding mechanisms established within international organizations,

481 *Duvic-Paoli* (n. 160), 342–343.
482 *Charney* (n. 428), 158; *Lefeber* (n. 105), 120–121; *Boyle/Redgwell* (n. 425), 244–245.
483 *Gaja* (n. 463), 961; *Boyle/Redgwell* (n. 425), 244–245; see chapter 11, section A.
484 See chapter 11, section B.II.1. Also see *Duvic-Paoli* (n. 160), 343, mentioning the example of carbon offset projects to mitigate the climate impact of a coal power project.
485 See *supra* section B.II.3.b), and chapter 11, section B.II.

which could administer the sum to the benefit of the collective interest impaired.[486] For instance, the *Antarctic Liability Annex* provides for a dedicated fund into which payments shall be made in the event that no prompt and effective response action was taken in the event of an environmental emergency.[487] The fund, which is administered by the *Antarctic Treaty Secretariat*, shall be used to reimburse costs for response action taken in other cases.[488] Similar mechanisms could also be established in other fora such as the CBD system, where dedicated funds serving particular purposes have previously been established by a decision of the Conference of Parties.[489] An alternative approach could be to harness existing financial mechanisms, such as the *Global Environmental Facility*, which is the mechanism through which developing countries receive financial assistance in implementing the CBD under Article 21 CBD.[490]

II. Claims for Injured Nationals

1. The Law of Diplomatic Protection in Cases of Transboundary Harm

In many cases of transboundary environmental damage, damage may be suffered not only by the affected states but also by their nationals, especially in the form of personal injury, property damage or economic loss. However, since individuals are not subjects of public international law, they are usually – safe for special provisions such as investor-state dispute settlement clauses – not entitled to make claims against other states under the law of state responsibility.[491] Instead, injury to persons and damage

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486 *Peel* (n. 428), 93.
487 Cf. Antarctic Liability Annex (n. 378), Article 12.
488 Cf. *ibid.*
489 See, e.g., CBD COP, Decision VII/16. Participatory Mechanisms for Indigenous and Local Communities, UN Doc. UNEP/CBD/COP/DEC/VII/16, p. 28 (2004), para. 10, which established a voluntary trust fund to facilitate the participation of indigenous and local communities in the work of the CBD.
490 Cf. *Peel* (n. 428), 93, suggesting the same for breaches of the Montreal Protocol on Substances that Deplete the Ozone Layer (16 September 1987; effective 01 January 1998), 1522 UNTS 3, which in Article 10 provides for a financial mechanism similar to that of the CBD. Also see *Xue* (n. 26), 259–266.
491 See *Lassa F. L. Oppenheim*, International Law: A Treatise (2nd ed. 1912), § 289. But note that according to Article 33 ARSIWA, the rules in these articles on reparation are without prejudice to any right which may accrue directly to any non-state actor as a result of state responsibility. This is the case under some

to property resulting from internationally wrongful acts causing environmental harm is seen as being part of the injury caused to the affected state.[492] Consequently, the state has the right (but no obligation[493]) to claim reparation for the damage to its territory, including damages caused to its nationals or other persons under its jurisdiction.[494]

The invocation of another state's international responsibility for injury caused to nationals is called *diplomatic protection*. The ILC has elaborated a set of *Draft Articles on Diplomatic Protection*,[495] which set out the rules governing the circumstances and conditions under which diplomatic protection may be exercised. The Draft Articles are widely regarded as a codification of the pertinent rules of customary international law,[496] although they 'involve a degree of progressive development'.[497]

Traditionally and typically, the law of diplomatic protection was concerned with international obligations relating to the treatment of aliens abroad, i.e. nationals of the claimant state while they were present in the

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human rights treaties and in bilateral investment protection agreements, see ARSIWA (n. 5), Commentary to Article 33, para. 4.

492 Cf. PCIJ, Mavrommatis Palestine Concessions (Greece v. United Kingdom), Judgment of 30 August 1924, PCIJ Rep. Ser. B, No. 3, 12, emphasizing that '[b]y taking up the case of one of its subjects and by resorting to diplomatic action or international judicial proceedings on his behalf, a State is in reality asserting its own rights'. Also see ICJ, Nottebohm Case (Liechtenstein v. Guatemala), Second Phase, Judgment of 06 April 1955, ICJ Rep. 4, 24.

493 Cf. ICJ, Barcelona Traction (n. 100), paras. 78–79.

494 *Gautier* (n. 300), 205; see PCIJ, Mavrommatis Palestine Concessions (n. 492), 12.

495 ILC, Draft Articles on Diplomatic Protection with Commentaries (2006), YBILC 2006, Vol. II(2), p. 26.

496 Cf. *John Dugard*, Diplomatic Protection, in: Wolfrum/Peters (ed.), MPEPIL, MN. 6; ICJ, Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo), Preliminary Objections, Judgment of 02 May 2007, ICJ Rep. 582, para. 39; *Anna M. H. Vermeer-Künzli*, The Protection of Individuals by Means of Diplomatic Protection (2007), 9. But see *Bordin* (n. 8), who argues that the 'non-legislative codifications' prepared by the ILC (i.e. those which did not culminate in binding international treaties) lend their authority as codifications of customary international law on a number of institutional and textual factors, such as the membership of the ILC, the procedure of how these codifications are adopted within the ILC and the fact that the codification projects result in coherent and systematic presentation of the relevant rules which are easy to apply to actual cases.

497 *Crawford* (n. 4), 568. The ILC has indicated that it exercised progressive development with regard to Article 5 (cf. commentary, para. 2), Article 8 (cf. commentary, para. 2), Article 15(d) (cf. commentary, para. 11), and Article 19(b) and (c) (cf. commentary, paras. 3 and 4).

responsible state.[498] But the scope of the ILC's Articles on Diplomatic Protection is broader and covers all cases where a state is held responsible for injury allegedly caused to nationals of the claimant state by an internationally wrongful act.[499] Consequently, there is also a case of diplomatic protection when a state invokes the responsibility of another state for an injury suffered by its nationals as a result of transboundary harm originating from the responsible state.[500]

2. The Requirement to Exhaust Local Remedies in Cases of Transboundary Harm

The right of a state to exercise diplomatic protection depends on two essential conditions.[501] The first of these conditions is the *nationality requirement*, which stipulates that a state may only exercise diplomatic protection for natural and legal persons who are nationals of that state.[502] This entails several issues that involve no particular problems in cases of transboundary harm, such as the requirement of a 'genuine link' between the individual and the state[503] and the role of shareholders of companies.[504]

The second condition for the exercise of diplomatic protection is the *exhaustion of local remedies*, which requires that a state may only bring an international claim on behalf of a national when the latter has exhausted all available legal remedies in the state alleged to be responsible for the injury.[505] The rationale behind this requirement is that the responsible

498 ILC, Draft Articles on Diplomatic Protection (n. 495), Commentary to Article 1, para. 4. On the history of diplomatic protection, see *Vermeer-Künzli* (n. 496), 3–17.
499 Cf. ILC, Draft Articles on Diplomatic Protection (n. 495), Commentary to Article 1, para. 4. Other areas where diplomatic protection is exercised for individuals not necessarily present in the jurisdiction of the defendant state are the field of investment protection, see *Crawford* (n. 4), 587–592.
500 Cf. *Lefeber* (n. 105), 122; ILC, Draft Articles on Diplomatic Protection (n. 495), Commentary to Article 15, para. 7–8.
501 Also see Article 44 ARSIWA, which mirrors these conditions as requirements for the admissibility of claims invoking state responsibility.
502 Cf. ILC, Draft Articles on Diplomatic Protection (n. 495), Part Two.
503 See ICJ, Nottebohm Case (Liechtenstein v. Guatemala) (n. 492), 23.
504 For an overview, see *Dugard* (n. 496), MN. 19–52; *Crawford* (n. 4), 573–580.
505 ILC, Draft Articles on Diplomatic Protection (n. 495), Article 14; cf. ICJ, Interhandel (Switzerland v. United States), Preliminary Objections, Judgment of 21 March 1959, ICJ Rep. 6, 27; ICJ, Elettronica Sicula S.p.A. (ELSI) (United States

state shall be given the opportunity to redress its violation by its own means before a case is escalated at the intergovernmental level.[506]

It appears possible that individuals affected by transboundary harm may be able to obtain compensation under the national legal system of the source state. As shown above, there is arguably an emerging rule of customary international law that states shall provide prompt, adequate and effective compensation to foreign victims of transboundary harm in their domestic legal systems.[507] Moreover, it has been argued that existing civil law regimes already provide sufficiently effective remedies for cross-border damage caused by LMOs.[508] At the same time, states are reluctant to accept harmonized standards on civil liability in cases of transboundary harm.[509] This is aptly demonstrated by the *Nagoya–Kuala Lumpur Supplementary Protocol*, which focuses on administrative liability[510] and only vaguely stipulates an obligation of states to provide for civil liability for LMO damage in their domestic legal systems.[511] Nevertheless, it cannot be generally assumed that there are no effective local remedies in the state of origin in situations of transboundary harm caused by LMOs. For an international claim based on state responsibility to be admissible, such remedies would first need to be exhausted, which would require that the claim was brought before the competent tribunals and pursued as far as permitted by the local laws and procedures.[512]

However, it is questionable whether the local remedies rule applies in the context of transboundary harm. Article 15(c) of the Articles on Diplo-

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of America v. Italy), Judgment of 20 July 1989, ICJ Rep. 15, para. 50. See generally *Borchard* (n. 29), 239–247; *Chittharanjan F. Amerasinghe*, Local Remedies in International Law (2nd ed. 2004).

506 ICJ, Interhandel (n. 505), 27.

507 See chapter 8, section F.

508 Cf. *Lucas Bergkamp*, Liability and Redress: Existing Legal Solutions for Traditional Damage, in: CropLife International (ed.), Compilation of Expert Papers Concerning Liability and Redress and Living Modified Organisms (2004) 21; *Thomas Kadner Graziano/Matthias Erhardt*, Cross-Broder Damage Caused by Genetically Modified Organisms: Jurisdiction and Applicable Law, in: Bernhard A. Koch (ed.), Damage Caused by Genetically Modified Organisms (2010) 784.

509 See generally *Anne Daniel*, Civil Liability Regimes as a Complement to Multilateral Environmental Agreements, 12 (2003) RECIEL 225; *Jutta Brunnée*, Of Sense and Sensibility: Reflections on International Liability Regimes as Tools for Environmental Protection, 53 (2004) ICLQ 351.

510 For a clarification of this term, see chapter 2, section G.

511 See chapter 6.

512 ICJ, Elettronica Sicula (n. 505), para. 59; see ILC, Draft Articles on Diplomatic Protection (n. 495), Commentary to Article 14, para. 6.

matic Protection provides that local remedies do not need to be exhausted in situations where there was 'no relevant connection' between the injured person and the state alleged to be responsible. In the view of the ILC, this includes cases of transboundary environmental harm, as it would be 'unreasonable and unfair' to require an injured person to exhaust local remedies even though there was no voluntary link or territorial connection between that person and the state from which the harm emanated.[513] Consequently, a state could make an interstate claim on behalf of its nationals affected by transboundary harm under the law of state responsibility without having to first exhaust any local remedies that might be available.

Nevertheless, it has been called into question whether the requirement to exhaust local remedies should be excluded in all cases of transboundary harm.[514] While governmental action at the interstate level may well be the only way to achieve effective reparation in cases of widespread damage, it has been argued that in more typical cases of transboundary nuisance, there was no obvious reason to exclude the requirement to exhaust local remedies where such remedies were available and feasible to pursue for the injured individuals.[515] Moreover, it has been submitted that state practice indicates that states usually prefer non-discriminatory, transnational access to civil liability under domestic jurisdictions over state liability processed through inter-state claims.[516]

However, this does not justify the assumption that the local remedies rule generally applies to cases of transboundary harm. The decisive difference to conventional cases of diplomatic protection is that in cases of transboundary harm, the victims have not voluntarily subordinated themselves to the jurisdiction of the source state.[517] Instead, damage is caused to individuals residing in the jurisdiction of the injured state, and the causation of damage may well be the only tangible link between the source state and the injured individuals.[518] Therefore, it seems unjustifiable to

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513 *Ibid.*, Commentary to Article 15, para. 7.

514 *Alan E. Boyle*, Globalising Environmental Liability: The Interplay of National and International Law, 17 (2005) J. Envt'l L. 3, 24; *Boyle/Redgwell* (n. 425), 234.

515 Cf. *Okowa* (n. 279), 219–220, who refers to cases where injury is suffered by a multiplicity of cases scattered in different states, as in the case of long-range air pollution or an incident of the Chernobyl type.

516 *Boyle/Redgwell* (n. 425), 234.

517 *Günther Handl*, The Environment: International Rights and Responsibilities, 74 (1980) ASIL Proceedings 223, 232; *Lammers* (n. 289), 622; *Lefeber* (n. 105), 123; *Okowa* (n. 279), 218–219.

518 *Lefeber* (n. 105), 123.

assume a general requirement to exhaust local remedies in the source state – even where they are available – before a state affected by transboundary harm can make claims on behalf of its nationals.[519]

This conclusion is also supported by the ILC's commentary on the *Principles on Allocation of Loss*, which underlines that these principles were 'without prejudice to the rules relating to state responsibility and any claim that may lie under those rules in the event of a breach of the obligations of prevention'.[520] Hence, the ILC envisaged the law of state responsibility and civil liability as complementary rather than mutually exclusive regimes.[521]

In any event, the local remedies rule does not apply where a state asserts claims not on behalf of its nationals but in its own name.[522] Article 14(3) of the Articles on Diplomatic Protection provides that the exhaustion of local remedies is only required where a claim is brought 'preponderantly on the basis of an injury to a national'. In cases of transboundary harm, the principal injury is that to the territorial integrity of the affected state, whereas damage suffered by individuals is only consequential to that injury. Consequently, claims for reparation are not – at least not preponderantly – based on injury to nationals, and thus the local remedies requirement is inapplicable in these cases.[523]

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519 Cf. *Dionyssios M. Poulantzas*, The Rule of Exhaustion of Local Remedies and Liability for Space Vehicle Accidents, 31 (1965) Journal of Air Law and Commerce 261; *C. Wilfried Jenks*, Liability for Ultra-Hazardous Activities in International Law, 117 (1966) RdC 99, 121; *Lefeber* (n. 105), 123; *Amerasinghe* (n. 505), fn. 5 at p. 248.

520 ILC, Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, with Commentaries (2006), YBILC 2006, vol. II(2), p. 56, General Commentary, para. 7; see chapter 8, section E.

521 Cf. *Boyle/Redgwell* (n. 425), 234.

522 ILC, Draft Articles on Diplomatic Protection (n. 495), Commentary to Article 14, para. 9; see *Amerasinghe* (n. 505), 146–168.

523 Cf. *Kenneth B. Hoffman*, State Responsibility in International Law and Transboundary Pollution Injuries, 25 (1976) ICLQ 509, 537–541; *Lammers* (n. 289), 622; *Lefeber* (n. 105), 123–124; *Alexandre Kiss*, Present Limits to the Enforcement of State Responsibility for Environmental Damage, in: Francesco Francioni/Tullio Scovazzi (eds.), International Responsibility for Environmental Harm (1991) 3, 7; *Gautier* (n. 300), 205.

III. Invocation and Enforcement of State Responsibility

While state responsibility arises automatically as a legal consequence of the commission of an internationally wrongful act, the injured state or other interested states commonly need to raise claims for cessation or reparation. Thus, once the standing of a state to invoke another state's international responsibility has been established, the question arises of how such a claim is to be made and how disputes over the existence of a breach of international law or the obligation to make reparation can be resolved.[524] The ILC's Articles on State Responsibility only provide some fundamental guidance on this issue (1.). In the event of controversies about a breach or its legal consequences, states resort to dispute settlement, which involves negotiations, arbitration and adjudication (2.). An alternative means to promoting compliance with multilateral environmental agreements may be seen in dedicated compliance procedures established by these agreements (3.).

1. The Claims Process Envisaged in the ARSIWA

In the version adopted by the ILC in its first reading, the ARSIWA included an elaborate system for resolving disputes regarding their application or interpretation.[525] However, when it became clear that the articles would not evolve into a binding multilateral treaty, these articles were discarded.[526] Consequently, the final ARSIWA only contain some fragmented rules on the process of invoking state responsibility, which only covers certain procedural aspects.

Article 43(1) ARSIWA provides that an injured state that invokes another state's responsibility shall give notice of its claim to that state. According to Article 43(2), the injured state may specify the conduct it expects the responsible state to take to cease the wrongful act and what form of reparation shall be made. In principle, the injured state is entitled to choose between the available forms of reparation; in particular, it may opt for compensation instead of restitution. However, there may be situations in which the injured state may not 'pocket compensation and walk away

524 See *Borchard* (n. 29), 247–250.

525 Cf. ILC, Draft Articles on State Responsibility with Commentaries Thereto Adopted by the ILC on First Reading (1997), UN Doc. A/CN.4/L.528/Add.3, 352–373.

526 *Crawford* (n. 4), 553.

from an unresolved situation',[527] especially in cases involving environmental damage. As shown below, international case law favours the implementation of clean-up and restoration measures over the mere payment of compensation for environmental damage.[528] This is particularly true where a state claims reparation as a non-injured state, acting on behalf of a collective interest.[529] The ILC also noted that such situations could not be resolved by a settlement, just as an injured state may not release the responsible state from continuing obligations owed to a larger group of states or the international community as a whole.[530]

Pursuant to Article 45 ARSIWA, the responsibility of a state may not be invoked if the injured state has validly waived the claim or acquiesced in its lapse. This refers to conduct by the injured state in response to the internationally wrongful act, as opposed to consent, which precludes the wrongfulness of the breach from the outset.[531] Besides, it is often disputed whether a lapse of time can result in a loss of the right to invoke responsibility. In the *Phosphate Lands* case, the ICJ acknowledged that international law does not specify any specific time limits and that it was for the Court to determine in the light of the circumstances of each case whether the passage of time has rendered an application inadmissible.[532]

2. Settlement of Disputes

In many cases, the invocation of another state's responsibility for a breach of international law will entail disagreements over the relevant facts and the pertinent rules of international law. A 'dispute' arises when a state addresses specific claims to another state, which the latter rejects.[533] Nu-

527 ARSIWA (n. 5), Commentary to Article 43, para. 6.

528 See chapter 11.

529 See *supra* section C.I.2.

530 ARSIWA (n. 5), Commentary to Article 43, para. 6.

531 *Crawford* (n. 4), 558.

532 ICJ, Certain Phosphate Lands in Nauru (Nauru v. Australia), Preliminary Objections, Judgment of 26 June 1992, ICJ Rep. 240, 253–254.

533 *Christian Tomuschat*, Article 2(3) UNC, in: Bruno Simma/Daniel-Erasmus Khan et al. (eds.), The Charter of the United Nations (3rd ed. 2012) 181–199, 27. See PCIJ, Mavrommatis Palestine Concessions (n. 492), 11, which noted that '[a] dispute is a disagreement on a point of law or fact, a conflict of legal views or of interests between two persons'. Also see ICJ, Right of Passage over Indian Territory (Portugal v. India), Preliminary Objections, Judgment of 26 November 1957, ICJ Rep. 125, 148–149; ICJ, Case Concerning East Timor (Por-

merous provisions of international law provide that states shall resolve their disputes peacefully, i.e. without resorting to armed force.[534] The most prominent instance is Article 2(3) of the *UN Charter*, which stipulates that all UN Members 'shall settle their international disputes by peaceful means in such a manner that international peace and security, and justice, are not endangered'.[535] Article 33(1) of the Charter provides a list of such peaceful means, namely 'negotiation, enquiry, mediation, conciliation, arbitration, judicial settlement, resort to regional agencies or arrangements, or other peaceful means of their choice'. However, this is merely indicative[536] because 'general international law takes an eclectic approach to the methods and fora used to settle international disputes'.[537]

In practice, most environmental disputes that are resolved are settled amicably through negotiations between the states concerned.[538] This is particularly true for cases of transboundary harm.[539] It has been observed that 'states often negotiate compensation or some other performance due for an internationally wrongful act'.[540] Such settlements usually do not address (or admit) state responsibility but are usually made *ex gratia* and expressly without prejudice to any question of responsibility.[541] The amount of compensation is usually not calculated in detail but determined by a lump-sum agreement that stipulates a global sum payable to the injured state and is understood to cover all claims.[542]

Cases which cannot be solved through diplomatic channels are ripe for settlement through arbitration or adjudication, albeit there is no obligation to participate in any such proceedings under general international

tugal v. Australia) (n. 471), 99–100. On the term 'international environmental disputes', see *Richard B. Bilder*, The Settlement of Disputes in the Field of the International Law of the Environment, 144 (1975) RdC 140, 153–156.

534 See *Bilder* (n. 533), 156–159; *Tomuschat* (n. 533), 37.

535 UN Charter (n. 178), Article 2(3); also see UNGA, Declaration on Principles of International Law Concerning Friendly Relations and Co-Operation Among States in Accordance with the Charter of the United Nations (24 October 1970), UN Doc. A/RES/2625 (XXV) (hereinafter 'Friendly Relations Declaration').

536 See *ibid.*, which provides that 'parties shall agree upon such peaceful means as may be appropriate to the circumstances and nature of the dispute'.

537 *Boyle/Redgwell* (n. 425), 264; also see *Bilder* (n. 533), 159–161.

538 *Bilder* (n. 533), 224–226.

539 See the cases discussed by *Barboza* (n. 366), 50–60.

540 *Michael Waibel*, The Diplomatic Channel, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 1085, 1095.

541 *Ibid.*; see chapter 11.

542 *Ibid.; Barboza* (n. 366), 62–64.

law. Moreover, although the *International Court of Justice* (ICJ) is the 'principal judicial organ' of the United Nations,[543] it enjoys no priority as a forum for dispute settlement.[544] The jurisdiction of the Court comprises all cases which the parties refer to it by special agreement, matters specifically provided for in the UN Charter and in international agreements,[545] and cases between those (currently 73[546]) states which have accepted the jurisdiction of the Court as compulsory.[547] While the ICJ has dealt with a number of cases involving environmental matters,[548] it is not the only available forum for the settlement of environmental disputes. Many of these disputes were submitted to *ad hoc* arbitration,[549] including under the auspices of the *Permanent Court of Arbitration*, which has elaborated dedicated rules for arbitration of disputes concerning natural resources or the environment.[550] Besides, the *International Tribunal of the Law of the Sea* (ITLOS) has addressed several cases concerning the marine environment,[551] although the obligatory dispute settlement mechanism under the

543 UN Charter (n. 178), Article 92.
544 *Boyle/Redgwell* (n. 425), 264.
545 ICJ Statute (n. 157), Article 36(1).
546 Cf. ICJ, Declarations Recognizing the Jurisdiction of the Court as Compulsory, available at: http://www.icj-cij.org/en/declarations (last accessed 28 May 2022).
547 ICJ Statute (n. 157), Article 36(2)-(5).
548 Some of the most prominent cases being ICJ, Nuclear Tests (Australia v. France) (n. 472); ICJ, Pulp Mills (n. 283); ICJ, Gabčíkovo-Nagymaros (n. 138); ICJ, Whaling in the Antarctic (Australia v. Japan: New Zealand intervening) (n. 472); ICJ, Certain Activities/Construction of a Road (Merits) (n. 160); ICJ, Certain Activities (Compensation) (n. 267).
549 See Trail Smelter Case, Decision of 1941 (n. 248); Affaire du Lac Lanoux (Spain v. France), 16 November 1957, XII RIAA 281; PCA, MOX Plant Case (Ireland v. United Kingdom), Award of 06 June 2008, Case No. 2002–01; PCA, Iron Rhine Arbitration (Belgium v. Netherlands), Award of 24 May 2005, Case No. 2003–02, XXVII RIAA 35.
550 PCA, Optional Rules for Arbitration of Disputes Relating to Natural Resources and/or the Environment (2001); see *Dane P. Ratliff*, The PCA Optional Rules for Arbitration of Disputes Relating to Natural Resources and/or the Environment, 14 (2001) Leiden J. Int'l L. 887.
551 See, e.g., ITLOS, The MOX Plant Case (Ireland v. United Kingdom), Order of 03 December 2001, Case No. 10, ITLOS Rep. 89; ITLOS, Case concerning Land Reclamation by Singapore in and around the Straits of Johor (Malaysia v. Singapore), Provisional Measures, Order of 08 October 2003, Case No. 12, ITLOS Rep. 10; ITLOS, Responsibilities and Obligations of States (n. 141); ITLOS, Southern Bluefin Tuna Cases (New Zealand v. Japan; Australia v. Japan), Provisional Measures, Order of 27 August 1999, ITLO cases Nos. 3 and 4, ITLOS Rep. 288.

UN Convention on the Law of the Sea is not adjudication by ITLOS, but arbitration.[552]

Many multilateral environmental agreements contain provisions for the settlement of disputes over their interpretation or application.[553] For instance, Article 27 of the CBD provides that parties shall first seek to resolve such disputes by negotiations; they may also 'seek the good offices of, or request mediation by, a third party'. If the dispute cannot be resolved by these means, the parties may submit the case either to arbitration under dedicated rules laid down in Annex II to the CBD or to the ICJ, which can both render a legally binding decision to resolve the dispute.[554] If neither of the procedures has been accepted by all parties to the dispute,[555] the dispute shall be submitted to 'conciliation' under rules also laid down in Annex II to the CBD.[556] The conciliation commission shall render a proposal for the resolution of the dispute, which is not legally binding[557] but which the parties must consider in good faith.[558] The CBD's provisions on dispute settlement also apply to the CBD protocols.[559] However, they have so far never been used.

In any event, arbitral and judicial proceedings seem not to be well equipped to deal with global environmental problems, particularly due

552 UNCLOS (n. 140), Article 287(5); see *Tullio Treves*, Article 287 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017), MN. 20.

553 See, e.g., Convention on International Trade in Endangered Species of Wild Fauna and Flora (03 March 1973; effective 01 July 1975), 993 UNTS 244, Article XVIII; Vienna Convention for the Protection of the Ozone Layer (22 March 1985; effective 22 September 1988), 2513 UNTS 293, Article 11; United Nations Framework Convention on Climate Change (09 May 1992; effective 21 March 1994), 1771 UNTS 107, Article 14; Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (22 March 1989; effective 05 May 1992), 1673 UNTS 57, Article 20; International Plant Protection Convention (New Revised Text) (17 November 1997; effective 02 October 2005), 2367 UNTS 223, Article XIII.

554 Convention on Biological Diversity (05 June 1992; effective 29 December 1993), 1760 UNTS 79 (hereinafter 'CBD'), Article 27(3); see *Lyle Glowka* et al., A Guide to the Convention on Biological Diversity (1994), 118.

555 So far, only four parties (namely Austria, Cuba, Georgia, and Latvia) have accepted one or both of the procedures, see CBD Secretariat, Handbook of the Convention on Biological Diversity (3rd ed. 2005), 385–395.

556 CBD (n. 554), Article 27(4).

557 See *Glowka* et al., IUCN Guide to the CBD (n. 554), 119.

558 CBD (n. 554), Annex II, Part 2, Article 5.

559 *Ibid.*, Article 27(5).

to the requirement to have *standing* to invoke breaches of international obligations.[560] While parties to multilateral treaties may intervene in proceedings concerning the interpretation of those treaties before the ICJ and ITLOS,[561] intervention in respect of customary obligations requires the third party to be 'affected' by the decision in the case and is also subject to judicial discretion.[562] Consequently, in his separate opinion in the *Gabčíkovo-Nagymaros* case, judge *Weeramantry* expressed the view that the Court's traditional *inter partes* procedures might be inadequate for dealing with allegations of breaches involving important obligations *erga omnes*, such as 'momentous environmental issues' with consequences spreading beyond the immediate litigants.[563]

3. Non-Compliance Procedures

Another instrument to address the non-compliance of states with their international obligations is dedicated *compliance mechanisms* (or *non-compliance procedures*), which have become a ubiquitous feature of multilateral environmental agreements.[564] Compliance mechanisms seek to address cases of non-compliance by inducing and aiding states to resume the performance of their obligations under the respective instrument. They usually operate in a non-adversarial, consultative manner and are thus situated between diplomatic negotiations and judicial forms of dispute settlement.[565] Moreover, they are usually 'strictly forward-looking' in the

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560 See *supra* section C.I.

561 ICJ Statute (n. 157), Article 63; ITLOS Statute, Annex VI of UNCLOS (n. 140), Article 32.

562 ICJ Statute (n. 157), Article 62; ITLOS Statute, Annex VI of UNCLOS (n. 140), Article 31; see *Boyle/Redgwell* (n. 425), 263.

563 ICJ, Gabčíkovo-Nagymaros (n. 138), Separate opinion Judge Weeramantry, p. 117–118.

564 Cf. See generally *Malgosia A. Fitzmaurice/C. Redgwell*, Environmental Non-Compliance Procedures and International Law, 31 (2000) Netherlands Yearbook of International Law 35; *Jutta Brunnée*, Enforcement Mechanisms in International Law and International Environmental Law, in: Ulrich Beyerlin/Peter-Tobias Stoll/Rüdiger Wolfrum (eds.), Ensuring Compliance with Multilateral Environmental Agreements (2006) 1, 12–22; *Jan Klabbers*, Compliance Procedures, in: Daniel Bodansky/Jutta Brunnée/Ellen Hey (eds.), The Oxford Handbook of International Environmental Law (2007); *Duvic-Paoli* (n. 160), 343–354; *Boyle/Redgwell* (n. 425), 254–260.

565 Cf. *Sands* et al. (n. 108), 172.

sense that their sole objective is to achieve future compliance rather than sanctioning past violations.[566] Compliance mechanisms rest on the recognition that many cases of non-compliance are not caused by intent or bad faith but rather by the inability of the party concerned to fulfil its obligations.[567] Consequently, the main feature of many compliance mechanisms is the provision of technical or financial support.[568]

a) The Compliance Mechanism Under the Cartagena Protocol

aa) Role, Functions and Procedures

The most relevant compliance mechanism in the present context is that of the Cartagena Protocol.[569] In line with Article 34 of the Protocol, the first meeting of the parties to the Protocol (COP-MOP) established *Procedures and Mechanisms on Compliance*.[570] The mechanism's objective is to promote compliance with the Protocol, address cases of non-compliance, and provide advice or assistance on matters relating to compliance.[571] The mechanism shall operate in a non-adversarial and cooperative manner and be guided by the principles of transparency, fairness and predictability.[572] The mechanism's functions are performed by a *Compliance Committee*

566 *Duvic-Paoli* (n. 160), 347.
567 *Brunnée* (n. 564), 19; *Klabbers* (n. 564), 103.
568 *Brunnée* (n. 564), 18; see *Duvic-Paoli* (n. 160), 345–346.
569 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 January 2000; effective 11 September 2003), 2226 UNTS 208.
570 CP COP-MOP, Procedures and Mechanisms on Compliance Under the Cartagena Protocol on Biosafety, Annex to Decision BS-I/7, UN Doc. UNEP/CBD/BS/COP-MOP/1/15, p. 65, Annex (2004); see *Veit Koester*, The Compliance Mechanism of the Cartagena Protocol on Biosafety: Development, Adoption, Content, and First Years of Life, in: Marie-Claire Cordonier Segger/Frederic Perron-Welch/Christine Frison (eds.), Legal Aspects of Implementing the Cartagena Protocol on Biosafety (2013) 164; *Chiara Ragni*, Procedures and Mechanisms on Compliance Under the 2000 Cartagena Protocol on Biosafety to the 1992 Convention on Biological Diversity, in: Tullio Treves/Laura Pineschi et al. (eds.), Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements (2009) 101.
571 Procedures and Mechanisms on Compliance under the Cartagena Protocol (n. 570), section I, para. 1.
572 *Ibid.*, section I, para. 2–3.

consisting of 15 individuals elected by the COP-MOP and serving in a personal capacity.[573]

Besides addressing general issues of compliance and making recommendations, the Compliance Committee's main task is to review individual cases of non-compliance referred to it.[574] Submissions can be made by any party either with respect to its own compliance (*self-trigger*) or with respect to another party (*party-to-party trigger*), provided that it is 'affected or likely to be affected' by the other party's alleged non-compliance.[575] This limits the potential of the compliance mechanism because it does not allow parties to defend the common interest of all parties in ensuring the safe handling and use of LMOs in cases where either no party is individually affected or where the affected party elects not to make a submission.[576] Also, unlike similar mechanisms,[577] neither the CBD Secretariat nor the public (including NGOs[578]) is entitled to make submissions.

Once a submission has been made, the party concerned shall respond and provide the 'necessary information'.[579] Besides the information provided by the party concerned and the party that has made the submission, the Compliance Committee may also consider relevant information from other (subsidiary) bodies of the CBD and the Cartagena Protocol,[580] which

573 *Ibid.*, section II; see *Ragni* (n. 570), 106–107.
574 Cf. Procedures and Mechanisms on Compliance under the Cartagena Protocol (n. 570), section III.
575 *Ibid.*, section IV, para. 1.
576 The limitation that only states which are affected or likely to be affected by the non-compliance of another party may trigger the compliance mechanism is a restriction which is common to MEAs that address bilateral transboundary relations, see *Francesca Jacur Romanin*, Triggering Non-Compliance Procedures, in: Tullio Treves/Laura Pineschi et al. (eds.), Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements (2009) 373, 375–376. Also see *Duvic-Paoli* (n. 160), 347–350, who argues that a merit of compliance mechanisms is that they allow for the enforcement of 'non-bilateralizable' *erga omnes* obligations. Yet, this shows once more that, although the stated objective of the Cartagena Protocol is to contribute to the conservation and sustainable use of biodiversity as a whole, the Protocol's actual focus is rather on ensuring each state's sovereignty with regard to the admission of LMOs into its territory.
577 See *Jacur Romanin* (n. 576), 377–381.
578 See *Astrid Epiney*, The Role of NGOs in the Process of Ensuring Compliance with MEAs, in: Ulrich Beyerlin/Peter-Tobias Stoll/Rüdiger Wolfrum (eds.), Ensuring Compliance with Multilateral Environmental Agreements (2006) 319.
579 Procedures and Mechanisms on Compliance under the Cartagena Protocol (n. 570), section IV, para. 3.
580 *Ibid.*, section V.

also (non-explicitly) includes the CBD Secretariat as a potential source of information.[581]

To address cases of non-compliance, the Committee may take a range of measures such as providing advice or assistance to the party concerned and making recommendations to the COP-MOP regarding the provision of financial and technical assistance.[582] The Committee may request the party concerned to develop a 'compliance action plan' setting out measures to return to compliance, although the timeframe for such a plan is to be agreed upon between the Committee and the party concerned.[583] The Committee may also 'invite' the party concerned to submit progress reports and report about its efforts to the COP-MOP.[584] Cases of non-compliance shall remain on the Committee's agenda until adequately resolved'.[585]

The COP-MOP may, upon the recommendations of the Compliance Committee, provide financial and technical assistance, issue a 'caution' to the concerned party, and request the CBD's Executive Secretary to publish cases of non-compliance in the Biosafety Clearing-House. The COP-MOP shall also be responsible for taking specific measures to address cases of repeated non-compliance.

In other compliance mechanisms, measures in response to persistent or repeated non-compliance include the suspension of treaty rights or even the imposition of trade restrictions,[586] which can be seen as an implementation of the right to treaty suspension under Article 60 VCLT.[587] However, developing a catalogue of such measures was deferred until

581 *Koester* (n. 570), 171.

582 Procedures and Mechanisms on Compliance under the Cartagena Protocol (n. 570), section VI, para. 1(a).

583 *Ibid.*, section V, para. 2(c).

584 *Ibid.*, section V, para. 1(e).

585 *Ibid.*

586 Cf. CP COP-MOP, Compliance (Article 34): Measures in Cases of Repeated Non-Compliance: Note by the Executive Secretary, UN Doc. UNEP/CBD/BS/COP-MOP/3/2/Add.1 (2006); *Ragni* (n. 570), 114–115; *Sand* (n. 429); also see *Brunnée* (n. 564), 19–20, noting that in providing for the suspension of privileges, these MEAs come close to deploying actual penalties for non-compliance, 'which has remained rare in general international law'.

587 VCLT (n. 243); cf. ARSIWA (n. 5), Commentary to Chapter II, para. 4 see *Malgosia A. Fitzmaurice*, Non-Compliance Procedures and the Law of Treaties, in: Tullio Treves/Laura Pineschi et al. (eds.), Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements (2009) 453, 467–472; *Sand* (n. 429), 259.

'experience may justify the need for developing and adopting such measures'.[588] One observer assumed that this made it unlikely that the COP-MOP would ever adopt stringent measures, as such measures could not be developed *in abstracto* when motivated by a concrete case of repeated non-compliance.[589]

bb) Recent Practice

To date, the Compliance Committee has not yet received any submission concerning individual non-compliance.[590] One of the reasons for this may be that only states can make submissions, while the compliance mechanisms of other multilateral environmental agreements are mostly triggered by the respective treaty secretariats and NGOs rather than states.[591] Consequently, the Compliance Committee has so far only been able to review 'general issues of compliance'.[592]

Nevertheless, apparently based on a broad interpretation of its mandate, the Compliance Committee has recently begun to address the compliance of individual states without having received a submission, especially concerning the obligation to implement the Protocol at the national level and with regard to reporting obligations.[593] In this respect, the Compliance Committee expressly decided to consider certain cases as *individual cases of non-compliance*.[594] Besides, it requested certain parties to develop and

588 Procedures and Mechanisms on Compliance under the Cartagena Protocol (n. 570), section VI, para. 2(d); CP COP-MOP, Decision BS-IV/1. Report of the Compliance Committee, UN Doc. UNEP/CBD/BS/COP-MOP/4/18, p. 33 (2008), para. 3.

589 *Koester* (n. 570), 182.

590 On the work of the Compliance Committee in its first years, see *Ragni* (n. 570), 109–110; *Koester* (n. 570), 172–186. There appears to be no more recent assessment of the Committee's work.

591 *Ragni* (n. 570), 119.

592 Cf. Procedures and Mechanisms on Compliance under the Cartagena Protocol (n. 570), section III, para. 1(d).

593 CP Compliance Committee, Report of the Committee on the Work of Its Fourteenth Meeting, UN Doc. CBD/CP/CC/14/5 (2017), para. 25; CP Compliance Committee, Report of the Committee on the Work of Its Fifteenth Meeting, UN Doc. CBD/CP/CC/15/5 (2018), paras. 25–29; also see CP Compliance Committee, Review of General Issues of Compliance: Report of the Executive Secretary, UN Doc. CBD/CP/CC/15/4 (2018).

594 CP Compliance Committee, Report of 15th Meeting (2018) (n. 593), para. 30.

implement *compliance actions plans*[595] and, in some instances, even recommended that the COP-MOP issue a caution to these parties.[596] However, the decision ultimately adopted by the COP-MOP neither expressly named nor cautioned the parties concerned.[597]

cc) Legal Status

The measures adopted by the Compliance Committees are not legally binding upon the parties concerned.[598] Arguably, the obligatory nature of non-compliance procedures lies more in the duty of parties to participate than in their outcomes and results.[599] At the same time, compliance mechanisms produce an 'authoritative, institutional finding of non-compliance' that not only exerts 'social pressure' on the party concerned but, over time, also generates a 'pattern of "institutionalized" protest against non-compliance'.[600] Therefore, the effect of most decisions can be described as entailing a 'soft' or 'de facto' binding effect,[601] thus coming close to the 'soft law' status of COP decisions.[602]

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595 *Ibid.*, para. 32.

596 CP Compliance Committee, Report of the Committee on the Work of Its Thirteenth Meeting, UN Doc. UNEP/CBD/BS/CC/13/6 (2016), para. 12(g) and Annex I; CP Compliance Committee, Report of 15th Meeting (2018) (n. 593), para. 37 and Annex I.

597 Cf. CP COP-MOP, Decision VIII/1. Compliance, UN Doc. CBD/CP/MOP/DEC/VIII/1 (2016); CP COP-MOP, Decision 9/1. Compliance, UN Doc. CBD/CP/MOP/DEC/9/1 (2018); see CP Compliance Committee, Report of the Committee on the Work of Its Sixteenth Meeting, UN Doc. CBD/CP/CC/16/7 (2019), paras. 12–13, noting with regret that the COP-MOP had not taken up the Committee's recommendation to caution the party concerned, and acknowledging that 'naming Parties in non-compliance could be a useful tool for promoting compliance'.

598 Cf. *Robin R. Churchill/Geir Ulfstein*, Autonomous Institutional Arrangements in Multilateral Environmental Agreements: A Little-Noticed Phenomenon in International Law, 94 (2000) AJIL 623, 643–647; *Klabbers* (n. 564), 999; *Enrico Milano*, The Outcomes of the Procedure and Their Legal Effects, in: Tullio Treves/Laura Pineschi et al. (eds.), Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements (2009) 407, 412.

599 *Milano* (n. 598), 417.

600 *Ibid.*, 414; also see *Duvic-Paoli* (n. 160), 352.

601 *Fitzmaurice* (n. 587), 463–467.

602 See chapter 5, section B.II.

b) The Relationship Between Non-Compliance Procedures and State Responsibility

As set out above, non-compliance procedures react to breaches of international law by inducing and aiding states to resume the performance of their obligations. Against this background, it is questionable how they relate to the other consequences of state responsibility, particularly the right of the injured state(s) to take countermeasures and the obligation to make full reparation for any injury caused by the breach. More specifically, one wonders whether non-compliance procedures constitute *lex specialis* regimes in the sense of Article 55 ARSIWA that precede over the general rules on state responsibility.[603]

However, these mechanisms are not intended to constitute 'self-contained regimes' that address all the consequences of non-compliance differently, separately and independently from the general rules on state responsibility.[604] As shown above, the sole objective of compliance mechanisms is to ensure future compliance with the obligation. In terms of state responsibility, compliance mechanisms focus on achieving cessation and non-repetition of the wrongful conduct, but not on repairing the injury that the non-compliance has caused in the past. However, this does not mean that the non-compliant state is relieved from its international responsibility for having acted inconsistently with its international obligations. Nor is a state 'immunized' from responsibility while implementing a compliance action plan agreed with the competent compliance committee.[605] Consequently, compliance mechanisms are not an alternative to the law of state responsibility but should rather be seen as an (albeit 'softer'[606]) means to implement the international responsibility of a state.[607]

The above conclusions also apply to the Cartagena Protocol's non-compliance mechanism. According to Article 13, the compliance procedures shall be 'separate from, and without prejudice to', the arbitration and

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603 See *Laura Pineschi*, Non-Compliance Procedures and the Law of State Responsibility, in: Tullio Treves/Laura Pineschi et al. (eds.), Non-Compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements (2009) 483, 483–486.

604 *Ibid.*, 490; *Fitzmaurice/Redgwell* (n. 564), 58; see generally *Eckart Klein*, Self-Contained Regime, in: Wolfrum/Peters (ed.), MPEPIL.

605 But see *Klabbers* (n. 564), 1006.

606 *Fitzmaurice/Redgwell* (n. 564), 39; *Boyle/Redgwell* (n. 425), 248.

607 *Pineschi* (n. 603), 497.

conciliation procedures under Article 27 of the CBD.[608] Moreover, the *Supplementary Protocol on Redress and Liability* to the Cartagena Protocol provides in Article 11 that it shall not affect the rights and obligations of states under the general rules of state responsibility.[609] Although this does not directly apply to the Cartagena Protocol, it can be seen as a clear expression of *opino iuris* by the parties to the latter that adopted the Supplementary Protocol by consensus.[610]

Before the Cartagena Protocol entered into force, a minority of parties proposed establishing a differentiated, more comprehensive regime on non-compliance. According to this approach, any failure by a developed country or LMO-exporting party to comply with the Cartagena Protocol would have triggered a judicial process and entailed sanctions, whereas non-compliance by a developing country or importing party should have only triggered a non-judicial cooperative procedure.[611] However, this approach was rejected in favour of the non-judicial, non-adversarial mechanism now in place.[612] Consequently, the Protocol's compliance mechanism does not constitute a 'self-contained regime' in the sense that it provides a legal framework for the consequences of non-compliance detached from the law of state responsibility.[613]

Two scenarios clearly demonstrate that compliance mechanisms are neither intended nor able to replace the law of state responsibility. The first case is where a state has suffered individual injury as a consequence of the non-compliance.[614] As shown above, non-compliance procedures generally focus on the resumption of the performance of the obligation but do not provide for reparation for the injury suffered as a consequence of the non-performance. Thus, when a state can establish that it has been injured by the breach within the meaning of Article 42 ARSIWA, it is entitled to reparation under the law of state responsibility.[615] This applies, in particu-

608 See *supra* section C.III.2.
609 See chapter 6, section E.III.
610 See chapter 6, section A.
611 ICCP, Report of the Intergovernmental Committee for the Cartagena Protocol on Biosafety on the Work of Its First Meeting, UN Doc. UNEP/CBD/ICCP/1/9 (2001), 33, para. 54; IISD, First Meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety: 11–15 December 2000, ENB Vol. 9 No. 173 (2000), 8.
612 Procedures and Mechanisms on Compliance under the Cartagena Protocol (n. 570), Section IV; see *Ragni* (n. 570), 119.
613 *Ibid.*; also see *Fitzmaurice/Redgwell* (n. 564), 57–59.
614 *Pineschi* (n. 603), 494.
615 *Ibid.*; see *supra* section B.II.

lar, where multilateral treaties create bilateral obligations,[616] such as the obligations relating to the transboundary movements of LMOs under the Cartagena Protocol.[617] In principle, such claims would have to be made independently from the non-compliance procedure.[618] While it would be advisable for the injured state to resort first to any available non-compliance procedure and makes individual claims for reparation only after the procedure has formally determined a case of non-compliance,[619] this appears not to be legally required.

The second case where a 'fallback' to the law of state responsibility is required is where a non-compliance mechanism fails to fulfil its objective. This may be either due to a continuous violation despite a decision of the system's competent organ or due to a procedural failure, i.e. the inability of the system to deliver on its mandate, for instance because there is a deadlock in the relevant decision-making organ.[620] In these cases, the non-compliance mechanism does not achieve the purpose for which it has been established.[621] Where the aim of achieving a resumption of performance by following the non-confrontational approach fails, it is required to resort to the general rules of state responsibility, including the right to take countermeasures in line with the principles set out above.[622] In this respect, the suspension of treaty rights as a 'last resort' to address persistent non-compliance could also be seen as a form of institutionalized, collective countermeasures.[623]

4. Conclusions

States have multiple options to invoke another state's responsibility for a breach of international law. If a breach is controversial, international arbitration or adjudication is most commonly used. However, states are

616 *Pineschi* (n. 603), 496.
617 See chapter 3, section A.II.
618 See *Fitzmaurice/Redgwell* (n. 564), 56–57.
619 Cf. *Ragni* (n. 570), 116.
620 *Pineschi* (n. 603), 492.
621 This is regarded as a case of 'regime failure', see *Martti Koskenniemi*, Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law: Report of the Study Group of the International Law Commission, UN Doc. A/CN.4/L.682 (2006), paras. 188–190.
622 See *Pineschi* (n. 603), 493 and fn. 42; see *supra* section B.III.
623 Cf. *Fitzmaurice/Redgwell* (n. 564), 55–56.

not generally obliged to participate in such proceedings unless they have agreed so, either in a general way (e.g. by accepting the ipso facto jurisdiction of the ICJ) or by way of a special agreement.

If binding dispute settlement is unavailable, non-compliance and conciliation procedures under international treaties are an alternative to draw attention to a state's (alleged) violations. In the present context, the conciliation process under the CBD and the non-compliance mechanism under the Cartagena Protocol could be relevant fora to address, for instance, unilateral releases of self-spreading LMOs that are likely to or already have spread to the territory of other states or in areas beyond national jurisdiction. These mechanisms do not produce enforceable 'hard' decisions but only quasi-normative 'soft law'. Nevertheless, even a 'soft' yet formal finding of non-compliance arguably exerts considerable pressure on a state, making it more likely that it ceases the conduct in question and makes reparation.

D. Summary and Outlook

The present chapter has assessed the requirements and conditions under which a state can be held responsible for a breach of international law. In principle, the law of state responsibility provides far-reaching consequences, including unlimited responsibility for any injury caused by the breach. At the same time, however, state responsibility is also subject to several limitations and caveats.

First of all, states are not generally responsible for the conduct of individuals within their jurisdiction. The conduct of natural or legal persons is only attributed to the state under certain limited conditions; there is no 'vicarious responsibility' of states for the conduct of private actors within their jurisdiction.[624] In the context of transboundary environmental interference, the focus is therefore on the obligations of states to adequately regulate hazardous activities and, in the event of damage, to provide for the liability and redress.[625] However, hazardous conduct can become directly attributable when the state itself engages in such conduct or effectively controls such conduct carried out by non-state actors.[626]

624 *Bratspies* (n. 41), 211; see *supra* section A.II.
625 See *supra* section A.II.6.
626 See *supra* section A.II.2.

Secondly, the main challenge to implementing state responsibility remains to establish a breach of an international obligation. In general terms, this requires showing that the conduct in question was not in conformity with the relevant obligation.[627] However, proving the relevant facts, including what the responsible state *could* and *should* have done to prevent damage and that this failure caused the damage, will often involve difficult evidentiary questions. Similar difficulties may arise regarding the proof of causation, especially when the damage only manifests in the long term or when there is more than one possible pathway or multiple states that are jointly responsible for the damage. While a detailed treatment of the law of evidence before international courts and tribunals is beyond the present study's scope,[628] it has been shown that international courts and tribunals are reluctant to lower the standard of proof required to establish the existence of a causal link between the responsible state's failure to adequately regulate a hazardous activity or organism and the resulting of damage.[629]

When a breach can be established, the responsible state must cease the wrongful conduct and make reparation for any injury caused by it. In principle, the obligation to make full reparation applies not only to 'traditional' damage such as personal injury, property damage, and economic loss, but also to damage to the environment *per se*.[630] This will become particularly relevant when self-spreading LMOs cause damage to native species, ecosystems or biological diversity at large. The extent to which such damage is compensable under international law is assessed separately in chapter 11.

A third critical aspect is a state's international responsibility can only be invoked by other states. In the absence of dedicated treaties, foreign private actors cannot directly make claims against the state of origin but need to be represented by their respective states. It has been shown that the requirement to exhaust *local remedies* does not apply in cases of transboundary harm because unlike in conventional cases of *diplomatic protection*, the victims have not voluntarily subordinated themselves to the jurisdiction of the source state.[631] However, since states are not bound to

627 See *supra* section A.III.2.
628 See *Markus Benzing*, Das Beweisrecht vor internationalen Gerichten und Schiedsgerichten in zwischenstaatlichen Streitigkeiten (2010).
629 See *supra* section B.II.2.a).
630 See *supra* section B.II.3.b)dd).
631 See *supra* section C.II.2.

accept the jurisdiction of any international court or tribunal, there will, in many cases, be no adequate legal mechanism to enforce the liability of the state of origin.[632] This may well prove to be the biggest obstacle to enforcing state responsibility for transboundary damage caused by biotechnology. Compliance mechanisms established by multilateral environmental agreements such as the Cartagena Protocol may be better equipped to promote adherence to international rules.[633] Yet, they fulfil different functions. While compliance mechanisms are 'forward-looking' and aim to ensure the future compliance of states with their obligations;[634] state responsibility remains the relevant regime to rectify injury that has already been caused by breaches of international obligations.

Taking all this together, it could be argued that the practical relevance of international law on state responsibility for addressing damage caused by applications of modern biotechnology is rather limited.[635] In fact, states may well regard the ambiguities of the law of state responsibility as a 'convenient buffer' against claims based on responsibility.[636] Against this background, it comes as no surprise that there have only been a few cases in which states were successfully held responsible *ex post facto* for breaching their preventive obligations.[637] Many writers have been sceptical about the utility of state responsibility to address transboundary and global environmental challenges.[638] Indeed, the responsibility of another state has been invoked formally only in a few cases, and its relevance in addressing international cases of damage caused by modern biotechnology could therefore be questioned.

Nevertheless, it has also been observed that the utility of state responsibility 'lies not so much in the number of cases resolved within the framework of litigation, but in acting as a springboard from which all other regulatory and accountability frameworks derive their ultimate legit-

632 See *supra* section C.III.2.
633 See *supra* section C.III.3.a).
634 See *supra* section C.III.3.b).
635 *Saxler* et al. (n. 98), 118–123, argue similarly in the field of geoengineering.
636 *Jutta Brunnée*, COPing with Consent: Law-Making Under Multilateral Environmental Agreements, 15 (2002) Leiden J. Int'l L. 1.
637 See *Barboza* (n. 366), 46–52.
638 See, e.g., *Klabbers* (n. 564), 1001; *Fitzmaurice/Redgwell* (n. 564), 37; *Saxler* et al. (n. 98), 118–123; *Brunnée* (n. 509), 354–356; *Boyle/Redgwell* (n. 425), 246–247.

imacy'.[639] This is all the more true in the context of the present study. As shown earlier, it seems currently more likely that states will move forward with releasing modified organisms capable of self-propagation unilaterally than in internationally coordinated efforts.[640] Against this background, the law of state responsibility and the ensuing potential liability for damage remains important to ensure compliance with the relevant international treaties, predominantly the CBD, the Cartagena Protocol and the Supplementary Protocol, as well as the pertinent rules of customary international law. Consequently, the law of state responsibility is of 'continuing significance'.[641]

639 *Phoebe N. Okowa*, Responsibility for Environmental Damage, in: Malgosia A. Fitzmaurice/David Ong/Panos Merkouris (eds.), Research Handbook on International Environmental Law (2010) 303, 317.

640 See chapter 5.

641 *Boyle/Redgwell* (n. 425), 247.

Chapter 10: Strict State Liability for Transboundary Harm?

The preceding chapters have shown that a state of origin will be internationally responsible for transboundary harm only when it has failed to act with due diligence in preventing that harm.[1] However, the due diligence standard is context-dependent, which means that the specific actions required of a state depend on a number of different factors under the particular circumstances of each case.[2] Moreover, the injured state bears the burden of proof, i.e. it must demonstrate that the state of origin has indeed failed to perform its obligations and that this failure was causal for the transboundary damage to occur. Finally, harm could also occur even though a state observed due diligence and complied with all other applicable obligations.[3] Consequently, there is a substantial likelihood that adverse effects caused by *living modified organisms* (LMOs) in a transboundary context remain unaddressed and that individuals suffering injury from such adverse effects remain uncompensated.[4]

But this result runs against the widespread consensus that the injurious consequences of hazardous activities should not 'lie where they fall' but should be borne by the party which has caused the damage (and benefitted from the activity).[5] Against this background, scholars have long maintained the idea of 'strict state liability', i.e. an obligation of states to compensate for transboundary harm independent of the existence of a breach of international law. It has been observed that the 'policy rationale underlying the concept of subsidiary state liability for hazardous activities

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1 See chapter 9.

2 See chapter 4.

3 *Alan E. Boyle/Catherine Redgwell*, Birnie, Boyle, and Redgwell's International Law and the Environment (4th ed. 2021), 231; *René Lefeber*, The Legal Significance of the Supplementary Protocol: The Result of a Paradigm Evolution, in: Akiho Shibata (ed.), International Liability Regime for Biodiversity Damage (2014) 73, 78.

4 *Günther Handl*, International Accountability for Transboundary Environmental Harm Revisited: What Role for State Liability?, 37 (2007) Environmental Policy and Law 117, 118.

5 *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 1–3.

[…] is intuitively convincing'.[6] Indeed, from a perspective of international public *policy*, several arguments militate in favour of strict state liability for transboundary damage caused by hazardous activities.[7]

First of all, state liability for transboundary damage may be warranted by fundamental considerations of international justice and fairness. The underlying assumption is that if international law allows a state to knowingly expose another state to a risk of significant harm, it would be inequitable to leave the loss 'lie where it falls'.[8] This is particularly true because the affected state can neither veto nor control the hazardous activity, nor does it necessarily benefit from it, however socially or economically beneficial the activity may be to the state of origin.[9] It has also been argued that it would be a case of 'unjust enrichment' if the burden were not imposed on the risk-creating actor who would usually derive an economic benefit from the activity.[10]

Secondly, the combination of state responsibility and operator liability may not provide a sufficient basis for compensation for harm caused by hazardous activities. As shown earlier, requirements for the imposition of operator liability are minimal,[11] and the requirement to ensure 'prompt and adequate compensation' stipulates hardly more than a minimum threshold.[12] At the same time, the responsibility of states is limited to breaches of due diligence, which does not guarantee that no harm will

6 *Handl* (n. 4), 120.
7 For discussions of different theoretical approaches to strict state liability, see *Julio Barboza*, The Environment, Risk and Liability in International Law (2011), 64–71; *Hanqin Xue*, Transboundary Damage in International Law (2003), 302–312.
8 *C. Wilfried Jenks*, Liability for Ultra-Hazardous Activities in International Law, 117 (1966) RdC 99, 152; *Günther Handl*, State Liability for Accidental Transnational Environmental Damage by Private Persons, 74 (1980) AJIL 525, 559; *Louise A. de La Fayette*, International Liability for Damage to the Environment, in: Malgosia A. Fitzmaurice/David Ong/Panos Merkouris (eds.), Research Handbook on International Environmental Law (2010) 320, 327.
9 *Alan E. Boyle*, Globalising Environmental Liability: The Interplay of National and International Law, 17 (2005) J. Envt'l L. 3, 7; *Handl* (n. 4), 119; *de La Fayette* (n. 8), 327; *Johan G. Lammers*, International Responsibility and Liability for Damage Caused by Environmental Interferences, 31 (2001) Environmental Policy and Law 42–50 and 94–105, 47.
10 *L.F.E. Goldie*, Concepts of Strict and Absolute Liability and the Ranking of Liability in Terms of Relative Exposure to Risk, 16 (1985) NYL 175, 212–213.
11 See chapter 6.
12 See chapter 8.

occur.[13] Consequently, harm might occur despite the source state's full compliance with its preventive obligations.[14]

Thirdly, the imposition of subsidiary state liability increases the deterrent effect of liability.[15] State responsibility for transboundary harm is premised on the understanding that the source state will incur liability if the transboundary harm results from the state's failure to act with due diligence towards preventing the harm caused.[16] However, as shown above, a breach of due diligence may be difficult to establish, as may be the existence of a causal link between such a breach and the eventual occurrence of harm.[17] Consequently, strict state liability may promote diligent action on the side of the source state:

> *'A source state's knowledge of the certainty of incurring liability simply upon the occurrence of transboundary harm may strengthen its resolve to prevent such harm to beyond the level of due diligence applicable in the circumstances.'*[18]

Fourthly, subsidiary state liability may also aid the implementation of transnational civil liability approaches, as the prospect of being held liable may encourage states to provide for more efficient and less costly processes for handling transboundary civil liability claims.[19] Thus, state liability can also facilitate effective implementation of the 'polluter-pays principle'.[20]

Despite these arguments, there is currently no international treaty expressly providing for strict state liability for transboundary harm, neither in general international law nor specifically in the context of modern biotechnology.[21] However, such liability could be part of customary international law.

It is generally accepted that for a rule of customary international law to emerge, there must be a consistent practice of states (*consuetudo*) carried by the belief that such practice is required by law (*opinio iuris sive necessi-*

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13 *Boyle* (n. 9), 7; *Handl* (n. 4), 118; see chapter 4, section C.
14 *Handl* (n. 4), 118; *Boyle* (n. 9), 7; see chapter 4, section E.
15 See the Introduction.
16 *Handl* (n. 4), 118; also see *Handl* (n. 8), 559.
17 See chapter 9, section A.II.2.a).
18 *Handl* (n. 4), 118.
19 *Ibid.*, 119.
20 See chapter 2, section D.
21 An exceptional provision of strict state liability could be seen in Article 25(2) of the Cartagena Protocol, which requires the state of origin to dispose of LMOs which have been subject to an illegal transboundary movement; see *infra* section A, and chapter 3, section A.II.2.c)bb).

tatis).[22] In the present case, such practice could arise from international treaty-making (A.) and the practice of states *vis-à-vis* actual cases of transboundary damage (B.). Besides, it has been suggested that strict state liability for transboundary harm could also arise from international human rights law (C.). Moreover, state liability has also been a long-standing issue in the *International Law Commission* (D.).

A. International Treaties

There are only a few instances of international treaties that unequivocally provide for strict state liability. The prime example in this regard is the *Space Liability Convention* of 1972, which provides that '[a] launching State shall be absolutely liable to pay compensation for damage caused by its space object on the surface of the earth or to aircraft in flight'.[23] Exoneration from such liability is only granted where the damage has been caused by the claimant state or its representatives through intentional or grossly negligent conduct[24] and with regard to nationals of the launching state and other persons participating in the operation of the space object.[25] Besides this strict liability, the Convention provides for fault-based liability for damage caused to space objects of other states.[26]

To date, the only claim presented under the Space Liability Convention concerned the crash of the Soviet nuclear satellite *Cosmos 954* over Canada in 1978.[27] Since the crash had caused neither physical nor property damage to Canadian citizens, the claim essentially concerned the costs incurred

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22 Cf. Statute of the International Court of Justice (18 April 1946), 33 UNTS 993, Article 38(1)(b); see *Malcolm N. Shaw*, International Law (8th ed. 2017), 53–66; *James Crawford*, Brownlie's Principles of Public International Law (9th ed. 2019), 21–25.

23 Convention on International Liability for Damage Caused by Space Objects (29 March 1972; effective 01 September 1972), 961 UNTS 187 (hereinafter 'Space Liability Convention'), Article II; also see Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies (27 January 1967; effective 10 October 1967), 610 UNTS 205, Article VII, which provides that a launching state is 'internationally liable' for damage caused by its object to another state.

24 Space Liability Convention (n. 23), Article VI.

25 *Ibid.*, Article VII.

26 *Ibid.*, Article III.

27 See generally *Bryan Schwartz/Mark L. Berlin*, After the Fall: An Analysis of Canadian Legal Claims for Damage Caused by Cosmos 954, 27 (1982) McGill Law

by the Canadian authorities in locating and recovering the radioactive debris spread by the satellite and for measures to clean up the affected areas.[28] Notably, the definition of 'damage' contained in the Space Liability Convention neither expressly includes environmental damage nor costs for response measures.[29] However, it has been argued that environmental assets could be regarded as 'property' of the state[30] and that the costs for preventing further harm were logically inherent in the notion of damage.[31] In any event, Canada also argued that the crash had violated its sovereignty and that 'the standard of absolute liability for space activities […] is considered to have become a general principle of international law'.[32] Eventually, the claim was settled through a lump-sum agreement that did not indicate the legal basis on which compensation was paid.[33]

The *Gut Dam* case concerned a dam built by Canada in the *Saint Lawrence River* in 1903, which, after several modifications, caused extensive flooding and erosion in 1951 and 1952, also inflicting significant damage to the territory of the United States.[34] Canada was strictly liable for the damage under an agreement between the parties which authorized the construction of the dam.[35] Thus, the tribunal established to resolve the

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Journal 676; *Lefeber* (n. 5), 163–165; *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 763.

28 Cf. Canada, Department of External Affairs, Claim Against the Union of Soviet Socialist Republics for Damage Caused by Soviet Cosmos 954 (23 January 1979), 18 ILM 889, para. 8.

29 Cf. Space Liability Convention (n. 23), Article I(a), which defines the term 'damage' as 'loss of life, personal injury or other impairment of health; or loss of or damage to property to States or of persons, natural or juridical, or property of international intergovernmental organizations'.

30 *Schwartz/Berlin* (n. 27), 714–718; *Sands* et al. (n. 27), 762.

31 *Schwartz/Berlin* (n. 27), 720; see chapter 11.

32 Claim Against the Union of Soviet Socialist Republics for Damage Caused by Soviet Cosmos 954 (n. 28), paras. 21–22.

33 Cf. Protocol Between Canada and the USSR on Settlement of Canada's Claim for Damages Caused by "Cosmos 954" (02 April 1981), 20 ILM 689.

34 Cf. Canada–United States Settlement of Gut Dam Claims, 27 September 1968, Report of the Agent of the United States before the Lake Ontario Claims Tribunal, 8 ILM 118, 119–121; see ILC, Survey of Liability Regimes Relevant to the Topic of International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law (International Liability in Case of Loss from Transboundary Harm Arising Out of Hazardous Activities): Prepared by the Secretariat, UN Doc. A/CN.4/543 (2004), paras. 415–416.

35 The agreement provided that 'if the construction and operation of said dam shall cause damage or detriment to the property owners of Les Galops Island or to the property of any other citizens of the United States, the government of Canada

matter did not have to rule on the legal basis of Canada's liability but only on the scope of liability and the amount of compensation due.[36]

Other instances of international agreements expressly providing for strict state liability are rather exotic. The *Treaty concerning the La Plata River and its Maritime Limits* concluded in 1973 between Argentina and Uruguay provides that 'each Party shall be liable to the other for damage inflicted as a result of pollution caused by its own activities or by those of individuals or legal entities domiciled in its territory'.[37] A similar provision can be found in an agreement concluded in 1964 between Finland and the Soviet Union concerning *Frontier Watercourses*.[38] Another example is the *Convention on Liability for Radiological Accidents in International Carriage of Spent Nuclear Fuel*, which was concluded in 1987 by states of the Soviet Bloc and which, like the Space Liability Convention, imposes absolute liability on states.[39]

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shall pay such amount of compensation as may be agreed upon between the said government and the parties damaged, or as may be awarded the said parties in the proper court of the United States before which claims for damage may be brought', see Canada–United States Settlement of Gut Dam Claims (n. 34), 120. See *Lefeber* (n. 5), 103, noting that the strict liability standard was not meant to apply to *international*, but to *transnational* claims (on this distinction, see chapter 4, section B.III). In any event, when cases were brought before a United States court in the 1950s, a Canadian plea of sovereign immunity was upheld, and it was only thereafter that the United States brought an international claim against Canada, see *Lefeber* (n. 5), 103.

36 Canada–United States Settlement of Gut Dam Claims (n. 34), 133–140; see *Handl* (n. 8), 538–539; ILC, Survey of liability regimes (n. 34), para. 416; *Barboza* (n. 7), 53–56.

37 Treaty Between Uruguay and Argentina Concerning the Rio de la Plata and the Corresponding Maritime Boundary (19 November 1973; effective 12 February 1974), 1295 UNTS 293, Article 51; see *Lefeber* (n. 5), 169–170; *Barboza* (n. 7), 67.

38 Agreement Between the Republic of Finland and the Soviet Socialist Republics Concerning Frontier Watercourses (24 April 1964; effective 06 May 1965), 537 UNTS 252; see *Lefeber* (n. 5), 170–171.

39 See CMEA, Конвенция Об Ответственности За Ущерб, Причиненный Радиационной Аварией При Международной Перевозке Отработавшего Ядерного Топлива От Атомных Электростанций Стран – Членов СЭВ (Convention on Liability for Damage Caused by Radiological Accidents in International Carriage of Spent Nuclear Fuel from Nuclear Power Plants of CMEA Member Countries) (15 September 1987), not officially published, Article VII, which provides that where it cannot be established that a radiological accident was caused by a failure of any of the states involved in the transport to comply with the pertinent regulations, liability shall be imposed on the state where the nuclear power plant is located if the accident has occurred in its own territory or in the

A number of other instruments do not expressly provide for strict liability but contain obligations to remediate transboundary incidents that come close to strict liability. As shown earlier, the *Cartagena Protocol* provides that a state party affected by an illegal transboundary movement may request the party of origin to dispose of the LMO in question by repatriation or destruction at its own expense.[40] A similar example can be found in the *Basel Convention on Hazardous Wastes*, which establishes a strict obligation of the export state to take back hazardous wastes when their transboundary movement was illegal or in the event that a lawful transboundary movement cannot be completed in accordance with the contract governing that movement.[41] It has been observed that given these 'far-reaching, indeed paternalistic obligations on the part of the state of export […] it was widely believed that the rules of state responsibility proper would provide a sufficient legal basis upon which transboundary environmental harm could be redressed' and that, for this reason, no additional rules on subsidiary state liability were included in the *Basel Liability Protocol*.[42] But this also shows that the aforementioned obligations are tailored to specific situations and do not give rise to a general liability of states for transboundary interferences.

In the regimes for nuclear damage, states are not primarily liable but must provide funds for supplementary compensation. For instance, the *Brussels Supplementary Convention* envisages three tiers of compensation: The first tier, amounting to at least 5 million *Special Drawing Rights* (SDR), is comprised of the primary liability of the operator under the *Paris Convention* that shall be guaranteed by insurance or other financial security.[43]

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territory of a transit state, and on the state where the regeneration plant is located if an accident has occurred there. Also see *Lefeber* (n. 5), 166.

40 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (29 January 2000; effective 11 September 2003), 2226 UNTS 208, Article 25(2); see chapter 3, section A.II.2.c)bb).

41 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (22 March 1989; effective 05 May 1992), 1673 UNTS 57, Articles 8 and 9(2).

42 *Handl* (n. 4), 120; cf. Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal (10 December 1999; not yet in force), UNEP/CHW.5/29, p. 88.

43 Convention Supplementary to the Paris Convention on Third Party Liability in the Field of Nuclear Energy (31 January 1963; effective 04 December 1974), 1041 UNTS 358, as amended by the Protocol of 16 November 1982 (effective 1 August 1991), 1650 UNTS 446 (hereinafter 'Brussels Supplementary Convention'), Article III(b)(i); see Convention on Third Party Liability in the Field of Nuclear

The second tier is a supplementary liability of the installation state, which shall provide the amount missing for a total compensation of up to 175 million SDR.[44] Finally, a third tier, ensuring a total compensation of up to 300 SDR, shall be provided out of public funds contributed by all contracting parties according to an agreed formula.[45] Notably, supplementary liability under the second and third tiers is subject to the same requirements as the liability of the operator under the first tier, which includes the requirement to establish a causal link as well as potential exonerations.[46] A similar tiered scheme involving a layer of state liability has also been established under the alternative regime of the *Vienna Convention on Civil Liability for Nuclear Damage.*[47]

Hence, (subsidiary) state liability is not without precedent in international treaties. However, a number of international agreements also expressly rule out state liability. For instance, the 2005 *Antarctic Liability Annex* provides that

> *'[a] Party shall not be liable for the failure of an operator, other than its State operators, to take response action to the extent that that Party took appropriate measures within its competence, including the adoption of laws*

Energy (29 July 1960; effective 01 April 1968), 956 UNTS 251, as amended by the Additional Protocol of 28 January 1964 and the Protocol of 16 November 1982 (effective 7 October 1988), 1519 UNTS 329, Articles III, VII and X.

44 Brussels Supplementary Convention (n. 43), Article III(b)(ii).

45 *Ibid.*, Article III(b)(iii). These amounts are to be raised to EUR 700 million, 1.2 billion, and 1.5 billion, respectively, by the Protocol to Amend the Brussels Supplementary Convention on Nuclear Third Party Liability (12 February 2004; not yet in force).

46 Brussels Supplementary Convention (n. 43), Article II(a)(i); see *Lefeber* (n. 5), 306.

47 See Vienna Convention on Civil Liability for Nuclear Damage (25 May 1963; effective 12 September 1997), 1063 UNTS 358, as amended by the Protocol of 12 September 1997 (effective 4 October 2003), IAEA Doc. INFCIRC/566; Convention on Supplementary Compensation for Nuclear Damage (12 September 1997; effective 15 April 2015), 36 ILM 1473, Article III(1). The OECD's *Paris Convention* and the IAEA's *Vienna Convention* are two alternative regimes on third party liability for nuclear damage. A link between both regimes, which mutually extends the benefits to the parties of either regime, was established by the Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention (21 September 1988; effective 27 April 1992), 1672 UNTS 301. See generally *Raphael J. Heffron* et al., The Global Nuclear Liability Regime Post Fukushima Daiichi, 90 (2016) Progress in Nuclear Energy 1.

and regulations, administrative actions and enforcement measures, to ensure compliance with this Annex'.[48]

This provision rules out any *liability* of the state except for cases of state *responsibility*, namely when the state has failed to take appropriate measures to ensure that the operator complies with the Annex.[49]

A similar provision can be found in the seabed mining regime of the *Convention on the Law of the Sea*, which provides that a state shall not be liable for damage if it has taken all necessary and appropriate measures to secure the effective compliance of its operators with the seabed mining regime.[50] The *International Tribunal for the Law of the Sea* (ITLOS) confirmed that 'the liability regime established by article 139 […] leaves no room for residual liability' of the state.[51]

Another example for an express disavowal of state liability can be found in the *Convention on Long-Range Transboundary Air Pollution* of 1979, which clarifies in a footnote that the Convention 'does not contain a rule on State liability as to damage'.[52] Moreover, when adopting the 2015 *Paris Climate Agreement*, the parties agreed that Article 8 of the Agreement, which addresses loss and damage,[53] 'does not involve or provide a basis for any liability or compensation'.[54]

48 Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty: Liability Arising from Environmental Emergencies (14 June 2005; not yet in force), ATCM Measure 1 (2005), Article 10.

49 *Alexandre Kiss/Dinah Shelton*, Guide to International Environmental Law (2007), 26.

50 United Nations Convention on the Law of the Sea (10 December 1982; effective 16 November 1994), 1833 UNTS 3, Article 139(2); see *Silja Vöneky/Anja Höfelmeier*, Article 139 UNCLOS, in: Alexander Proelss (ed.), United Nations Convention on the Law of the Sea: A Commentary (2017) 968, MN. 17–18; also see Annex III to UNCLOS, Article 4(4).

51 ITLOS, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, Advisory Opinion of 01 November 2011, Case No. 17, ITLOS Rep. 10, para. 204.

52 Convention on Long-Range Transboundary Air Pollution (13 November 1979; effective 16 March 1983), 1302 UNTS 217, footnote 1 to Article 8(f).

53 Cf. Paris Agreement (12 December 2015; effective 04 November 2016), 55 ILM 743, Article 8.

54 UNFCCC COP, Decision 1/CP.21. Adoption of the Paris Agreement (12 December 2015), UN Doc. FCCC/CP/2015/L.9/Rev.1, para. 52.

B. State Practice

It could be argued that, besides international treaties, the practice of states in dealing with actual cases of transboundary damage indicates a general acceptance of (subsidiary) state liability. In fact, there are numerous cases in which states have provided compensation for transboundary damage that originated from activities under their jurisdiction.[55] This arguably includes the ubiquitous *Trail Smelter* case. As noted earlier, the arbitral tribunal in that case ruled that states may not use or permit the use of their territory in a manner that causes serious transboundary injury.[56] Subsequently, the tribunal prescribed a regime for the future operation of the smelter, which it expected to prevent any future transboundary harm.[57] However, the tribunal also held that

> *'if any damage […] shall occur in the future, whether through failure on the part of the Smelter to comply with the regulations herein prescribed or notwithstanding the maintenance of the régime, an indemnity shall be paid for such damage'.*[58]

Because the tribunal stressed the irrelevance of due diligence for the future obligation to compensate, some authors have interpreted this statement as establishing a form of *sine delicto* liability.[59] Others have argued that liability would be triggered by a violation of an absolute international obligation and, hence, was *ex delicto*.[60] Either way, Canada was held unconditionally liable for any future transboundary harm caused by the smelter. The legal grounds for such liability could be seen in the bilateral treaty that referred the case to the tribunal and by which Canada, in the tribunal's view, had voluntarily 'assumed an international responsibility' for the operation

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55 For a comprehensive survey, see e.g. ILC, Survey of liability regimes (n. 34), paras. 387–433; *Barboza* (n. 7), 53–62.

56 Cf. Trail Smelter Case (United States v. Canada), Decision of 11 March 1941, III RIAA 1938, 1965; see chapter 4, section A.

57 *Ibid.*, 1981.

58 *Ibid.*, 1980.

59 See e.g. *Johan G. Lammers*, Pollution of International Watercourses (1984), 524–525; *Günther Handl*, Liability as an Obligation Established by a Primary Rule of International Law, 16 (1985) NYL 49, 61–62; *Barboza* (n. 7), 49.

60 Cf. *Lefeber* (n. 5), 174–175; *Michel Montjoie*, The Concept of Liability in the Absence of an Internationally Wrongful Act, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010), 507.

of the smelter.[61] However, as the transboundary harm was not caused accidentally but rather resulted from the smelter's regular operation, the latter could hardly be seen as a 'hazardous' activity.[62] Consequently, the obligation to prevent such harm was no longer a 'due diligence' obligation of conduct but came close to a genuine obligation of result.[63] Against this background, it can be explained why the tribunal held that compensation would be due 'only when and if the two Governments shall make arrangements for the disposition of claims for indemnity'.[64] If no such arrangements were made despite the smelter continuing to cause transboundary harm, closing the smelter would have been inevitable.

Subsequently, the principles established in the *Trail Smelter* case were also invoked by Canada in cases in which it was not responsible for, but affected by, transboundary harm.[65] Following the oil spill caused by a Liberian tanker when unloading at *Cherry Point* in the United States in 1972,[66] Canada claimed 'full and prompt compensation for all damages suffered in Canada, as well as full clean-up costs, to be paid by those responsible'.[67] Expressly referring to *Trail Smelter*, Canada invoked the 'principle […] that one country may not permit the use of its territory in such a manner as to cause injury to the territory of another and shall be responsible to pay compensation for any injury so suffered'.[68] As the private company responsible for the spill agreed to pay the costs of the clean-up operations, it remains unclear whether there had been an official response by the United States.[69]

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61 Cf. Trail Smelter Case (United States v. Canada), Decision of 16 April 1938, III RIAA 1911, 1912; see *Lefeber* (n. 5), 174.

62 Cf. *ibid.*, 174; but see *Barboza* (n. 7), 49, who argues that tribunal regarded the future operation of the smelter as a hazardous activity, since it expected its regime to prevent future damage except for accidents.

63 See chapter 4, section C.

64 Cf. Trail Smelter Case, Decision of 1941 (n. 56), 1980.

65 *Lefeber* (n. 5), 177. In its claim for compensation in the *Cosmos 954* incident, Canada did not expressly rely on the Trial Smelter case, but invoked a general principle of international law that 'a violation of sovereignty gives rise to an obligation to pay compensation' (see *supra* text at n. 32).

66 See ILC, Survey of liability regimes (n. 34), para. 427.

67 Canada, Statement on Cherry Point Oil Spill by Mitchell Sharp, Secretary of State for External Affairs (08 June 1972), 11 (1973) Canadian YBIL 333.

68 *Ibid.*, 334; see *Handl* (n. 8), 545.

69 ILC, Survey of liability regimes (n. 34), para. 428.

While most cases involving maritime oil pollution have been settled through civil liability remedies,[70] states have assumed direct liability for damage caused by ships flying their flag in a few cases. In 1971, the Liberian-registered tanker *Juliana* ran aground off the coast of Japan, and the resulting oil spill caused considerable injury to local fisheries.[71] The Liberian government offered JPY 200 million to the affected fishermen, which they reportedly accepted.[72] Apparently, there were no allegations of any specific wrongdoing on the part of Liberia. Therefore, this is one of the few cases in which a state has assumed strict liability for extraterritorial damage caused by a private activity.[73] In another incident caused by the Japanese tanker *Showa Maru* in 1975 in the *Strait of Malacca*, the Japanese government was reportedly willing to compensate for the resulting pollution damage.[74] It has been suggested that this was motivated by Japan's interest in maintaining the right of navigation through the said strait, although there were no reports that compensation was actually paid in this case.[75]

Another case in which the injured state successfully invoked the direct liability of the state of origin was the case concerning the *Mura River*, which forms the border between the former Yugoslavia and Austria.[76] In 1956, the river was substantially polluted by sediments and mud released by several Austrian hydroelectric plants, which had drained their reservoirs to forestall a major flooding.[77] After the case had been submitted to the permanent *Mura Riva Commission*, both states agreed on a settlement in 1959, under which Austria paid monetary compensation and delivered a certain amount of paper to Yugoslavia.[78]

The question of state liability was also raised in the context of nuclear weapons tests carried out by the United States between 1946 and 1958 in the *Marshall Islands*.[79] At that time, such tests were not considered to

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70 See generally *Xue* (n. 7), 52–60; *Sands* et al. (n. 27), 779–789.

71 See *Handl* (n. 8), 546–547; *Lefeber* (n. 5), 176; ILC, Survey of liability regimes (n. 34), para. 426.

72 *Handl* (n. 8), 547; ILC, Survey of liability regimes (n. 34), para. 426.

73 *Handl* (n. 8), 547; *Lefeber* (n. 5), 176.

74 *Handl* (n. 8), 547 at n. 102.

75 Cf. *Lefeber* (n. 5), 176–177.

76 Cf. *Handl* (n. 8), 545–546; *Lefeber* (n. 5), 111–112; ILC, Survey of liability regimes (n. 34), para. 425.

77 *Handl* (n. 8), 546.

78 *Ibid.*

79 See *Marjorie M. Whiteman* (ed.), Digest of International Law, Vol. 4 (1965), 533–603.

be unlawful *per se*, at least not by the nuclear powers.[80] However, a thermonuclear test conducted in March 1954 caused considerable damage far exceeding the evacuated 'danger zone', as the magnitude of the detonation had been underestimated and there had been an unexpected wind shift.[81] Consequently, the radioactive fallout generated by the detonation caused injury to the crews of several Japanese fishing vessels on the high seas, including the *Fukuryu Maru*, who suffered from exposure to radiation.[82] Moreover, the Japanese fishing industry sustained considerable losses due to the radioactive contamination of fish stocks in the following months.[83] In January 1955, the United States agreed to pay USD 2 million to Japan in compensation for the injuries or damages sustained as a result of these tests.[84] However, the payment was expressly declared to be 'ex gratia' and 'without reference to the question of legal liability'.[85]

Besides the Japanese fishermen, injury was also caused to the inhabitants of the Marshall Islands, which then belonged to the *Trust Territory of the Pacific Islands* administered by the United States on behalf of the United Nations.[86] By a law signed in 1964, the United States assumed 'compassionate responsibility' to compensate the inhabitants of the *Rongelap Atoll* for radiation exposures sustained due to the nuclear test of March 1954, and authorized USD 950,000 to be paid in equal amounts to the affected inhabitants.[87] In the *Compact of Free Association* concluded in 1983, the United States accepted its responsibility to compensate the citizens of the Marshall Islands for 'loss or damage to property and person' resulting from the nuclear tests, and a dedicated tribunal was established to process claims.[88] The tribunal reportedly issued awards of more than

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80 Cf. *ibid.*, 568; *Emanuel Margolis*, The Hydrogen Bomb Experiments and International Law, 64 (1955) Yale L.J. 629; *Lefeber* (n. 5), 166–167.

81 *Margolis* (n. 80), 637; Whiteman (ed.) (n. 79), 563–570.

82 *Margolis* (n. 80), 638; *Lefeber* (n. 5), 167.

83 *Margolis* (n. 80), 638.

84 Cf. Exchange of Notes Constituting an Agreement Between the United States and Japan Relating to the Settlement of Japanese Claims for Personal and Property Damages Resulting from Nuclear Tests in the Marshall Islands in 1954 (04 January 1955), 237 UNTS 197.

85 Cf. *ibid.*

86 ILC, Survey of liability regimes (n. 34), para. 406; *Amy Hindman/René Lefeber*, 4. International/Civil Liability and Compensation, 19 (2008) YB Int'l Env. L. 214, 168; *Barboza* (n. 7), 55–56.

87 Whiteman (ed.) (n. 79), 567; ILC, Survey of liability regimes (n. 34), para. 406.

88 Compact of Free Association (14 January 1986), US Public Law No. 99–239, 99 Stat. 1770, as amended by Public Law 108–188 of 17 December 2003, 117

USD 2 billion, but most of them could not be disbursed because the USD 150 million fund created by the United States had been largely exhausted around 2006.[89]

Another instance of compensation for nuclear tests can be found in an agreement concluded in 1993 between the United Kingdom and Australia, whereby the latter accepted an *ex gratia* payment of GBP 20 million in 'full and final settlement of all claims whatsoever' in relation to the British nuclear tests carried out between 1952 and 1963 at different sites in Australia, including for the decontamination and clearance of the test sites.[90]

The preceding survey has shown that there are many instances where states have compensated for transboundary harm caused by activities carried out under their jurisdiction or control, although such compensation was often made *ex gratia* and without acknowledging legal liability. However, there have also been cases in which the relevant states have strictly denied any liability, such as the 1979 blowout of the *IXTOC I* oil well drilled by the Mexican state-owned petroleum company *Pemex*.[91] Although the resulting oil spill also reached the coast of the United States, the Mexican government refused to accept any international responsibility or liability, leaving the matter to be resolved in civil liability claims.[92]

Moreover, as noted earlier, no compensation was ever made for transboundary damage arising out of the peaceful use of nuclear energy. After the *Chernobyl* disaster in 1986, which had caused widespread harm to agricultural produce and livestock in Europe, no state formally claimed compensation from the former USSR, nor did the Soviet government offer

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Stat. 2720 (effective 30 June 2004), Section 177; see ILC, Survey of liability regimes (n. 34), paras. 407–410; *Davor Pevec*, The Marshall Islands Nuclear Claims Tribunal: The Claims of the Enewetak People, 35 (2006) Denver J. Int'l. L. & Pol'y 221.

89 See Marshall Islands Nuclear Claims Tribunal (11 June 2007), available at: https://web.archive.org/web/20110716110909/http://www.nuclearclaimstribunal.com/ (last accessed 28 May 2022); *Renee Lewis*, Bikinians Evacuated 'For Good of Mankind' Endure Lengthy Nuclear Fallout, Al Jazeera America, 28 July 2015, available at: http://america.aljazeera.com/articles/2015/7/28/bikini-nuclear-test-survivors-demand-compensation.html (last accessed 28 May 2022).

90 Exchange of Notes Constituting an Agreement Between Australia and the United Kingdom Concerning Maralinga and Other Sites in Australia (10 December 1993), 1770 UNS 450; see *Boyle/Redgwell* (n. 3), 435 n. 210.

91 ILC, Survey of liability regimes (n. 34), para. 417; *Barboza* (n. 7), 61.

92 *Barboza* (n. 7), 61–62.

any voluntary compensation.[93] No international claims were made either following the accident at *Fukushima* in 2011.[94]

C. Human Rights Law

A recognition of strict state liability for transboundary harm could be seen in the advisory opinion on *Human Rights and the Environment* delivered by the *Inter-American Court of Human Rights* in 2018.[95] As shown earlier, the Court assumed that persons residing outside the territory of a state are nevertheless considered to be under the 'jurisdiction' of that state for the purposes of the *American Convention on Human Rights*[96] when they suffer injury in consequence of transboundary harm originating from hazardous activities carried out in the territory of that state.[97] But even more, the Court assumed that states could be held 'responsible for significant damage caused to persons located outside their territory as a result of activities originating in their territory or under their authority or effective control'.[98] In the view of the Court, this does not depend on the lawfulness of the conduct causing the damage because

> *'[…] States are obliged to repair promptly, adequately and effectively, transboundary damage resulting from activities undertaken in their territory or under their jurisdiction.'*[99]

A literal reading of this statement suggests that the Court recognized the existence of strict liability of the state of origin for any transboundary damage. However, the Court gave no explanation as to the legal basis for such liability. It cited the ILC's *Articles on Prevention* and the ITLOS' advisory opinion on *Responsibilities and Obligations of States Sponsoring*

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93 Cf. ILC, Survey of liability regimes (n. 34), paras. 412–414.
94 See chapter 9, section A.II.2.b)bb).
95 IACtHR, The Environment and Human Rights (State Obligations in Relation to the Environment in the Context of the Protection and Guarantee of the Rights to Life and to Personal Integrity – Interpretation and Scope of Articles 4(1) and 5(1) of the American Convention on Human Rights), Advisory Opinion OC-23/18 of 15 November 2017, IACtHR Ser. A, No. 23, paras. 101–102.
96 Cf. American Convention on Human Rights (22 November 1969; effective 18 July 1978), 1144 UNTS 123, Article 1(1).
97 IACtHR, Advisory Opinion on Human Rights and the Environment (n. 95); see chapter 9, section A.II.5.
98 *Ibid.*, para. 103.
99 *Ibid.*

Activities in the Area. But strikingly, neither of these documents provides for strict state liability. Instead, the ITLOS advisory opinion even expressly ruled out strict state liability by pointing out that 'liability for damage of the sponsoring State arises *only* from its failure to meet its obligation of due diligence'.[100] The ILC's Prevention Articles are similarly clear that the obligation to prevent transboundary harm is one of due diligence, and that the occurrence of harm does not necessarily entail the state of origin's international liability for such harm.[101]

Besides, the *Inter-American Court* did not explain how it envisaged such an obligation to repair transboundary damage to be implemented. Referring, *inter alia*, to the ILC's *Principles on Allocation of Loss*, it held that the responsible state must 'mitigate significant environmental damage if it occurs', by which it referred to clean-up and containment measures as well as notification of and cooperation with the affected states.[102] The Court also held that the state of origin was obliged to provide non-discriminatory access to judicial and administrative procedures for persons affected by transboundary harm that originated in their territory.[103] However, these obligations do not amount to strict liability for any injury suffered from the occurrence of transboundary harm. After all, the Court's position concerning state liability for transboundary harm remains dubious, and it is doubtful that it reflects the *lex lata* in the context of international environmental and human rights law.

D. International Law Commission

As noted earlier, strict state liability for transboundary damage has also been contemplated by the International Law Commission (ILC). The ILC dealt with the topic of *International Liability for Injurious Consequences arising out of Acts not Prohibited by International Law* from 1978 to 2006 in

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100 ITLOS, Responsibilities and Obligations of States (n. 51), para. 189 (emphasis added).

101 Cf. ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148 (hereinafter 'ILC, Articles on Prevention'), Article 3, commentary para. 7; see chapter 4.

102 IACtHR, Advisory Opinion on Human Rights and the Environment (n. 95), paras. 172–173.

103 *Ibid.*, paras. 238–240.

what has aptly been described as an 'odyssey'.[104] Great controversies arose from the fact that the scope of the topic was not clearly defined. Until the mid-1990s, there were fundamentally diverging views among the ILC's members on whether the topic should be restricted to 'ultra-hazardous activities' (i.e. activities involving a low probability of causing disastrous harm[105]) or whether, at the other end of the spectrum, the topic should extend to activities that foreseeably (or regularly) caused transboundary harm (which entailed the question whether such activities were at all permitted under international law).[106] Another major source of controversy was the role of state liability in cases where the state had complied with its preventive obligations.

In 1996, the Commission appointed a working group to consolidate the work done up to then and suggest a way forward.[107] The working group adopted a set of *Draft Articles*,[108] which arguably provided for strict state liability for significant transboundary harm caused by hazardous activities:[109] Article 5 stipulated in general terms that 'liability arises from significant transboundary harm […] and shall give rise to compensation or other relief'. Subsequently, the Draft Articles provided for two alternative procedures through which the injured parties could seek remedies.[110] In the first alternative, victims would pursue civil claims in the courts of the state of origin, which would be required to provide these foreign victims with non-discriminatory access to its domestic judicial system.[111] This obligation later became the procedural component of the *obligation to*

104 *Boyle/Redgwell* (n. 3), 230.
105 See chapter 4, section B.V.
106 *Alan E. Boyle*, Liability for Injurious Consequences of Acts Not Prohibited by International Law, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 95, 96; see *Barboza* (n. 7), 73–129.
107 See *ibid.*, 109–110.
108 ILC, Draft Articles on International Liability for the Injurious Consequences of Acts Not Prohibited by International Law, as Adopted by the Working Group of the Commission (1996), YBILC 1996, Vol. II(2), p. 101 (hereinafter 'ILC, 1996 Draft Articles on Liability').
109 Cf. *Louise* de *La Fayette*, The ILC and International Liability: A Commentary, 6 (1997) RECIEL 322, 329–330; *Boyle* (n. 9), 4–5; *Boyle* (n. 106), 98.
110 ILC, 1996 Draft Articles on Liability (n. 108), General commentary on Chapter III, para. 1.
111 *Ibid.*, Article 20.

ensure prompt and adequate compensation postulated in the ILC's *Principles on Allocation of Loss*.[112]

According to the second alternative proposed by the 1996 Draft Articles, the nature and extent of compensation were to be determined through direct negotiations between the state of origin and the affected state.[113] In these negotiations, parties were to take into account various 'factors' stipulated by the Draft Articles, including the extent to which the state of origin had complied with its preventive obligations and the extent to which it had benefitted from the harmful activity.[114] Moreover, the compensation should be determined 'in accordance with the principle that the victim of harm should not be left to bear the entire loss'.[115] Consequently, the objective of compensation as envisaged by the Draft Articles was to ensure an equitable balance of interests rather than full compensation or *restitutio ad integrum*.[116] The commentary clearly indicated that '[t]here may be situations in which the victim of significant transboundary harm may have to bear some loss'.[117]

Notably, the 1996 Draft Articles did not expressly stipulate whether liability for transboundary harm should be imposed on the operator of the hazardous activity or the state under whose jurisdiction the activity is carried out.[118] The working group's commentary to Article 5 noted that 'the principle of liability is without prejudice to the question of […] the entity that is liable and must make reparation'.[119] But the settlement approach mentioned before clearly implies that the state of origin should be responsible for ensuring payment of the compensation mutually agreed upon with the affected state. In fact, the working group envisaged operator liability and state liability as mutually exclusive concepts, since it assumed that negotiations should not be sought while civil procedures were pend-

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112 ILC, Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, with Commentaries (2006), YBILC 2006, vol. II(2), p. 56 (hereinafter 'ILC, Allocation of Loss Principles'), Principle 6(2); see chapter 8, section D.

113 ILC, 1996 Draft Articles on Liability (n. 108), Article 21.

114 Cf. *ibid.*, Article 22.

115 *Ibid.*, Article 21.

116 *Boyle* (n. 9), 5.

117 ILC, 1996 Draft Articles on Liability (n. 108), Commentary to Article 21, para. 4.

118 See *Barboza* (n. 7), 112–114; *Barbara Saxler* et al., International Liability for Transboundary Damage Arising from Stratospheric Aerosol Injections, 7 (2015) Law, Innovation and Technology 112, 129.

119 ILC, 1996 Draft Articles on Liability (n. 108), Commentary to Article 5, para. 6.

ing and, *vice versa*, that lodging complaints in the state of origin should be postponed when the states concerned decided to settle the matter through negotiations.[120] Notably, some members of the working group expressed concerns that a settlement negotiated between the states concerned may be disadvantageous to injured private parties, who could perhaps obtain more favourable remedies through civil liability claims in the courts of the state of origin.[121]

In any event, the concept of strict state liability proved not to be in line with the *opinio iuris* of states.[122] As noted earlier, the ILC decided in 1997 to subdivide the liability topic and to first move forward with the issue of prevention. This resulted in the adoption of the *Articles on Prevention* in 2001,[123] which unequivocally stipulate a (primary) obligation to prevent significant transboundary harm, the breach of which entails state responsibility for wrongful conduct.[124] After the ILC had returned to the issue of liability, the Commission's *Special Rapporteur* on the topic noted:

> *'State liability and strict liability are not widely supported at the international level, nor is liability for any type of activity located within the territory of a state in the performance of which no state officials or agents are involved. (…) The case law on the subject is scant and the basis on which some claims of compensation between states were eventually settled is open to different interpretations. The role of customary international law in this respect is equally modest.'*[125]

Consequently, the ILC shifted its focus away from state liability to the broader issue of 'allocation of loss', which, as shown earlier, emphasized the (primary) obligation to ensure that foreign victims can obtain prompt and adequate compensation through civil law remedies in the state of ori-

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120 *Ibid.*, Commentary to Article 21, para. 2.
121 *Ibid.*, Commentary to Article 21, para. 8.
122 Cf. *Pemmaraju S. Rao*, First Report on the Legal Regime for Allocation of Loss in Case of Transboundary Harm Arising Out of Hazardous Activities, UN Doc. A/CN.4/531 (2003), paras. 19–25, criticizing state liability as a 'case of misplaced emphasis'. Also see *Barboza* (n. 7), 125–129.
123 ILC, Articles on Prevention (n. 101).
124 *Barboza* (n. 7), 119; see chapter 4.
125 *Rao* (n. 122), para. 3.

gin.[126] Having assessed the comments of states on the issue,[127] the Special Rapporteur later even concluded that state liability 'does not appear to have support even as a measure of progressive development of law'.[128] The final *Principles on Allocation of Loss* adopted in 2006 no longer contain an express reference to state liability, although they maintain the idea that the state of origin should make additional financial resources available where civil law remedies are insufficient to provide adequate compensation.[129]

E. Conclusions

It is widely acknowledged in legal scholarship that, *de lege ferenda*, there should be a form of subsidiary state liability for significant transboundary harm caused by hazardous activities, at least in cases where no sufficient compensation can be obtained through available civil law remedies.[130] Moreover, the preceding survey of international practice has shown that although states are reluctant to accept such liability in international treaties, there are only a few cases in which transboundary harm was left entirely unanswered by the state of origin.[131] In many cases, payments were made explicitly on an *ex gratia* basis, and states insisted on not accepting a *legal* responsibility or liability for the damage.[132] Hence, although there

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126 *Boyle* (n. 9), 5–6; *Caroline E. Foster*, The ILC Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, 14 (2005) RECIEL 265, 271; *Handl* (n. 4), 116; *Barboza* (n. 7), 125–128.

127 *Pemmaraju S. Rao*, Second Report on the Legal Regime for the Allocation of Loss in Case of Transboundary Harm Arising Out of Hazardous Activities, UN Doc. A/CN.4/540 (2004), paras. 25–29.

128 *Pemmaraju S. Rao*, Third Report on the Legal Regime for the Allocation of Loss in Case of Transboundary Harm Arising Out of Hazardous Activities, UN Doc. A/CN.4/566 (2006), para. 31.

129 ILC, Allocation of Loss Principles (n. 112), Principle 4(5); see *Foster* (n. 126), 267–277; see chapter 8, section B.III.

130 See, e.g., *La Fayette* (n. 109); *Lammers* (n. 9), 47; *Handl* (n. 4), 122–123; *Boyle* (n. 9); also see Institut de Droit International, Responsibility and Liability Under International Law for Environmental Damage: Resolution Adopted on September 4, 1997, 37 ILM 1474, Article 4(1), which reads: 'The rules of international law may also provide for the engagement of strict responsibility of the State on the basis of harm or injury alone. This type of responsibility is most appropriate in case of ultra-hazardous activities, and activities entailing risk or having other similar characteristics.'

131 *Barboza* (n. 7), 157.

132 ILC, Survey of liability regimes (n. 34), para. 399; *Barboza* (n. 7), 157.

is arguably a widespread practice of states, this practice seems not to be carried by a corresponding *opinio iuris* that such practice is required by law.[133]

However, it has also been argued that 'no argument that the sum paid in settlement was given *ex gratia* can wholly overcome the implication […] that the settlement reflected an *opinio juris* shared by both the claimant and the respondent state that the settlement was legally compelled'.[134] Another scholar observed that 'it would be disingenuous not to acknowledge that legal significance inevitably attaches to "*ex gratia*" payments of compensation, notwithstanding the label', and that observable state conduct was a 'key element in the chain of evidence pointing to states' recognition of an underlying legal obligation'.[135]

But still, the insistence of states that their payments were not to be understood as recognizing a legal obligation cannot be disregarded. Although the existence of *opinio iuris* is often inferred from the existence of a general practice,[136] both elements should not be conflated, and the 'presumption of acceptance' is at least 'rebuttable'.[137] Given the persistent refusal of states to acknowledge legal liability beyond responsibility for wrongful conduct in international treaty-making,[138] the pertinent state practice currently does not provide sufficient ground to assume the existence of a customary rule providing for strict state liability.[139]

In the present context, this finding means that a state is not generally liable for transboundary harm caused by biotechnology products apart from in cases of a breach of international law. Thus, if a state has taken all

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133 Cf. *Lefeber* (n. 5), 177.

134 *Alfred P. Rubin*, Pollution by Analogy: The Trail Smelter Arbitration, 50 (1971) Oregon Law Review 259, 279; *Barboza* (n. 7), 63–64.

135 *Handl* (n. 4), note 80.

136 *Shaw* (n. 22), 64–66.

137 *Crawford* (n. 22), 26; see ICJ, North Sea Continental Shelf (Federal Republic of Germany v. Denmark; Federal Republic of Germany v. Netherlands), Judgment of 20 February 1969, ICJ Rep. 3, para. 76; ICJ, Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States of America), Merits Judgment of 27 June 1986, ICJ Rep. 14, paras. 206–207.

138 See *supra* section A.

139 Cf. *Lefeber* (n. 5), 187; *Jutta Brunnée*, Of Sense and Sensibility: Reflections on International Liability Regimes as Tools for Environmental Protection, 53 (2004) ICLQ 351, 355–356; *Handl* (n. 4), 120; *Saxler* et al. (n. 118), 507; *Montjoie* (n. 60), 507; ITLOS, Responsibilities and Obligations of States (n. 51), para. 209; *Ulrich Beyerlin/Thilo Marauhn*, International Environmental Law (2011), 367; *Boyle/Redgwell* (n. 3), 228.

measures deemed 'appropriate' to prevent adverse transboundary effects, it is under no obligation to compensate for damage that occurs nevertheless. This again demonstrates the need to strengthen the preventive obligations and, since a moratorium seems difficult to achieve, to agree to clear conditions for unilateral releases, particularly of organisms containing self-spreading biotechnology.

Chapter 11: Compensation for Environmental Damage in International Law

The preceding chapters have identified potential sources of responsibility and liability for damage caused by applications of modern biotechnology in a transboundary context. A remaining question is whether damage to the environment is subject to reparation and how the 'nature and quantum' of such reparation can be determined. It has been observed that the 'complexity of the environment means that the traditional principles of compensation in international law are challenged'.[1] These challenges result, at least in part, from the fact that there is still no universally accepted definition of what constitutes 'environmental damage'.[2] According to a narrow understanding, the meaning of this term is limited to damage to natural resources such as air, water, soil, flora and fauna, and their interaction,[3] while a broader definition also includes the loss of 'non-use values' or 'environmental amenities'.[4]

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1 *Jason Rudall*, Compensation for Environmental Damage Under International Law (2020), 24.

2 Cf. *Philippe Sands* et al., Principles of International Environmental Law (4th ed. 2018), 741–743.

3 *Ibid.*, 741; see United States, Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund), as Amended Through P.L. 109–591, Enacted August 10, 2005, 42 U.S.C. §§ 9601–9675, 42 U.S.C. § 9607(a)(4)(C). The term 'natural resources' is defined as 'land, fish, wildlife, biota, air, water, ground water, drinking water supplies, and other such resources […]'; see *ibid.*, 42 U.S.C. § 9601(16).

4 ILC, Draft Principles on the Allocation of Loss in the Case of Transboundary Harm Arising Out of Hazardous Activities, with Commentaries (2006), YBILC 2006, vol. II(2), p. 56 (hereinafter 'ILC, Allocation of Loss Principles'), Principle 2, MN. 20; UNEP Working Group of Experts on Liability and Compensation for Environmental Damage Arising from Military Activities, Conclusions by the Working Group, in: Aleksandr S. Timoshenko (ed.), Liability and Compensation for Environmental Damage (1998) 119, para. 34. See Convention on the Regulation of Antarctic Mineral Resource Activities (02 June 1988; not in force), 27 ILM 868 (hereinafter 'CRAMRA'), Article 1(15); Protocol on Environmental Protection to the Antarctic Treaty (04 October 1991; effective 14 January 1998), 30 ILM 1455, Article 3(1); Convention on Civil Liability for Damage Resulting from Activities

Some liability instruments focus on specific components of the environment. For instance, the *Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress* applies exclusively to adverse effects caused by LMOs on the conservation and sustainable use of biological diversity. At the same time, the scope of the European Union's *Environmental Liability Directive* is limited to adverse effects on protected species and natural habitats, water damage, and land contamination.[5] The vast majority of international treaties on liability for environmental damage do not define the term 'environmental damage' at all, but merely stipulate that liability for impairment of the environment shall be limited to the costs of reasonable clean-up and reinstatement measures.[6] In the commentary to its *Draft Articles on Prevention of Transboundary Harm*, the *International Law Commission* (ILC) even assumed that the notion of *harm to the environment* was 'self-explanatory'.[7]

Against this background, it has been asserted that 'general international law neither defines environmental damage nor provides any guidance as to

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Dangerous to the Environment (21 June 1993; not yet in force), 32 ILM 1228 (hereinafter 'Lugano Convention on Civil Liability'), Article II(10).

5 See Directive 2004/35/CE on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage (21 April 2004), OJ L 143, p. 56 (hereinafter 'EU Environmental Liability Directive'), Article 2(1)(a).

6 See, e.g., Vienna Convention on Civil Liability for Nuclear Damage (25 May 1963; effective 12 September 1997), 1063 UNTS 358, as amended by the Protocol of 12 September 1997 (effective 4 October 2003), IAEA Doc. INFCIRC/566 (hereinafter '1997 Vienna Convention on Civil Liability for Nuclear Damage'), Article 1(1)(k)(iv); Convention on Civil Liability for Damage Caused During Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels (10 October 1989; not yet in force), UN Doc. ECE/TRANS/79 (hereinafter 'CRTD'), Article 1(10)(c); Kiev Protocol on Civil Liability and Compensation for Damage Caused by the Transboundary Effects of Industrial Accidents on Transboundary Waters (21 May 2003; not yet in force), UN Doc. ECE/MP.WAT/11-ECE/CP.TEIA/9 (hereinafter 'Kiev Liability Protocol'), Article II(2)(d); Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal (10 December 1999; not yet in force), UNEP/CHW.5/29, p. 88 (hereinafter 'Basel Protocol on Liability for Hazardous Wastes'), Article 2(2)(c); International Convention on Civil Liability for Bunker Oil Pollution Damage (23 March 2001; effective 21 November 2008), IMO Doc. LEG/CONF.12/19 (hereinafter 'Bunker Oil Convention'), Article 1(10); Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty: Liability Arising from Environmental Emergencies (14 June 2005; not yet in force), ATCM Measure 1 (2005) (hereinafter 'Antarctic Liability Annex'), Article 6(2).

7 ILC, Draft Articles on Prevention of Transboundary Harm from Hazardous Activities, with Commentaries (2001), YBILC 2001, vol. II(2), p. 148, Article 2, MN. 8.

how it should be valued'.[8] Although a wide range of international treaties provides for some form of liability for environmental damage,[9] the instances of relevant practice at the intergovernmental level are rare.[10] There have only been a few contentious international cases in which compensation for environmental damage was claimed and awarded.[11] But in recent years, international courts and tribunals have increasingly recognized that responsibility for environmental damage can entail an obligation to serve pecuniary relief.[12] In its recent judgment on compensation in the case concerning *Certain Activities Carried out by Nicaragua in the Border Area*, the

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8 *Alan E. Boyle*, Reparation for Environmental Damage in International Law: Some Preliminary Problems, in: Michael Bowman/Alan E. Boyle (eds.), Environmental Damage in International and Comparative Law (2002) 17, 26.

9 See *supra* n. 6 and *Hannes Descamps/Robin Slabbinck* et al. (eds.), International Documents on Environmental Liability (2008).

10 See ILC, Survey of Liability Regimes Relevant to the Topic of International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law (International Liability in Case of Loss from Transboundary Harm Arising Out of Hazardous Activities): Prepared by the Secretariat, UN Doc. A/CN.4/543 (2004); *Julio Barboza*, The Environment, Risk and Liability in International Law (2011), 50–62; *Sands* et al. (n. 2), 752–755. Notable cases in which the responsible state agreed to pay compensation were the crash of the Soviet nuclear-powered satellite *Cosmos 954* (see *Alexander F. Cohen*, Cosmos 954 and the International Law of Satellite Accidents, 10 (1984) Yale L.J. 78), the chemical accident at *Sandoz* which polluted the shared river *Rhine* (see *Astrid Boos-Hersberger*, Transboundary Water Pollution and State Responsibility: The Sandoz Spill, 4 (1997) Annual Survey of International & Comparative Law 103), the *Gut Dam arbitration* (see *Said Mahmoudi*, Gut Dam Claims, in: Wolfrum/Peters (ed.), MPEPIL), the compensation paid by Australia for rehabilitation of certain phosphate lands in *Nauru* mined under Australian administration (see *Nico J. Schrijver*, Certain Phosphate Lands in Nauru Case (Nauru v Australia), in: Wolfrum/Peters (ed.), MPEPIL), and the responsibilities accepted by the United States following nuclear tests in the South Pacific (see *Barboza* (n. 10), 55–57).

11 See e.g. Trail Smelter Case (United States v. Canada), Decision of 16 April 1938, III RIAA 1911, 1933; ICSID, Burlington Resources v. Ecuador, Decision on Ecuador's Counterclaim of 07 February 2017, ICSID Case No. ARB/08/05, paras. 79–889. On the award of environmental damages in investor-state disputes, see *Rudall* (n. 1), 31–36.

12 Cf. ITLOS, Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, Advisory Opinion of 01 November 2011, Case No. 17, ITLOS Rep. 10, MN. 193–198; ICSID, Perenco v. Ecuador and Empresa Estatal Petróleos del Ecuador (Petroecuador), Interim Decision on the Environmental Counterclaim of 11 August 2015, ICSID Case No. ARB/08/6; also see IACtHR, The Environment and Human Rights (State Obligations in Relation to the Environment in the Context of the Protection and Guarantee of the Rights to Life and to Personal Integrity – Interpretation and Scope of Articles

ICJ expressly stated that 'damage to the environment, and the consequent impairment or loss of the ability of the environment to provide goods and services, is compensable under international law'.[13]

Based on the international treaties, instances of state practice, and case law mentioned above, the present chapter seeks to identify the pertinent principles on compensation and valuation of environmental damage. These principles will likely also be relevant when determining compensation for damage caused by applications of self-spreading biotechnology such as engineered gene drives.

There are two different approaches to rectifying environmental damage in international law. The first approach is through *response measures*, i.e. 'tangible action' aimed at containing the cause of the damage, preventing and mitigating further damage, and restoring the impaired environment as much as possible to its *status quo ante*. Compensation for response measures is generally served by reimbursing the expenses incurred by the affected state(s) in taking the necessary measures. This approach is applied in most of the civil liability treaties mentioned above[14] and appears to be generally recognized (A.).

The second approach is compensation *stricto sensu*, i.e. pecuniary relief for environmental damage that cannot be remedied by response measures. This includes both interim losses incurred until the impaired environment has recovered and irrecoverable permanent injury, such as the loss of a species. However, it is both controversial whether such 'pure' environmental damage is compensable at all and how it can be expressed in financial terms (B).

A. *The Reparative Approach: Mitigating, Evaluating, and Restoring Environmental Damage*

The first approach to remedying environmental damage is to take *response measures*, i.e. measures to prevent further harm, clean up pollution or contamination, and restore the impaired components of the environment

4(1) and 5(1) of the American Convention on Human Rights), Advisory Opinion OC-23/18 of 15 November 2017, IACtHR Ser. A, No. 23, para. 103.

13 ICJ, Certain Activities Carried out by Nicaragua in the Border Area (Costa Rica v. Nicaragua), Compensation Owed by Nicaragua to Costa Rica, Judgment of 02 February 2018, ICJ Rep. 15, para. 42.

14 See *supra* n. 6.

to their previous state. As shown earlier, the so-called 'administrative approach' to operator liability seeks to require the responsible operator to implement such measures instead of merely holding the operator liable for financial compensation.[15] But in a transboundary context, response measures will most often not be implemented by a foreign liable party (i.e., the responsible operator or the state of origin) but by the state in whose territory the damage occurred.[16] This raises the question of under what conditions the injured party is entitled to be reimbursed for the expenses incurred in taking such response measures.

It appears to be uncontroversial that costs incurred for response measures are, in principle, subject to compensation under international law. In its commentary to the *Articles on State Responsibility* (ARSIWA), the ILC expressly recognized 'the costs incurred in responding to pollution damage' as one of the appropriate heads of compensable damage.[17] Similarly, the *International Court of Justice* (ICJ) held in the *Certain Activities* case that the injured state is entitled to compensation for its expenses incurred as a consequence of the internationally wrongful act, provided that there is a 'sufficiently direct and certain causal nexus' between the wrongful conduct and the heads of expenses for which compensation is sought.[18] Moreover, most international treaties on operator liability, including the *Nagoya – Kuala Lumpur Supplementary Protocol*, provide for the reimbursement of costs incurred for implementing reasonable measures of reinstatement and prevention.[19]

15 See chapter 2, section G, and chapter 6, section C.I.

16 See chapter 9, section B.II.3.a)bb).

17 ILC, Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries (2001), YBILC 2001, vol. II(2), p. 31 (hereinafter 'ARSIWA'), Commentary to Article 36, para. 8.

18 ICJ, Certain Activities (Compensation) (n. 13), para. 89. For details on the case, see *infra* section B.I.4 and B.III.

19 See, e.g., International Convention on Civil Liability for Oil Pollution Damage (29 November 1969; effective 19 June 1975), 973 UNTS 3, as amended by the Protocol of 27 November 1992 (effective 30 May 1996), 1956 UNTS 255 (hereinafter '1992 Oil Pollution Convention'), Article I(6) and (7); Bunker Oil Convention (n. 6), Article I(9); Lugano Convention on Civil Liability (n. 4), Article II(7)(c) and (d); International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea (03 May 1996; not yet in force), 25 ILM 1406, as amended by the Protocol of 30 April 2010, IMO Doc. LEG/CONF.17/DC/1 (hereinafter 'HNS Convention'), Article I(6)(c) and (d); Basel Protocol on Liability for Hazardous Wastes (n. 6), Article II(c)(c)(iv) and (v); 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 6), Article I(1)(k) and (m-o); Kiev Liability Protocol

International case law and treaty practice allow distinguishing between different types of response measures that are commonly subject to reimbursement (I.). However, compensation for expenses is usually subject to certain conditions and limitations (II.). A special question concerns the reimbursement of costs incurred by third states who assist the affected states in abating and mitigating environmental damage (III.).

I. Types of Response Measures Subject to Reimbursement

Three different types of response measures are generally accepted as being compensable under international law, namely *mitigation measures* to prevent further injury (1.), *restoration measures* to repair the injury already suffered (2.), and *evaluation measures* to assess the damage and to determine the necessary responses (3.).

1. Mitigation Measures

'Mitigation measures' refer to measures to avoid further damage to the environment from the consequences of the internationally wrongful act. Expenses incurred for such measures are generally accepted as a compensable head of damage. For instance, following Iraq's invasion of Kuwait in 1990, the *United Nations Compensation Commission* (UNCC) awarded compensation for expenses relating to fighting oil fires and stemming the flow of oil in coastal and international waters caused by Iraq.[20] Payments

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(n. 6), Article II82)(d)(iv-v) and, (g-h); Antarctic Liability Annex (n. 6), Article VI(1); Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (15 October 2010; effective 05 March 2018), UN Doc. UNEP/CBD/BS/COP-MOP/5/17, p. 64 (hereinafter 'Supplementary Protocol'), Article 5(5); see *infra* section B.I.1.

20 UNCC, Governing Council Decision 7. Criteria for Additional Categories of Claims (16 March 1992), UN Doc. S/AC.26/1991/7/Rev.1, 35(a); see *Philippe Gautier*, Environmental Damage and the United Nations Claims Commission: New Directions for Future International Environmental Cases?, in: Tafsir M. Ndiaye/Rüdiger Wolfrum (eds.), Law of the Sea, Environmental Law, and Settlement of Disputes (2010) 177, 188. On the mandate of the UNCC, see *infra* section B.I.3.

were also awarded for removing landmines and other remnants of war and for recovering oil from oil lakes.[21]

In the *Certain Activities* case, the ICJ awarded compensation for costs and expenses incurred in taking measures to prevent 'irreparable prejudice to the environment'. In that case, Costa Rica constructed a dyke to ensure that waters from the San Juan River were not diverted through one of the channels unlawfully excavated by Nicaragua.[22] The Court held that Costa Rica was to be compensated for both the construction of the dyke and overflights required to monitor its effectiveness.[23]

In the context of damage resulting from biotechnology, mitigation measures may include actions taken to contain a malicious LMO or, where possible, to remove it from the affected environment. This is in line with Article 25(2) of the *Cartagena Protocol on Biosafety*, under which the affected party may request the party of origin to dispose of the LMO in question by repatriation or destruction.[24] Moreover, Article 5(5) of the *Nagoya–Kuala Lumpur Supplementary Protocol* provides that the competent authority of an affected party has the right to recover from the responsible operator the costs and expenses of, and incidental to, the evaluation of the damage and the implementation of appropriate response measures.[25]

2. Restoration Measures

'Restoration measures' refer to actions aimed at restoring the impaired environment to its baseline condition or *status quo ante*, i.e. the condition it had before it was affected by the consequences of the internationally wrongful act.[26] Restoration measures are thus aimed to achieve *restitution*

21 UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the Second Instalment of "F4" Claims, S/AC.26/2002/26 (2002), paras. 85–133.
22 ICJ, Certain Activities (Compensation) (n. 13), paras. 135–138.
23 *Ibid.*, para. 146.
24 See chapter 3, section A.II.2.c.bb).
25 See chapter 6, section C.IV.5.
26 See 'Status quo ante', in: *Aaron X. Fellmeth/Maurice Horwitz*, Guide to Latin in International Law (2011), 267. These measures are also referred to as 'primary restoration', as opposed to 'compensatory restoration' which seeks to compensate for interim or irreparable losses, see *Michael T. Huguenin* et al., Assessment and Valuation of Damage to the Environment, in: Cymie R. Payne/Peter H. Sand (eds.), Gulf War Reparations and the UN Compensation Commission (2011) 67, 77. On compensatory restoration, see *infra* section B.II.1.

in the sense of Article 35 of the ILC's Articles on State Responsibility, which means the re-establishment of the situation which existed before the wrongful act was committed.[27]

In line with the aforementioned principle established by the PCIJ in the *Chorzów Factory* case,[28] the environmental panel of the UNCC held that the 'appropriate objective of remediation is to restore the damaged environment or resource to the condition in which it would have been if Iraq's invasion and occupation of Kuwait had not occurred'.[29] This was confirmed by the ICJ in its judgment on compensation in the *Certain Activities* case, where it held that compensation for damage to the environment could include 'payment for the restoration of the damaged environment'.[30] Moreover, the ICJ noted that:

> *'Payment for restoration accounts for the fact that natural recovery may not always suffice to return an environment to the state in which it was before the damage occurred. In such instances, active restoration measures may be required in order to return the environment to its prior condition, in so far as that is possible.'*

Interestingly, the ICJ did not actually award any compensation for restoration measures. Although Costa Rica had claimed compensation for 'restoration costs', including for the replacement of soil,[31] it apparently had neither taken such measures nor indicated that it intended to implement them in the future, which led the Court to reject these claims.[32]

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27 See *Barboza* (n. 10), 139, who argues that 'restitutio naturalis' should be the primary form of reparation also in cases of environmental damage, and appears to construe restoration measures to constitute 'reparation' regardless of which party is implementing them. However, if not the responsible state but the injured state implements response measures, reimbursement of the related expenses does not constitute restitution, but compensation under the law of state responsibility.

28 Cf. PCIJ, Factory at Chorzów (Germany v. Poland), Merits Judgment of 13 September 1928, PCJI Rep. Ser. A, No. 17, 47.

29 UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the Third Instalment of "F4" Claims, UN Doc. S/AC.26/2003/31 (2003), para. 47; see *Gautier* (n. 20), 207.

30 ICJ, Certain Activities (Compensation) (n. 13), para. 42.

31 *Ibid.*, para. 57.

32 Cf. *ibid.*, para. 74. Insofar as the Court awarded 'payment of compensation for restoration measures in respect of the wetland' (cf. *ibid.*, para. 87), it apparently overlooked that Costa Rica's claim for US$ 2,708.39 for 'restoration of the wetland' was part of a proposed valuation of damaged environment and referred to natural restoration rather than active restoration measures actually carried out, see ICJ, Certain Activities Carried Out by Nicaragua in the Border Area (Costa

Hence, the Court's conclusions on payments for active restoration measures appear to constitute an *obiter dictum*[33] by which the Court went beyond what was at stake in the case before it.

The reimbursement of expenses for restoration measures is also recognized in many international liability instruments. For instance, the *Nagoya/Kuala Lumpur Supplementary Protocol* provides that the competent authority may recover from the responsible operator the costs and expenses of implementing response measures, including measures to restore impaired biological diversity.[34] Similar provisions can also be found in the *Antarctic Liability Annex*[35] and in some international conventions on civil liability.[36]

In sum, it appears to be an established rule under international law that the obligation to make reparation for environmental damage includes payment for restoration measures. Interestingly, only little attention has so far been paid to the precise legal nature of this form of reparation, especially whether reimbursement of costs for restoration measures taken by the injured state constitutes a form of *restitution in kind* (in terms of Article 35 ARSIWA)[37] or *compensation* (in the sense of Article 36 ARSIWA).[38] It could be argued that since restoration measures are aimed at re-establishing the situation which existed prior to the wrongful act, payments for implementing such measures are a form of restitution.[39] However, restitution is commonly understood as tangible action taken by the responsible state to restore the *status quo ante*.[40] Thus, if the injured state takes response measures, reimbursement of the expenses thereby incurred constitutes a form of compensation in the sense of Article 36 ARSIWA.

Rica V. Nicaragua): Memorial of Costa Rica on Compensation, Volume I (2017), 147.

33 See 'Obiter dictum', in: *Fellmeth/Horwitz* (n. 26), 205.

34 Supplementary Protocol (n. 19), Article 5(5).

35 Antarctic Liability Annex (n. 6), Article 6(1).

36 Cf. 1992 Oil Pollution Convention (n. 19), Article I(6)(a) and (b); Lugano Convention on Civil Liability (n. 4), Article II(7)(c) and (d); HNS Convention (n. 19), Article I(6)(c) and (d); Basel Protocol on Liability for Hazardous Wastes (n. 6), Article II(c)(c)(iv) and (v).

37 See chapter 9, section B.II.3.a).

38 See chapter 9, section B.II.3.b).

39 This seems to be implied by ICJ, Certain Activities (Compensation) (n. 13), Separate Opinion of Judge Cançado Trindade, paras. 53–58.

40 ARSIWA (n. 17), Article 35, para. 5.

3. Evaluation Measures

Before mitigation and restoration measures can be implemented, it might be necessary to assess and evaluate the damage to determine the necessary measures.[41] The UNCC's environmental panel awarded compensation for monitoring and determined that assessment activities were compensable as long as there was a 'plausible risk' of environmental harm, even if the monitoring eventually established that no damage had been caused.[42] In the panel's view, conclusive proof of environmental damage is not required for a monitoring and assessment activity to be compensable, as such a requirement would be 'both illogical and inequitable'.[43] Instead, the panel only required a 'sufficient nexus' between the proposed activity and the alleged damage or risk of damage.[44] At the same time, it rejected claims which were only theoretical or speculative or which had only a tenuous link with damage resulting from Iraq's invasion.[45]

Similarly, the *International Oil Pollution Compensation Funds* (IOPC Funds) provide for the reimbursement of costs for studies to establish the nature and extent of damage and to determine whether reinstatement measures are necessary and feasible.[46] In this respect, the Funds' Claims Manual clarifies that

> *'[…] the mere fact that a post-spill study demonstrates that no significant long-term environmental damage has occurred or that no reinstatement measures are necessary, does not by itself exclude compensation for the costs of the study.'*[47]

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41 Cf. *Gautier* (n. 20), 202–204; *Daniela M. Schmitt*, Staatenverantwortlichkeit für Schäden an der biologischen Vielfalt (2018), 384–385.

42 UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the First Instalment of "F4" Claims, UN Doc. S/AC.26/2001/16 (2001), paras. 31–32; see *Peter H. Sand*, Compensation for Environmental Damage from the 1991 Gulf War, 35 (2005) Environmental Policy and Law 244, 246; *Sands* et al. (n. 2), 757; *Cymie R. Payne*, Legal Liability for Environmental Damage: The United Nations Compensation Commission and the 1990–1991 Gulf War, in: Carl Bruch/Carroll Muffett/Sandra S. Nichols (eds.), Governance, Natural Resources, and Post-Conflict Peacebuilding (2016) 719, 727.

43 UNCC Panel Report F4/1 (2001) (n. 42), paras. 29–30.

44 *Ibid.*, para. 31.

45 *Ibid.*

46 IOPC Funds, Claims Manual, as adopted by the 1992 Fund Assembly in April 1998 and amended, most recently in April 2018, by the 1992 Fund Administrative Council (2019), para. 3.6.7–8.

47 *Ibid.*, paras. 3.6.9.

It has been questioned whether these lowered requirements for the compensability of environmental monitoring and assessment activities can be transferred to other cases.[48] Notably, the UNCC's conclusions were not based on an assessment of general international law but on the Security Council resolutions[49] and Governing Council decisions[50] which had already established that Iraq was liable for the consequences resulting from its unlawful activities.[51] In other cases, such responsibility would still need to be established before any compensation can be awarded, even for activities assessing possible injury and its causes.[52] However, these concerns are rather a matter of timing or procedure than substance. Once a state's international responsibility has been established, compensation extends to all monitoring and assessment measures, including those required to assess the extent of damage and its causes and to determine potential response measures.[53]

The above conclusions were confirmed in the *Certain Activities* case, in which the ICJ concluded that Nicaragua was internationally responsible for environmental damage on Costa Rican territory.[54] Subsequently, the ICJ held that expenses incurred by the injured party for assessing and evaluating the damage resulting from the unlawful act constitute compensable damage under the law of state responsibility.[55] In particular, compensation was awarded for costs incurred for purchasing satellite images of the affected area,[56] obtaining technical evaluations of these images[57] and inspection visits to assess the environmental situation in the area and identify actions needed to prevent further irreparable damage.[58] Hence, costs and expenses for assessing and evaluating environmental damage are compensable

48 Cf. *Gautier* (n. 20), 203.
49 See, in particular, UNSC, Resolution 687 (1991). Iraq-Kuwait (03 April 1991), UN Doc. S/RES/687(1991).
50 See, in particular, UNCC Governing Council Decision 7 (n. 20), para. 35(c).
51 *Gautier* (n. 20), 203; see *infra* section B.I.3.
52 *Ibid.*
53 See *ibid.*, who argues that a court could order studies or an expert opinion to determine the appropriate response measures to be taken; *Schmitt* (n. 41), 385.
54 Cf. ICJ, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica v. Nicaragua) and Construction of a Road in Costa Rica along the San Juan River (Nicaragua v. Costa Rica), Merits Judgment of 16 December 2015, ICJ Rep. 665, para. 142.
55 ICJ, Certain Activities (Compensation) (n. 13), para. 113.
56 *Ibid.*, paras. 118–120.
57 *Ibid.*, paras. 98, 123–124.
58 *Ibid.*, para. 113.

under the law of state responsibility, provided that there exists a 'sufficiently direct and certain causal nexus' between the internationally wrongful act and the expenses claimed, even when the assessment reveals that no environmental damage resulted from the internationally wrongful act.[59] In the *Trail Smelter* case, the tribunal even awarded compensation for possible future investigations to establish whether further damage occurred despite the measures ordered in the award.[60]

II. Limitations to Compensability

Costs incurred for response measures are not compensable unconditionally. In particular, reimbursement is limited to such measures that are 'appropriate' or 'reasonable' (1.). Moreover, expenses are only compensable when incurred as a direct consequence of the damage and when they would not have accrued anyway (2.). Finally, some regimes limit compensation for response measures to the monetary value of the impaired environment (3.).

1. Limitation to 'Reasonable' Measures

It is widely recognized that expenses incurred for implementing restoration measures are only compensable to the extent that the measures in question are 'appropriate'[61] or 'reasonable'.[62]

The requirement of reasonableness was also applied by the UNCC's environmental panel, which assessed the cost-effectiveness and appropriateness of proposed monitoring and reinstatement measures by referring

59 Cf. *ibid.*, para. 123; *Schmitt* (n. 41), 385.

60 Trail Smelter Case (United States v. Canada), Decision of 11 March 1941, III RIAA 1938, 1980; see *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 140.

61 See., e.g., Antarctic Liability Annex (n. 6), Article II(e); ILC, Allocation of Loss Principles (n. 4), Principle 5(b); Supplementary Protocol (n. 19), Article 5(1)(c).

62 See, e.g., 1992 Oil Pollution Convention (n. 19), Article I(6)(a); UNCC Governing Council Decision 7 (n. 20), para. 35; Lugano Convention on Civil Liability (n. 4), Article II(7)(c); HNS Convention (n. 19), Article I(6)(c); Basel Protocol on Liability for Hazardous Wastes (n. 6), Article II(c)(c)(iv); Supplementary Protocol (n. 19), Article 2(1)(d).

to 'generally accepted scientific criteria and methodologies'.[63] According to the panel, the primary emphasis should be placed on restoring the environment to its prior conditions, 'in terms of its overall ecological functioning rather than on the removal of specific contaminants or restoration of the environment to a particular physical condition'.[64] Consequently, the panel held that even where sufficient baseline information allowed to determine the exact historical state of the environment prior to Iraq's invasion of Kuwait, it might not always be feasible or reasonable to fully recreate pre-existing physical conditions.[65]

The panel also refused compensation for restoration measures that were 'likely to result in more negative than positive effects'.[66] For instance, it rejected proposed studies on the release of genetically modified bacteria to combat residual oil pollution.[67] The panel noted that it had 'serious reservations' about the deliberate release of genetically modified organisms into the environment, in particular considering the absence of reliable scientific knowledge about the threat posed by these organisms and in the view of the low probability that such an experiment would have 'any practical utility'.[68] Other proposals rejected by the panel concerned, among others, the introduction of non-native tree species into damaged forest areas,[69] and the removal of contaminated sediments by treating them with *high-temperature thermal desorption*.[70] The panel held that the latter approach would pose 'unacceptable risks of adverse environmental impacts' and preferred an alternative approach that targeted the impediments to ecological recov-

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63 UNEP Working Group of Experts on Liability and Compensation for Environmental Damage Arising from Military Activities (n. 4), para. 47; UNCC Panel Report F4/1 (2001) (n. 42), para. 35.

64 UNCC Panel Report F4/3 (2003) (n. 29), para. 48; see *Sands* et al. (n. 2), 759.

65 UNCC Panel Report F4/3 (2003) (n. 29), para. 48.

66 UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning Part One of the Fourth Instalment of "F4" Claims, UN Doc. S/AC.26/2004/16 (2004), para. 50; UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning Part Two of the Fourth Instalment of "F4" Claims, UN Doc. S/AC.26/2004/17 (2004), para. 41; see *Sands* et al. (n. 2), 759; *Gautier* (n. 20), 203–204.

67 UNCC Panel Report F4/1 (2001) (n. 42), paras. 169–172.

68 *Ibid.*, para. 171.

69 *Ibid.*, paras. 238–241.

70 'High temperature thermal desorption' refers to a process using heat to separate contaminants from contaminated material, during which water and organic contaminants are volatilized from the material. The volatilized contaminants usually require further treatment. See the glossary in UNCC Panel Report F4/3 (2003) (n. 29), 56.

ery and accelerated natural recovery[71] In some instances, the panel also concluded that it was more reasonable to rely on and assist the natural recovery of damaged areas.[72]

The aforementioned examples indicate that the objective of environmental restoration does not justify taking additional environmental risks, at least as long as no clear benefits can be expected from these measures. Applied to the case of a malicious LMO causing environmental harm, this means that the release of other LMOs designed to contain or eliminate the malicious organism is generally not justified. For example, when a gene drive exceeds its intended target species or geographical scope or otherwise causes harm, the release of a 'reversal drive'[73] would at least require that the expected environmental benefits clearly outweigh the additional risks.

2. Limitation of Reimbursement to Incremental and Extraordinary Expenses

In general, the reimbursement of costs incurred for response and restoration action is limited to *incremental costs*, i.e. expenses that would not have been incurred if the internationally wrongful act had not been committed.[74] However, this principle is sometimes questioned concerning the salaries of civil servants and the costs of using state-owned equipment. For instance, in the case concerning the *Amoco Cadiz* oil spill, a *United States District Court* (applying French law) awarded compensation for the time public employees took from their regular duties to devote their efforts to clean-up activities.[75] With regard to the equipment used for clean-up, the District Court only granted the incremental operating costs exceeding those expenses that would have occurred during the regular operation

71 *Ibid.*, paras. 179–183; see *Payne* (n. 42), 730.
72 Cf., e.g., UNCC Panel Report F4/3 (2003) (n. 29), para. 129.
73 See *Kevin M. Esvelt* et al., Concerning RNA-Guided Gene Drives for the Alteration of Wild Populations, 3 (2014) eLife e03401, 10; *Stephanie James* et al., Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group, 98 (2018) Am. J. Trop. Med. Hyg. 1, 13.
74 *Lefeber* (n. 60), 135–136; see *Cohen* (n. 10), 86.
75 United States District Court for the Northern District of Illinois, Eastern Division, In re Oil Spill By "AMOCO Cadiz" etc., Judgment of 11 November 2988, 1988 U.S. Dist. LEXIS 16832, *14–*15; see *Alexandre Kiss/Dinah Shelton*, International Environmental Law (3rd ed. 2004), 283–285; *Gautier* (n. 20), 206.

of the equipment.[76] Later, the *United States Court of Appeals* found it inconsistent to apply different standards to civil servants and to equipment and also awarded the regular costs of using the equipment during the clean-up.[77]

In the practice of the UNCC, compensation was only awarded for expenses that were 'incurred as a direct result of Iraq's invasion and occupation of Kuwait and were extraordinary in nature'.[78] Consequently, no compensation was awarded for salaries and other expenses for personnel that would have been incurred regardless of Iraq's unlawful conduct.[79] The same stance was taken by the *International Tribunal for the Law of the Sea* (ITLOS) in the second *Saiga* case.[80]

In the *Certain Activities* case, the ICJ held that salaries of government officials dealing with a situation resulting from an internationally wrongful act were only compensable if they were 'temporary and extraordinary in nature'.[81] In the view of the ICJ, this only applies to expenses a state incurred in paying its officials over the regular wage or where it had to hire supplementary personnel.[82] The Court found this approach to be 'in line with international practice'.[83] For the same reason, it also refused compensation for insurance costs for aircraft used in response measures.[84] Hence, current international law only provides compensation for staff and

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76 United States District Court for the Northern District of Illinois, Eastern Division, In re Oil Spill By "AMOCO Cadiz" etc. (n. 75), *17–*18.

77 United States Court of Appeals, Oil Spill by the Amoco Cadiz Off the Coast of France on March 16, 1978, Judgment of 24 January 1992, 954 F.2d 1279 (7th Cir. 1992), 1313–1314.

78 UNCC Panel Report F4/2 (2003) (n. 21), para. 30.

79 UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the First Instalment of "F2" Claims, UN Doc. S/AC.26/1999/23 (1999), para. 101; UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the Second Instalment of "F2" Claims, UN Doc. S/AC.26/2000/26 (2000), paras. 52–58; UNCC Panel Report F4/2 (2003) (n. 21), paras. 30, 245–246; also see *Gautier* (n. 20), 206.

80 ITLOS, The M/V "SAIGA" (No. 2) Case (Saint Vincent and the Grenadines v. Guinea), Judgment of 01 July 1999, ITLOS Rep. 10, para. 177.

81 ICJ, Certain Activities (Compensation) (n. 13), para. 101.

82 *Ibid.*

83 *Ibid.*

84 *Ibid.*, para. 95; also see *Lefeber* (n. 60), 136. *Jason Rudall*, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica V. Nicaragua), 112 (2018) AJIL 288, 291 observed that 'it would appear that the Court made a distinction between variable and fixed costs in certain aspects of its valuation methodology'.

equipment expenses if such expenses are directly related to the internationally wrongful act and would otherwise not have occurred.

3. Limitation of Restoration Costs to the Monetary Value of the Impaired Environment?

Under certain circumstances, the costs to restore the impaired environment to its baseline conditions may exceed the monetary value of the affected environment.[85] In many civil law regimes, damages for injury to property are awarded lesser of the cost of repair or the diminution in the property's market value. It has been proposed that this 'lesser of' rule should also be applied to environmental damage where reinstating an injured environment exceeds the value that is attached to it by society.[86] However, this overlooks that damaged property can be replaced according to its market value, while an impaired environment cannot be substituted in the same manner. Moreover, as shown below, any approaches to valuing environmental damage are necessarily imperfect because they are limited to ascribing values to certain elements or aspects of the environment.[87]

III. Compensability of 'Environmental Solidarity Costs'

In cases of large-scale environmental damage, injured states may require assistance from states from outside the affected region in abating and preventing environmental damage. In these situations, the question arises whether the expenses of these assisting states, also referred to as 'environmental solidarity costs',[88] are compensable under international law. In the case of Iraq's invasion of Kuwait, the UNCC's environmental panel held that expenses incurred by third parties (states from other regions and international organizations) were compensable to the extent that such

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85 On monetary valuation of environmental damage, see *infra* section B.II.

86 *Philippe Sands/Richard B. Stewart*, Valuation of Environmental Damage – US and International Law Approaches, 5 (1995) RECIEL 290, 294; CBD COP, Synthesis Report on Technical Information Relating to Damage to Biological Diversity and Approaches to Valuation and Restoration of Damage to Biological Diversity, as Well as Information on National/Domestic Measures and Experiences: Note by the Executive Secretary, UN Doc. UNEP/CBD/COP/9/20/Add.1 (2008), para. 115.

87 See *infra* section B.II.2.

88 See e.g. *Sand* (n. 42), 246.

assistance was provided for the predominant purpose of responding to actual or threatened environmental damage or damage to public health.[89] Although the panel based its conclusion mainly on the respective resolutions by the UN Security Council and the UNCC's Governing Council,[90] this also appears to reflect general international law. It has been argued that by legitimizing the costs of assistance, the panel reinforced the norm that the international community has a role in assisting with environmental emergencies even though the ultimate responsibility rests with the country that caused the damage.[91] Hence, expenses incurred by third parties in providing assistance are equally compensable, provided that the injured state requested or agreed to such assistance.[92] As with the injured party's own measures, the decisive criterion is whether the measures taken were required and reasonable.[93]

B. The Compensatory Approach: Monetary Compensation for Damage to the Environment

The preceding section dealt with the compensability of costs for the assessment, mitigation and remediation of environmental damage. As shown above, the objective of these measures is to restore the injured environment to the condition in which it would be if the wrongful act had not occurred.[94] In many cases, however, neither restoration measures nor

89 UNCC Panel Report F4/2 (2003) (n. 21), paras. 32–35; see *Sands* et al. (n. 2), 758. Note that expenses for military operations were expressly excluded, cf. UNCC, Governing Council Decision 19. Military Costs (24 March 1994), UN Doc. S/AC.26/Dec.19 (1994); see *Sand* (n. 42), 246.

90 UNCC Panel Report F4/2 (2003) (n. 21), para. 33.

91 *Payne* (n. 42), 742; *Sand* (n. 42), 246.

92 See United States Court of Appeals, Oil Spill by the Amoco Cadiz Off the Coast of France on March 16, 1978 (n. 77), 1313, where it was held that instead of devoting its own resources (including the time of its employees) a state could also hire the navy of another state to aid in cleaning oil spills affecting its shoreline.

93 Cf., e.g., UNCC Panel Report F4/2 (2003) (n. 21), para. 228; see *supra* section A.II.1; but see *Hanqin Xue*, Transboundary Damage in International Law (2003), 96, who fears that 'if the author State were required to reimburse all claims submitted by the injured State for operations carried out by the third party, this might be tantamount to requiring the author State to issue a blank check.'

94 Cf. UNCC Panel Report F4/3 (2003) (n. 29), para. 47.

natural regeneration can fully restore the damaged environment.[95] This is particularly true for damage to biodiversity, as it will often be impossible to restore a lost species or recover complex ecosystems to their original state.[96] In addition, costs for restoration measures are usually only reimbursed to the extent that such measures were 'reasonable'.[97] It has also been argued that the loss of diversity in one place cannot be offset by simply increasing diversity in another place.[98] Even where full restoration is possible, payment for remediation measures does not account for the impairment of the environment in the time period between the injury and the eventual recovery to baseline conditions.[99]

Temporary or permanent impairments of the environment that cannot be remedied by restoration measures, but are also not reflected in 'traditional' heads of damage such as personal injury, property damage, and loss of profit, are referred to as 'pure' environmental damage or 'damage to the environment *per se*'.[100] However, it is questionable whether this type of damage is at all subject to compensation under international (I.) and, if it is, what form compensation should take (II.). The recent judgment of the ICJ on compensation in the case of Costa Rica v. Nicaragua confirmed the compensability of pure environmental damage in principle but applied a questionable methodology to determine the amount of compensation (III.).

95 *Huguenin* et al. (n. 26), 77–78.
96 *Schmitt* (n. 41), 386.
97 See supra section A.II.1.
98 *Susanne Förster*, Internationale Haftungsregeln für schädliche Folgewirkungen gentechnisch veränderter Organismen (2007), 346.
99 *Huguenin* et al. (n. 26), 77.
100 Different terms are used to denote this type of damage, including 'damage caused to the environment, in and of itself' (ICJ, Certain Activities (Compensation) (n. 13), para. 41), 'pure environmental damage' (e.g. ICJ, Certain Activities (Compensation) (n. 13), Separate Opinion of Judge Donoghue, para. 3; *Gautier* (n. 20), 206), 'interim losses' (e.g. *Huguenin* et al. (n. 26), 78), and 'damage to natural resources' (e.g. *Edward H. P. Brans*, Liability for Damage to Public Natural Resources (2001)). Although there are different understandings as to the types, scope and valuation of damage, there appears to be coherence in that certain forms of environmental harm neither materialize in traditional heads of damage nor can be restored by mitigation and restoration measures.

I. Compensability of 'Pure' Environmental Damage

According to Article 36(2) ARSIWA, compensation only covers damage that is 'financially assessable'. As damage to the environment *per se* is, in many cases, not financially assessable without having recourse to artificial valuation techniques, it has been contended that such pure environmental damage was not eligible for compensation.[101]

1. The Practice of International Liability Treaties

A number of international instruments expressly exclude compensation for pure environmental damage. For instance, most conventions on operator civil liability for hazardous activities provide that compensation for impairment of the environment is limited to costs of reasonable measures of prevention or reinstatement actually undertaken or to be undertaken.[102] Similarly, the IOPC Funds also exclude compensation for interim loss of ecological services (e.g. access to beaches), as it constitutes 'damage in respect of which the quantum of the damage cannot be assessed according

101 Cf. *Joachim Wolf*, Gibt es im Völkerrecht einen einheitlichen Schadensbegriff?, 49 (1989) ZaöRV 403, 429–432; UNCC, Report and Recommendations Made by the Panel of Commissioners Concerning the Fifth Instalment of "F4" Claims, UN Doc. S/AC.26/2005/10 (2005), para. 46; *Phoebe N. Okowa*, State Responsibility for Transboundary Air Pollution in International Law (2000), 178; *Tullio Scovazzi*, Some Remarks on International Responsibility in the Field of Environmental Protection, in: Maurizio Ragazzi (ed.), International Responsibility Today (2005) 209, 221; also see *Lefeber* (n. 60), 136–138; *Lucas Bergkamp*, Liability and Environment (2001), 332–338; *Boyle* (n. 8), 24; *Förster* (n. 98), 176; *Payne* (n. 42), 737; *Schmitt* (n. 41), 387.

102 See, e.g., 1992 Oil Pollution Convention (n. 19), Article 1(6); Convention on Civil Liability for Oil Pollution Damage Resulting from Exploration for and Exploitation of Seabed Mineral Resources (01 May 1977; not yet in force), 16 ILM 1451, Article 1(6) and (7); Bunker Oil Convention (n. 6), Article 1(9); Lugano Convention on Civil Liability (n. 4), Article II(7)(c) and (d); 1997 Vienna Convention on Civil Liability for Nuclear Damage (n. 6), Article 1(1)(k); CRTD (n. 6), Article 1(10); HNS Convention (n. 19), Article 1(6)(c) and (d); Basel Protocol on Liability for Hazardous Wastes (n. 6), Article II(2)(c)(iv) and (v); Kiev Liability Protocol (n. 6), Article II(2)(d)(iv); see *Sand* (n. 42), 247; *Gautier* (n. 20), 185.

to market price'.[103] By the same token, they reject valuation methods based on 'theoretical models'.[104]

In contrast, other treaties expressly provide for liability for pure environmental damage that cannot be, or has not been, restored. For instance, under the 1988 *Convention on the Regulation of Antarctic Mineral Resource Activities* (CRAMRA), a state can be held liable for 'damage to the Antarctic environment […] including payment in the event that there has been no restoration to the *status quo ante*'.[105] Although the Convention never entered into force, the idea of providing for liability in the event that no response measures were taken was not abandoned. The 2005 *Liability Annex* to the Antarctic Treaty's Protocol on Environmental Protection provides that when no response action was taken in an environmental emergency, the responsible operator shall be liable to pay to an international fund the 'costs of response action which should have been undertaken'.[106] Moreover, the *Nagoya – Kuala Lumpur Supplementary Protocol*[107] and the European Union's *Environmental Liability Directive*[108] provide that damage to the environment that cannot be restored shall be compensated by improving or preserving other components of the environment.[109]

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103 IOPC Funds (n. 46), para. 1.4.12; also see IOPC Funds, Guidelines for Presenting Claims for Environmental Damage, As approved by the 1992 Fund Assembly and Supplementary Fund Assembly in October 2017 (2018), para. 5.24; *Brans* (n. 100), 324–326.

104 IOPC Funds (n. 46), paras 1.4.13; also see IOPC Funds (n. 103), para. 5.25; but see *Schmitt* (n. 41), 389–393, who shows that national courts have indeed awarded compensation for pure environmental damage in cases of oil pollution damage.

105 CRAMRA (n. 4), Article VII(2)(a).

106 Antarctic Liability Annex (n. 6), Article VI(2). During the negotiations of the Annex, it was highly controversial whether liability should go beyond providing for response action to environmental emergencies, see *Mari Skåre*, Liability Annex or Annexes to the Environmental Protocol: A Review of the Process Within the Antarctic Treaty System, in: Davor Vidas (ed.), Implementing the Environmental Protection Regime for the Antarctic (2000) 163, 177; *David J. Bederman/Soniya P. Keskar*, Antarctic Environmental Liability : The Stockholm Annex and Beyond, 19 (2005) Emory International Law Review 1383, 1387–1389.

107 Cf. Supplementary Protocol (n. 19), Article 2(2)(d)(ii)(b), which provides for restoration by 'replacing the loss of biological diversity with other components of biological diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location'. See chapter 6, section C.I.

108 Cf. EU Environmental Liability Directive (n. 5), Annex II, para. 1.1.2 and 1.1.3.

109 See *infra* section B.II.1.

2. The Stance of the International Law Commission

In Article 31(2) of its *Articles on State Responsibility*, the International Law Commission concluded that reparation for an internationally wrongful act must be made for 'any damage, whether material or moral'. According to Article 36(2), compensation shall cover 'any financially assessable damage'. In its commentary, the ILC clarified that the criterion 'financially assessable' was only intended to exclude compensation for 'moral damage'.[110] Moreover, the ILC recognized that

> *'[…] environmental damage will often extend beyond that which can be readily quantified in terms of clean-up costs or property devaluation. Damage to such environmental values (biodiversity, amenity, etc – sometimes referred to as 'non-use values') is, as a matter of principle no less real and compensable than damage to property, though it may be difficult to quantify'.*[111]

The ILC has also confirmed the compensability of environmental damage in its *Draft Principles on Allocation of Loss*.[112] According to Principle 2, the term 'damage' expressly includes 'loss or damage by impairment of the environment'.[113] In its commentary, the ILC clarified that this not only encompasses 'loss of income deriving from an economic interest in any use of the environment', but also aspects of the environment that are considered to be common property (*res communis omnium*).[114] Moreover, the ILC found it 'important to emphasize that damage to the environment *per se* could constitute damage subject to prompt and adequate compensation'.[115]

110 The ILC furthermore clarified that such moral injury 'is the subject matter of satisfaction', dealt with in Article 37 ARSIWA, cf. ARSIWA (n. 17), Commentary to Article 36, para. 1; see chapter 9, section B.II.3.c).
111 *Ibid.*, Article 36, para. 15.
112 See Chapter 8, section A.
113 ILC, Allocation of Loss Principles (n. 4), Principle 2(a)(iii).
114 *Ibid.*, Commentary to Principle 2, paras. 13–14; see 'Res communis (omnium)', in *Fellmeth/Horwitz* (n. 26), 250.
115 ILC, Allocation of Loss Principles (n. 4), Commentary to Principle 3, para. 6.

3. Compensability of Environmental Damage in the United Nations Compensation Commission

The compensability of pure environmental damage was also recognized by the *United Nations Security Council*. With respect to the substantial environmental damage caused by Iraq's 'unlawful invasion and occupation of Kuwait' in 1990 and 1991, the Security Council decided that Iraq was

> *'liable under international law for any direct loss, damage, including environmental damage and the depletion of natural resources […]'.*[116]

To implement Iraq's liability, the Security Council established the aforementioned *United Nations Claims Commission* (UNCC), which was mandated to evaluate claims and award compensation from a dedicated fund created from a fixed percentage of Iraq's oil export revenues.[117] The claims for compensation for environmental damage were assessed by a dedicated panel of Commissioners (commonly referred to as the 'environmental panel').[118]

With regard to the loss of environmental resources that are not 'traded in the market' and thus have no commercial value, Iraq had argued that such damage was not financially assessable and therefore not eligible for compensation.[119] Although the UNCC's environmental panel recognized the 'inherent difficulties in attempting to place a monetary value on dam-

116 UNSC Resolution 687 (1991) (n. 49), para. 16.

117 UNSC, Resolution 692 (1991). Iraq-Kuwait (20 May 1991), UN Doc. S/RES/692(1991). For an overview of the UNCC and its handling of environmental claims, see *Gautier* (n. 20); *Payne* (n. 42); *Sands* et al. (n. 2), 755–760. The Commission concluded the processing of claims in 2005, and there is only one claim that has not been paid in full, which was for production and sales losses as a result of damages to Kuwait's oil-field assets, see UNCC, UNCC at a Glance, available at: https://uncc.ch/uncc-glance (last accessed 28 May 2022).

118 The UNCC's environmental panel is sometimes also referred to as the 'F4 panel', as environmental claims were assigned the category 'F4' in the UNCC's organization of work; see *Gautier* (n. 20), 187; *Payne* (n. 42), 727. Also see UNCC Governing Council Decision 7 (n. 20), para. 35, which provided a non-exclusive list of compensable losses and expenses resulting from environmental damage and the depletion of natural resources caused by Iraq's invasion and occupation of Kuwait. For a general account of the UNCC's work, see *Dražen Petrović*, Other Specific Regimes of Responsibility: The UN Compensation Commission, in: James Crawford/Alain Pellet/Simon Olleson (eds.), The Law of International Responsibility (2010) 849, 849–859.

119 UNCC Panel Report F4/5 (2005) (n. 101), para. 46.

aged natural resources, particularly resources that are not traded on the market',[120] it held that

> *'[…] there is no justification for the contention that general international law precludes compensation for pure environmental damage.'*[121]

In the panel's view, the exclusion of compensation for pure environmental damage in the aforementioned civil liability conventions[122] did not justify the assertion that international law generally prohibits compensation for such damage, especially where the damage results from an internationally wrongful act.[123] The panel also held that compensation is not excluded when the impairment of the environment is only temporary, although the panel recognized that this might affect the *nature and quantum* of compensation.[124] However, the panel acknowledged that 'international law does not prescribe any specific and exclusive methods of measurement for awards of damages for internationally wrongful acts by states'.[125] Consequently, it held that international courts and tribunals were 'entitled and required' to rely on general principles when evaluating environmental damage and determining appropriate compensation.[126]

4. Compensation of Environmental Damage Before the International Court of Justice (Case of Costa Riva v. Nicaragua)

The matter of compensation for pure environmental damage was also addressed by the ICJ in its judgment on compensation in the *Certain Activities* case between Costa Rica and Nicaragua in 2018.[127] The case

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120 *Ibid.*, para. 81.
121 *Ibid.*, para. 58; see *Payne* (n. 42), 737.
122 See *supra* section B.I.1.
123 UNCC Panel Report F4/5 (2005) (n. 101), para. 58.
124 *Ibid.*, para. 56.
125 *Ibid.*, para. 80.
126 *Ibid.*
127 ICJ, Certain Activities (Compensation) (n. 13); for commentaries on the judgment, see *Tomme R. Young*, Recognition of "Environmental Services" in the ICJ's First Award of Compensation for International Environmental Damage, 48 (2018) Environmental Policy and Law 36; *Rudall* (n. 84); *Jefferi H. Sendut*, The International Court of Justice and Compensation for Environmental Harm: A Missed Opportunity?, 1 (2018) De Lege Ferenda 17. The ICJ had already confirmed in the *Gabčíkovo-Nagymaros* case that Hungary was entitled to 'compensation for the damage sustained as a result of the diversion of the Danube',

concerned a territorial dispute between both states, in which Nicaragua had, *inter alia*, excavated three channels in the disputed wetland area.[128] In an earlier judgment on the merits, the ICJ had already ruled that Costa Rica had sovereignty over the disputed territory, that Nicaragua's activities in the territory were illegal and that Nicaragua was therefore obliged to compensate Costa Rica for material damages caused by those activities.[129] After both parties were unable to reach an agreement on the amount of compensation payable by Nicaragua, the ICJ was requested to settle the question of compensation in a separate judgment.[130]

Before considering the different heads of damage claimed in the case before it, the Court reiterated a number of principles on state responsibility it had already established in previous cases. In particular, it recalled the obligation to make full reparation for the damage caused by a wrongful act[131] and that reparation may be an appropriate form of reparation, especially where restitution is 'materially impossible or unduly burdensome'.[132] The Court also pointed out that in order to award compensation, it must be determined 'whether there is a sufficiently direct and certain causal nexus between the wrongful act […] and the injury suffered by the Applicant'.[133]

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although the Court did not specifically indicate that this included reparation for purely environmental damage, cf. ICJ, Gabčíkovo-Nagymaros Project (Hungary v. Slovakia), Judgment of 25 September 1997, ICJ Rep. 7, paras. 151–152; see *Sands* et al. (n. 2), 754.

128 For the background of the dispute, see *Stefan Geens*, About Costa Rica, Nicaragua, Their Mutual Border, and Google, Ogle Earth, 07 November 2010, available at: https://ogleearth.com/2010/11/about-costa-rica-nicaragua-their-border-and-google/ (last accessed 28 May 2022); *Jacob K. Cogan*, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica V. Nicaragua); Construction of a Road in Costa Rica Along the San Juan River (Nicaragua V. Costa Rica), 110 (2016) AJIL 320.

129 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 54), para. 229.

130 ICJ, Certain Activities (Compensation) (n. 13), para. 11.

131 *Ibid.*, paras. 29–30, quoting PCIJ, Factory at Chorzów (Germany v. Poland) (n. 28), 47 and citing, *inter alia*, ICJ, Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo), Merits Judgment of 30 November 2010, ICJ Rep. 639, para. 161 and ICJ, Gabčíkovo-Nagymaros (n. 127), para. 150.

132 ICJ, Certain Activities (Compensation) (n. 13), para. 31, citing ICJ, Pulp Mills on the River Uruguay (Argentina v. Uruguay), Judgment of 20 April 2010, ICJ Rep. 14, para. 273.

133 ICJ, Certain Activities (Compensation) (n. 13), para. 32 (ellipses in the original), quoting ICJ, Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo), Judgment on Compensation of 19 June 2012, ICJ Rep. 324, para. 14.

Moreover, the Court pointed to the principle that 'it is for the party which alleges a particular fact in support of its claims to prove the existence of that fact', although 'this general rule may be applied flexibly in certain circumstances, where, for example, the respondent may be in a better position to establish certain facts'.[134]

The Court then addressed the application of these principles to cases of environmental damage. It first recognized the likely difficulties to prove the existence of damage and causation in these cases:

> *'In cases of alleged environmental damage, particular issues may arise with respect to the existence of damage and causation. The damage may be due to several concurrent causes, or the state of science regarding the causal link between the wrongful act and the damage may be uncertain. These are difficulties that must be addressed as and when they arise in light of the facts of the case at hand and the evidence presented to the Court.'*[135]

The Court then recalled that 'the absence of adequate evidence as to the extent of material damage will not, in all situations, preclude an award of compensation.'[136] It also pointed to the *Diallo* case, where it had relied on 'equitable considerations' to determine the amount of compensation,[137] and the *Trail Smelter* award, in which it was held that difficulties in ascertaining the amount of compensation for a certain injury with certainty should not preclude the compensability of such injury.[138]

The ICJ noted that it had not previously adjudicated a claim for compensation for environmental damage. However, it found that

> *'[…] it is consistent with the principles of international law governing the consequences of internationally wrongful acts, including the principle of full reparation, to hold that compensation is due for damage caused*

134 ICJ, Certain Activities (Compensation) (n. 13), para. 32, quoting ICJ, Diallo (Compensation) (n. 133), paras. 54–56.

135 ICJ, Certain Activities (Compensation) (n. 13), para. 34.

136 *Ibid.*, para. 35.

137 *Ibid.*, see ICJ, Diallo (Compensation) (n. 133), para. 33.

138 ICJ, Certain Activities (Compensation) (n. 13), para. 35; see Trail Smelter Case, Decision of 1941 (n. 60), 1920 quoting United States Supreme Court, Story Parchment Company v. Paterson Parchment Paper Company, 1931, 282 United States Rep. 555, 563, where it was held that: 'Where the tort itself is of such a nature as to preclude the ascertainment of the amount of damages with certainty, it would be a perversion of fundamental principles of justice to deny all relief to the injured person, and thereby relieve the wrongdoer from making any amend for his acts.'

> *to the environment, in and of itself, in addition to the expenses incurred by an injured State as a consequence of such damage. […] The Court is therefore of the view that damage to the environment, and the consequent impairment or loss of the ability of the environment to provide goods and services, is compensable under international law. Such compensation may include indemnification for the impairment or loss of environmental goods and services in the period prior to recovery […].*'[139]

Hence, the Court clearly confirmed that damage to the environment *per se* is subject to compensation under the law of state responsibility.[140]

5. Conclusions

In 1996, *Lefeber* concluded that 'compensation of harm to the environment is not entirely unknown in international law, but is has certainly not become common practice'.[141] Given the more recent instances of international legal practice analysed above, it can be assumed that such a 'common practice' has now emerged and that the compensability of damage to the environment *per se* has become part of customary international law.[142] The only notable deviations from this principle can be found in a number of international conventions on the civil liability of operators

139 ICJ, Certain Activities (Compensation) (n. 13), paras. 41–42.

140 The Court also addressed the more controversial issue of valuation of environmental damage, i.e. how to express environmental damage in monetary terms. The Court's elaborations on these issues are assessed separately below, see *supra* section B.III.

141 *Lefeber* (n. 60), 138; citing *Andrea Bianchi*, Environmental Harm Resulting from the Use of Nuclear Power Sources in Outer Space: Some Remarks on State Responsibility and Liability, in: Francesco Francioni/Tullio Scovazzi (eds.), International Responsibility for Environmental Harm (1991) 231, 264; *Rudolf Dolzer*, Völkerrechtliche Verantwortlichkeit und Haftung für Umweltschäden, in: Rudolf Dolzer (ed.), Umweltschutz im Völkerrecht und Kollisionsrecht (1992) 195, 221. A similar stance was taken by *Scovazzi* (n. 101), 221.

142 Cf. Institut de Droit International, Responsibility and Liability Under International Law for Environmental Damage: Resolution Adopted on September 4, 1997, 37 ILM 1474, Article 25(1), noting that: 'The fact that environmental damage is irreparable or unquantifiable shall not result in exemption from compensation. An entity which causes environmental damage of an irreparable nature must not end up in a possibly more favorable condition than other entities causing damage that allows for quantification.' Also see *Schmitt* (n. 41), 395.

engaged with hazardous activities or substances. However, most of these conventions – except those relating to oil pollution and nuclear damage – have never entered into force and thus are of limited value in documenting a relevant *opinio iuris* of states.[143] Nevertheless, as shown in the next section, there is still substantial disagreement about the means and methods to determine the 'nature and quantum' of compensation for damage to the environment *per se*.

II. Forms of Compensation for Damage to the Environment

In the previous section, it has been shown that damage to the environment *per* se is, in principle, compensable under international law. The question remains about how the amount of compensation for such damage shall be determined. As mentioned before, Article 36(2) ARSIWA provides that compensation shall cover 'any financially assessable damage'. Hence, compensation for environmental damage requires determining a monetary equivalent to such damage.

In international legal practice, two different approaches to this problem can be identified. The first approach relies on the costs of *compensatory restoration*, i.e. measures to offset the environmental injury by preserving or improving other elements of the environment (1.). Under the second approach, the value of the damage is established in monetary terms (2.). These approaches can be applied either singly or in combination, as required, to fully compensate for the injury.[144]

143 Of the instruments cited in section B.II.1 *supra*, only the 1992 Oil Pollution Convention (n. 19) and the Supplementary Protocol (n. 19) are in force. The other instruments, namely the Lugano Convention on Civil Liability (n. 4), the HNS Convention (n. 19), and the Basel Protocol on Liability for Hazardous Wastes (n. 6), have not yet entered into force and it seems unlikely that they will in the future; see *Jutta Brunnée*, Of Sense and Sensibility: Reflections on International Liability Regimes as Tools for Environmental Protection, 53 (2004) ICLQ 351.

144 See MacAlister Elliott and Partners Ltd/Economics for the Environment Consultancy Ltd, Study on the Valuation and Restoration of Damage to Natural Resources for the Purpose of Environmental Liability, Report for the European Commission, Directorate-General Environment, B4–3040/2000/265781/MAR/B3 (2001), 3.

1. Compensatory Restoration

The most widely recognized approach to compensating temporary or permanent environmental damage is *compensatory restoration*.[145] Compensatory restoration must be distinguished from *primary restoration*, which refers to measures aimed at evaluating the damage, preventing further damage and restoring the impaired environment to its baseline condition.[146] In contrast, the purpose of compensatory restoration is to offset either the *temporary losses* that occur during the time until the environment has recovered or *permanent losses* in cases where the damage is irrecoverable and full restoration is impossible.[147] The idea behind compensatory restoration is to offset these losses by taking measures to preserve or improve other components of the environment capable of providing ecological services equivalent to those impaired or lost.[148] Ideally, these measures are adjusted to the type of environmental service lost or impaired and implemented as closely as possible to the site of the original injury.[149]

Usually, compensatory restoration projects are carried out by the injured state, while the responsible state must reimburse the related expenses as a form of compensation.[150] Hence, compensation for pure environmental damage is valued as the cost of environmental projects designed to offset the environmental loss suffered due to the internationally wrongful act.[151]

Compensatory restoration is recognized in many of the more recent international liability instruments. In the context of the present study, the most relevant example is the *Nagoya – Kuala Lumpur Supplementary Protocol*, which provides that when it is not possible to restore biological diversity to the condition that existed before the damage occurred (i.e., the *status quo ante*), the loss shall be compensated by

145 *Brans* (n. 100), 130–131; *Barboza* (n. 10), 139.
146 See *supra* section A.I.2.
147 MEP/eftec, Study on Valuation and Restoration (n. 144), 4.
148 See, e.g., EU Environmental Liability Directive (n. 5), Annex II; Oil Pollution Act, 15 C.cf. *Brans* (n. 100), 130; *Huguenin* et al. (n. 26), 78; also see *Sands/Stewart* (n. 86), 294.
149 *Huguenin* et al. (n. 26), 78.
150 See *supra* section A.I.2.
151 Cf. MEP/eftec, Study on Valuation and Restoration (n. 144), 47; *Payne* (n. 42), 737–738; *Sands* et al. (n. 2), 759.

> *'replacing the loss of biological diversity with other components of biological diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location'.*[152]

Similarly, the *Environmental Liability Directive* of the European Union provides for 'complementary remediation' where the damaged natural resources or services cannot be restored to their baseline condition.[153] According to the Directive, complementary remediation shall provide a similar level of natural resources or services as would have been provided if the damaged site had been returned to its baseline condition.[154] When complementary remediation needs to be implemented at an alternative site, it should be geographically linked to the damaged site.[155] Compensatory restoration is also recognized in the environmental liability law of the United States, namely in the regulations on natural resource damage assessments under the *Comprehensive Environmental Response, Compensation, and Liability Act*[156] and the *Oil Pollution Act*.[157]

To determine appropriate projects capable of providing for compensatory restoration, methodologies such as *habitat equivalency analysis* (HEA) are frequently employed.[158] With HEA, the compensation is calculated by referring to the costs required to implement projects to establish or conserve habitats capable of providing ecological services similar to those lost.[159] Another approach is *resource equivalency analysis* (REA), which quantifies

152 Supplementary Protocol (n. 19), Article 2(2)(d)(ii)(b); see chapter 6, section C.I.
153 EU Environmental Liability Directive (n. 5), Annex II, para. 1.1.2.
154 *Ibid.*
155 *Ibid.*
156 Cf. United States Department of the Interior, Regulations on Natural Resource Damage Assessments Under CERCLA, 43 C.F.R. Part 11, §§ 11.14(a) and 11.83(c); see *Huguenin* et al. (n. 26), 71–72.
157 Cf. United States National Oceanic and Atmospheric Administration, Regulations on Natural Resource Damage Assessments Under the Oil Pollution Act, 15 C.F.R. Part 990, § 990.53(c)(2); see *Brans* (n. 100), 128–133; *Huguenin* et al. (n. 26), 72–73.
158 Cf. *Brans* (n. 100), 134–136; *Huguenin* et al. (n. 26), 78; *Sands* et al. (n. 2), 758; on the characteristics of equivalency analysis methods in an *ex post* context, see *Thomas C. Paul*, Substitution Costs, in: Patricia A. Champ/Kevin J. Boyle/Thomas C. Brown (eds.), A Primer on Nonmarket Valuation (2nd ed. 2017) 347, 370–376.
159 *Brans* (n. 100), 134–136.

the injury by referring not to the affected habitat but to individual resources such as 'bird years' or the annual production of fish biomass.[160]

The HEA approach was accepted by the UNCC's environmental panel as an appropriate method for determining the nature and extent of compensatory restoration measures required to offset environmental damage.[161] While the panel acknowledged the difficulties inherent in using these valuation methodologies, it held these difficulties were no sufficient reason for 'a wholesale rejection of these methodologies, or for concluding that their use is contrary to international law principles'.[162] Subsequently, it awarded payments for several compensatory projects, including a cooperative management program for damaged rangeland reserves[163] and the establishment of marine and coastal preserves to compensate for coastal damage caused by oil spills.[164] At the same time, the panel held that merely hypothetical projects that were not actually feasible did not provide a reasonable basis for estimating monetary compensation.[165]

2. Monetary Valuation of Environmental Damage

Another approach to determining the amount of compensation for damage to the environment *per se* is to assign a monetary value to those elements of the environment that have been impaired or destroyed. The framework commonly used for describing the different types of economic value ascribed to natural resources is known as *Total Economic Value* (TEV).[166] TEV is based on the assumption that the total value of the envi-

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160 *Huguenin* et al. (n. 26), 78; see MEP/eftec, Study on Valuation and Restoration (n. 144), 42–43.

161 Cf. UNCC Panel Report F4/5 (2005) (n. 101), para. 73.

162 *Ibid.*, para. 81.

163 *Ibid.*, para. 363; cf. *Payne* (n. 42), 738.

164 See, e.g., UNCC Panel Report F4/5 (2005) (n. 101), paras. 446–455 and 630–635; see *Payne* (n. 42), 739; *Gautier* (n. 20), 199–200.

165 Cf. Cf. UNCC Panel Report F4/5 (2005) (n. 101), para. 362; in contrast, see UNCC Panel Report F4/5 (2005) (n. 101), para. 632 where the proposes compensatory project was held to be 'feasible, cost-effective and [to] pose a low risk of adverse impacts'. Also see *Huguenin* et al. (n. 26), 88.

166 See CBD Secretariat, An Exploration of Tools and Methodologies for Valuation of Biodiversity and Biodiversity Resources and Functions, CBD Technical Series No. 28 (2007), 11–12; *Kathleen Segerson*, Valuing Environmental Goods and Services: An Economic Perspective, in: Patricia A. Champ/Kevin J. Boyle/Thomas C. Brown (eds.), A Primer on Nonmarket Valuation (2nd ed. 2017) 1, 10–11;

ronment is comprised of *use values* and *non-use values*. The term ‘use value’ denotes the human-derived value from direct or indirect use, interaction with, or reliance on, environmental resources and services. In contrast, a ‘non-use value’ attaches to the mere existence of a natural resource that is not used by humans.

To determine the value of the environment and the damage to it, economists have developed a wide range of different approaches.[167] These approaches can generally be categorized into market-based methods (a)) and non-market-based methods (b)). Where such valuation studies are not possible, existing values determined in comparable situations can be transferred to the present situation (c)). Another possible approach is to rely on the hypothetical costs of response measures that should have been undertaken (d)).

a) Valuation Based on Market Prices

The monetary value of environmental damage can be inferred from market prices if the injury directly or indirectly affects the commercial use of a natural resource. This may be the case where a natural resource is reduced in quality or quantity, or where the injury induces changes in the market price of the resource.[168] Moreover, impairment of environmental quality may also cause an increase in costs for using a natural resource or a reduction in yields.[169] For instance, the UNCC’s environmental panel awarded compensation for reduced yields of agricultural crops based on the ‘local

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DEFRA, An Introductory Guide to Valuing Ecosystem Services (2007), 29–35; *Unai Pascual* et al., The Economics of Valuing Ecosystem Services and Biodiversity, in: Pushpam Kumar (ed.), The Economics of Ecosystems and Biodiversity: Ecological and Economic Foundations (2010) 183, 192–196.

167 See *Nick Hanley*, The Economic Value of Environmental Damage, in: Michael Bowman/Alan E. Boyle (eds.), Environmental Damage in International and Comparative Law (2002) 27; *Pascual* et al. (n. 166); *Barry C. Field/Martha K. Field*, Environmental Economics (7th ed. 2017), 130–152; *Bartosz Bartkowski*, Economic Valuation of Biodiversity: An Interdisciplinary Conceptual Perspective (2017). Also see ISO, Monetary Valuation of Environmental Impacts and Related Environmental Aspects, ISO 14008:2019 (E) (2019).

168 CBD Secretariat (n. 166), 15; *Huguenin* et al. (n. 26), 79; *Sylvia Schwermer*, Annex A: Economic Valuation Methods, in: UBA (ed.), Economic Valuation of Environmental Damage (2012), 6–7; *Rudall* (n. 1), 97–98.

169 *Hanley* (n. 167), 29; CBD Secretariat (n. 166), 15; *Schwermer* (n. 168), 6–7.

producer prices' determined by the *Food and Agriculture Organization of the United Nations*.[170]

Another approach refers to the costs incurred in replacing environmental goods and services (so-called 'replacement cost' approach).[171] Following this approach, the UNCC's environmental panel estimated the value of damaged rangelands based on the market price of fodder required to substitute the use of the rangeland for grazing during the relevant periods.[172] In addition, replacement costs may also be incurred in taking technical measures to replace lost environmental functions, such as the construction of dams where the environment has lost its natural capability to prevent flooding.[173] The *compensatory restoration* approach discussed above could be seen as a practical implementation of the replacement cost approach.[174]

With regard to genetic resources, it has been argued that the increasing use of these resources in pharmaceutical and agricultural research may allow us to determine their value by referring to economic valuation methods.[175] According to a different view, there are usually no comparable market values for the information contained in the wild gene pool, which has allegedly caused the global stock of genetic capital to be 'consistently undervalued'.[176]

b) Non-Market-Based Valuation Techniques

For many environmental goods and services, it is not possible to derive a monetary value directly or indirectly from market prices. In these situations, non-market-based valuation techniques must be used. Most of these techniques seek to determine the monetary value of a particular environment, or of particular goods or services provided by the environment, by referring to the prices that individuals are willing to pay to use or preserve them. Generally, these approaches are divided into *stated preference* and *revealed preference* methods.[177]

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170 Cf. UNCC Panel Report F4/5 (2005) (n. 101), paras. 114–115.
171 DEFRA (n. 166), 35.
172 Cf. UNCC Panel Report F4/5 (2005) (n. 101), para. 178; see *Gautier* (n. 20), 208.
173 Cf. CBD Secretariat (n. 166), 16–17; *Paul* (n. 158), 365–367.
174 *Paul* (n. 158), 368–370; see *supra* section B.II.1.
175 *Förster* (n. 98), 355.
176 *Field/Field* (n. 167), 380.
177 *Huguenin* et al. (n. 26), 79; *Rudall* (n. 1), 97–100.

Revealed preference methods infer values from the actual behaviour of consumers in relation to an environmental good or amenity.[178] For instance, the *travel costs* approach assumes that the recreational value of a natural site or landscape (for instance, a beach or a nature park) is at least as high as the expenses that individuals make to enjoy that site (travel costs to the site, and admission cost, where applicable).[179] The impairment of a site or landscape is valued by the consequential reduction of these expenses, i.e. the money visitors would spend if they continued to visit the site.[180] An advanced version of the travel costs approach called *random utility modelling* also takes into account that individuals may switch to substitute sites when environmental damage occurs.[181]

Another revealed preference method is *hedonic pricing*, which seeks to identify statistical relationships between environmental quality levels and the price of marketed goods, especially in the housing market.[182] The underlying assumption is that the environmental quality in the area surrounding a real estate (e.g. air and water quality, noise, landscape quality, or biodiversity) is a pricing factor and that changes in the environmental quality will influence the market price of the real estate.[183] The value of environmental damage can thus be inferred from the consequential decrease in the price of goods which has a statistical relationship to environmental factors.[184]

Stated preference methods seek to establish the value that individuals ascribe to a particular natural resource or environmental resource.[185] The most common of these methods is *contingent valuation*,[186] which is based on surveys asking individuals about their maximum willingness to pay for preserving a particular environmental quality (such as biodiversity) or

178 *Segerson* (n. 166), 21; *Huguenin* et al. (n. 26), 79; *Rudall* (n. 1), 99.

179 See *George R. Parsons*, Travel Cost Models, in: Patricia A. Champ/Kevin J. Boyle/Thomas C. Brown (eds.), A Primer on Nonmarket Valuation (2nd ed. 2017) 187; *Rudall* (n. 1), 99.

180 *Schwermer* (n. 168), 12; *Hanley* (n. 167), 32.

181 *Hanley* (n. 167), 32; see *Parsons* (n. 179), 196–203.

182 *Hanley* (n. 167), 32; *Rudall* (n. 1), 100; see *Laura O. Taylor*, Hedonics, in: Patricia A. Champ/Kevin J. Boyle/Thomas C. Brown (eds.), A Primer on Nonmarket Valuation (2nd ed. 2017) 235.

183 Cf. *Hanley* (n. 167), 32–33; *Taylor* (n. 182), 236.

184 *Schwermer* (n. 168), 11.

185 *Huguenin* et al. (n. 26), 80.

186 See *Kevin J. Boyle*, Contingent Valuation in Practice, in: Patricia A. Champ/Kevin J. Boyle/Thomas C. Brown (eds.), A Primer on Nonmarket Valuation (2nd ed. 2017) 83.

the minimum compensation they would accept for the loss of a particular environmental quality.[187] The reliability of contingent valuation studies is controversial, as they cannot reflect multidimensional changes in environmental quality related to the interdependence of different species and the complexity of ecosystems.[188] Moreover, spiritual and emotional factors can significantly influence the resulting values, which may lead to differing valuations depending on whether the value of an environmental good is assessed in an industrialized society or a local indigenous society.[189] A technique closely related to contingent valuation that seeks to mitigate these weaknesses is the *choice experiment* or *conjoint analysis* method. According to this method, environmental goods are valued by comparing specified alternatives which the respondents are asked to sort in their order of preference.[190]

Although non-market valuation techniques are frequently employed in environmental economics, they have only rarely been relied upon in legal practice on compensation for environmental damage.[191] In the claims procedure following Iraq's invasion and occupation of Kuwait in 1990, the UNCC rejected the use of non-market valuation approaches on several occasions. Concerning the lost recreational use of beaches, the UNCC's environmental panel refused to award funding for travel costs surveys, arguing that they were 'unlikely to produce reliable data', especially since more than ten years had already elapsed since Iraq's invasion of Kuwait.[192] Subsequently, the panel rejected a claim for compensation based on contingent valuation surveys because it found that the claimant's data did not provide 'a sufficiently reliable basis for estimating the value of any lost recreational opportunities'.[193]

187 *Hanley* (n. 167), 31.

188 Cf. *Bergkamp* (n. 101), 339–342; *Förster* (n. 98), 357; CBD Secretariat (n. 166), 18; *Schwermer* (n. 168), 16; *Boyle* (n. 186), 119–120.

189 *Förster* (n. 98), 358.

190 *Schwermer* (n. 168), 17; *Thomas P. Holmes* et al., Choice Experiments, in: Patricia A. Champ/Kevin J. Boyle/Thomas C. Brown (eds.), A Primer on Nonmarket Valuation (2nd ed. 2017) 133.

191 See *Brian D. Israel* et al., Legal Obstacles for Contingent Valuation Methods in Environmental Litigation, in: Kenneth Train/Daniel McFadden (eds.), Contingent Valuation of Environmental Goods: A Comprehensive Critique (2017) 292, 296–303.

192 UNCC Panel Report F4/1 (2001) (n. 42), paras. 444–450, 584–587.

193 UNCC Panel Report F4/5 (2005) (n. 101), paras. 457–465; see *Sand* (n. 42), 247.

c) Benefit (Or Value) Transfer Method

When primary valuation studies are not possible or feasible in a specific situation, the *benefit transfer* (or *value transfer)* approach may be used.[194] This refers to using pre-existing valuation data gathered elsewhere and adjusting them to accord with the situation under investigation.[195] A prerequisite for performing a benefit transfer is that primary studies are available that value a sufficiently comparable environmental asset.[196] A number of online databases contain numerous valuation studies that could be used as sources for benefit transfers.[197]

Critically, the accuracy and reliability of benefit transfers depend on the similarity of the environmental and economic context of the original research.[198] Moreover, the transfer must be capable of adapting the available data to the local conditions. There are various methods that differ both in the input needed for transferring the data as well as regarding their theoretical plausibility.[199] While the benefit transfer method is comparatively quick and easy to apply, there are also considerable disadvantages concerning the validity and reliability of the results.[200] Errors may result from both the original measurement and the transfer process.[201]

d) Costs for 'Hypothetical' Response Measures

Finally, a special valuation technique could be seen in relying on the hypothetical costs of response measures that were not undertaken but should have been. As noted above, this approach is followed by the *Antarctic*

194 See *Randall S. Rosenberger/John B. Loomis*, Benefit Transfer, in: Patricia A. Champ/Kevin J. Boyle/Thomas C. Brown (eds.), A Primer on Nonmarket Valuation (2nd ed. 2017) 431; *Rudall* (n. 1), 100–101.

195 *Huguenin* et al. (n. 26), 80; *Schwermer* (n. 168), 19; *Hanley* (n. 167), 34; DEFRA (n. 166), 38–39.

196 *Schwermer* (n. 168), 19; *Huguenin* et al. (n. 26), 80.

197 *Schwermer* (n. 168), 21. See, for instance, Environment and Climate Change Canada, Environmental Valuation Reference Inventory, available at: https://www.evri.ca/en (last accessed 28 May 2022), which contains over 4,000 summaries of valuation studies.

198 *Huguenin* et al. (n. 26), 80.

199 *Schwermer* (n. 168), 19–20.

200 *Ibid.*, 19–21; *Hanley* (n. 167), 36–37.

201 *Rosenberger/Loomis* (n. 194), 454.

Liability Annex.[202] Similar schemes seem to exist in a few national jurisdictions such as Argentina and Mexico.[203]

This approach is particularly valuable in cases of damage to 'global commons' such as global biodiversity or the environment in areas beyond national jurisdiction. In these situations, neither compensatory restoration nor monetary valuation according to any of the techniques above may be feasible. However, if it is possible to identify response measures that could have effectively mitigated the damage had they been implemented in time,[204] it seems justifiable to rely on the hypothetical costs of such measures. In the absence of an injured party, such payments could be directed to relevant international institutions, such as the CBD's *Global Environmental Facility*.[205]

3. Conclusions

The preceding sections have shown that there are numerous approaches to determining the monetary value of damage to the environment and its components. While some of these have already been referred to in international legal practice, international law so far does neither seem to prescribe any particular technique nor contain general rules on which rule to apply in which circumstances.[206]

It should, however, be noted that the aforementioned approaches also have significant shortcomings. The most significant difficulty relates to the interdependence of ecosystems and the services they provide. Due to this interdependence, injury to one ecosystem component (such as a species or habitat) may well affect other components or services. However, valuation approaches necessarily look at the environment from pre-defined angles and are mostly focused on specific components of the environment. For this reason, a monetary valuation may not easily reflect damage to other

202 Cf. Antarctic Liability Annex (n. 6), Article VI(2); see *supra* section B.I.1.
203 Cf. Synthesis Report on Article 14(2) CBD (n. 86), paras. 66–67.
204 On the potential challenges on establishing the costs of hypothetical response action, see *Silja Vöneky*, The Liability Annex to the Protocol on Environmental Protection to the Antarctic Treaty, in: Doris König/Peter-Tobias Stoll et al. (eds.), International Law Today: New Challenges and the Need for Reform? (2008) 165, 185–186.
205 See chapter 9, section C.I.2.b).
206 UNCC Panel Report F4/5 (2005) (n. 101), para. 80; ICJ, Certain Activities (Compensation) (n. 13), para. 52.

ecosystem components or services that are not in the focus of the particular approach employed.[207] Moreover, non-market valuation techniques are criticized for being anthropocentric. As laid out above, most of these techniques attempt to determine the value of an environmental asset by assessing the stated or revealed willingness of a target group to pay for this asset. It has been argued that by focusing on human satisfaction, these approaches underestimate the economic value of the ecosystem, especially concerning systemic features that have no direct value but are still essential to maintain the overall functioning of an ecosystem.[208] On the other hand, non-anthropocentric values of nature do not easily fit into economic models and are thus impossible to estimate in monetary terms (e.g. the mere fact of the loss of an extinct species).[209]

In any event, it is important to see that the monetary valuation of environmental damage is independent of the costs for clean-up or restoration measures incurred after an incident. While the monetary value of environmental damage is based on market prices (for environmental goods traded on the market) or on replacement costs or public preferences (for goods and services that have no commercial value), the costs of response measures are primarily based on the technical options available. For this reason, the cost of restoration may well be greater than the value of the damage.[210] In these instances, it could be argued that claims for the restorations costs are excessive and that monetary compensation should prevail over reinstatement.[211] However, as can be seen from the work of the UNCC, the ILC, and pertinent international treaties, the current international legal practice appears to prefer primary and compensatory restoration over mere monetary compensation. Thus, there is no clear indication that claims for restoration measures are generally rejected if they exceed the market and non-market values of the affected environment.

207 DEFRA (n. 166), 41.
208 *Hanley* (n. 167), 33.
209 *Ibid.*
210 MEP/eftec, Study on Valuation and Restoration (n. 144), 3.
211 *Ibid.*, 47.

III. Case Study: Valuation of Environmental Damage in the 'Certain Activities' Case Before the ICJ

In its judgment on compensation in the *Certain Activities* case between Costa Rica and Nicaragua, the ICJ addressed the issue of compensation for environmental damage in-depth for the first time.[212] As mentioned above, the Court confirmed that the law of state responsibility provides for compensation for damage to the environment 'in and of itself'.[213] In principle, this view was shared by the parties to the dispute.[214] However, the parties substantially disagreed on which method should be used to value the damage and thus quantify the amount of compensation payable by Nicaragua. Costa Rica, for its part, submitted an 'eco-system services approach' (1.). On the other hand, Nicaragua invoked a 'replacement costs approach' (2.) and, in the alternative, presented a 'corrected analysis' based on Costa Rica's proposal (3.). The Court eventually developed its own method, which it called 'overall assessment' (4.).

1. Costa Rica's 'Ecosystem Services Approach'

Costa Rica submitted that the damage should be valued according to principles of environmental economics.[215] To this end, Costa Rica identified six categories of 'ecosystem goods and services' provided by the affected environment prior to Nicaragua's actions.[216] With regard to the value of standing timber, it applied available market prices.[217] For the other goods and services, Costa Rica proposed determining the monetary value by applying the *value transfer approach*, i.e. by referring to studies determin-

212 ICJ, Certain Activities (Compensation) (n. 13).

213 *Ibid.*, para. 41; see *supra* section B.I.4.

214 *Ibid.*

215 Memorial of Costa Rica on Compensation (n. 32), 32–36. The memorial largely relies on a study by *Fundación Neotrópica*, a Costa Rican environmental NGO, which can be found in Annex 1 to Costa Rica's memorial.

216 *Ibid.*, 32. The ecosystem goods and services which Costa Rica referred to in its valuation were standing timber, other raw materials (namely, fibre and energy), gas regulation, natural hazards mitigation, soil formation and erosion control, and biodiversity, in terms of habitat and nursery, see ICJ, Certain Activities (Compensation) (n. 13), para. 55. For the Court's assessment of these heads of damage, see ICJ, Certain Activities (Compensation) (n. 13), paras. 60–71.

217 Memorial of Costa Rica on Compensation (n. 32), 134, see *supra* section B.II.2.a).

ing the value of such services in purportedly comparable ecosystems and adjusting these values to the present situation.[218] In its submission, Costa Rica assumed that the affected area would require at least 50 years to recover[219] and claimed a total compensation for environmental damage of approximately USD 2.88 million.[220]

2. Nicaragua's 'Replacement Costs Approach'

Nicaragua strictly rejected the valuation approach used by Costa Rica, arguing that it was 'not consistent with accepted practice in the field of natural resource damage assessment'.[221] Moreover, it invoked that the UNCC had declined to accept this approach.[222] Instead, Nicaragua submitted a 'replacement costs approach', under which the amount of compensation should correspond to the (hypothetical) costs to preserve an equivalent area until the environmental services provided by the impacted area had recovered.[223] To determine this price, Nicaragua referred to the amounts which Costa Rica pays to landowners and communities for conserving habitats under its domestic environmental conservation scheme.[224] Based on this amount (adjusted to 2017 prices), specifically USD 309 per hectare per year, and assuming that the period until full recovery of the affected area would be 20 to 30 years, Nicaragua concluded that the replacement costs would be a maximum of approximately USD 35,000.[225] Notably, Nicaragua did not suggest that the funds should actually be used to preserve equivalent areas but proposed its approach as a mere valuation

218 *Ibid.*, 32; see supra section B.II.2.c).
219 *Ibid.*, 33.
220 *Ibid.*, 34.
221 ICJ, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica V. Nicaragua): Counter-Memorial of the Republic of Nicaragua on Compensation (2017), 43.
222 ICJ, Certain Activities Carried Out by Nicaragua in the Border Area (Costa Rica V. Nicaragua): Rejoinder of the Republic of Nicaragua on Compensation (2017), 10.
223 The exact amount claimed was USD 2,880,745.82, cf. ICJ, Certain Activities (Compensation) (n. 13), para. 49.
224 Counter-Memorial of Nicaragua on Compensation (n. 221), 61–62.
225 The exact maximum amount Nicaragua was willing to pay was USD 34,987, cf. *ibid.*

technique. Hence, the approach resembles the aforementioned approach of referring to the costs of 'hypothetical' restoration measures.[226]

3. Nicaragua's 'Corrected Analysis'

Besides proposing its own valuation method, Nicaragua also alleged that Costa Rica had applied the ecosystem services approach incorrectly and in a way that led to a 'dramatic overvaluation' of the damage.[227] In the event that the Court nevertheless considered the approach to be appropriate, Nicaragua presented a 'corrected analysis' that made significant adjustments to Costa Rica's calculation, in particular by recognizing only four instead of six heads of damage (namely timber, other raw material, gas regulation, and biodiversity).[228] Under Nicaragua's corrected analysis, the monetary value of the damage, if calculated according to Costa Rica's approach, amounted to approximately USD 85,000,[229] which is less than 3 % of the amount claimed by Costa Rica.

4. The Court's Judgment: 'Overall Assessment' of Environmental Damage

In its judgment, the ICJ acknowledged that the valuation methods proposed by both parties are 'sometimes used for environmental damage valuation in the practice of national and international bodies'.[230] However, the Court saw no need to choose between these methods or use one of them exclusively. In its view,

> *'international law does not prescribe any specific method of valuation for the purposes of compensation for environmental damage'.*[231]

Instead, the Court stressed the need to take account of the specific circumstances and characteristics of each case, which it saw best catered for by referring to certain elements of either method where they would provide a reasonable basis for valuation.[232]

226 See *supra* section B.II.2.d).
227 Counter-Memorial of Nicaragua on Compensation (n. 221), 47.
228 *Ibid.*, 125–135.
229 The exact amount was USD 83,296; cf. *ibid.*, 135.
230 ICJ, Certain Activities (Compensation) (n. 13), para. 52.
231 *Ibid.*
232 *Ibid.*

Before assigning a monetary value to the damage caused by Nicaragua, the Court first assessed the existence of damage. In doing so, it found that two of the categories of environmental goods and services submitted by Costa Rica (namely, damage to natural hazards mitigation as well as soil formation and erosion control) were not sufficiently supported by the evidence before the Court.[233] Moreover, the Court expressed doubts regarding the reliability of certain aspects of Costa Rica's valuation methodology.[234] On the other hand, it also rejected Nicaragua's 'replacement costs approach', as compensation for environmental damage could not be based on the general incentive paid to particular individuals or groups to manage a habitat.[235]

According to the ICJ, the valuation of environmental damage must be approached 'from the perspective of the ecosystem as a whole' rather than by attributing valuations to specific categories of environmental goods and services with different recovery periods each.[236] The Court found these needs to be best catered for in an 'overall valuation' of the damage.[237] In its view, an overall valuation could best account for the correlation between the removal of trees in the area concerned – which the Court found to be the most significant damage – and the harm caused to other environmental goods and services.[238] Secondly, the Court held that an overall valuation was required because the affected area was a protected wetland where various environmental services were closely interlinked.[239] Thirdly, the Court believed that an overall valuation allowed it to take into account both the area's 'high capability for natural regeneration'[240] and the fact that, in the view of the Court, a single recovery period could not be established for all of the affected environmental goods and services.[241]

For the purposes of its overall evaluation, the ICJ essentially adopted Nicaragua's 'corrected analysis'.[242] Although the Court found that this analysis had underestimated the value of certain categories,[243] it held that

233 *Ibid.*, paras. 74–75.
234 *Ibid.*, para. 76.
235 *Ibid.*, para. 77.
236 *Ibid.*, para. 78.
237 *Ibid.*
238 *Ibid.*, para. 79.
239 *Ibid.*, para. 80.
240 *Ibid.*, para. 81.
241 *Ibid.*, para. 82.
242 Cf. *ibid.*, para. 85; see *Rudall* (n. 1), 28.
243 ICJ, Certain Activities (Compensation) (n. 13), para. 85.

these shortcomings could be accounted for by making an adjustment to the overall sum.[244] Without giving further explanations on the nature or calculation of these adjustments, the Court then concluded that Costa Rica was entitled to a total of USD 120,000 for the impairment of the environment in the period prior to recovery.[245]

5. Assessment

The judgment is notable because it explicitly recognizes the compensability of damage to the environment itself, in terms of the ability of the environment to provide 'environmental goods and services', regardless of any loss suffered by a particular person or community.[246] Moreover, the Court's statement that international law does not prescribe any specific valuation method for environmental damage[247] can be seen as an important clarification of the state of development of international law in this context.

Nevertheless, the judgment has also attracted criticism, including for its focus on monetary compensation as the only applicable form of reparation.[248] In fact, restitution was only very briefly addressed at the beginning of the judgment's text, and only to clarify that compensation 'may be an appropriate form of reparation, particularly in those cases where restitution is materially impossible or unduly burdensome'.[249] However, whether restitution was indeed unviable was not further assessed by the Court. It seems like this narrow approach was already predetermined by the Court's merits judgment of 2015,[250] in which it had ruled that 'Costa Rica is entitled to receive *compensation* for the material damage' caused by Nicaragua's actions.[251] Nevertheless, judge *Cançado Trindade* argued in his separate opinion to the judgment on compensation that the Court's outlook should

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244 *Ibid.*, para. 86.
245 *Ibid.*, para. 87.
246 *Young* (n. 127), 40; *Rudall* (n. 84), 291.
247 ICJ, Certain Activities (Compensation) (n. 13), para. 52.
248 Cf. *ibid.*, Separate Opinion of Judge Cançado Trindade; *Kévine Kindji/Michael G. Faure*, Assessing Reparation of Environmental Damage by the ICJ: A Lost Opportunity?, 57 (2019) QIL 5, 24–25.
249 ICJ, Certain Activities (Compensation) (n. 13), para. 31.
250 *Kindji/Faure* (n. 248), 24.
251 Cf. ICJ, Certain Activities/Construction of a Road (Merits) (n. 54), paras. 142 and 229(5)(a) (emphasis added).

have been much wider, also encompassing the consideration of restoration measures and different forms of reparation besides compensation.[252] In his view, any compensation awarded for environmental damage should be used for restoration measures.[253] However, the Court did not make any statement that Costa Rica would be bound to use the compensation for any specific purposes, leaving Costa Rica at liberty to use the funds as it deemed fit.

Even assuming that compensation was the appropriate form of reparation in the case at hand, the ICJ's determination of the amount of compensation is highly questionable. By awarding USD 120,000, the Court granted about 40 % more than what Nicaragua had proposed in its 'corrected analysis' but only 4 % of what Costa Rica had claimed in its original calculation. This shows the enormous discrepancy between the valuations presented by the parties to the dispute. Nevertheless, the Court gave no detailed explanation or justification on how it reached the amount of USD 120,000.[254] In other words, the Court went more or less straight from declaring that it would undertake an overall assessment to announcing its result.[255]

On closer inspection, the Court's reasoning with regard to the 'overall approach' appears contradictory. At first, the Court justified its adoption of an overall assessment with the need to consider the ecosystem as a whole, rather than attributing values to specific categories of environmental goods and services, and estimating recovery periods for each of them.[256] In the next step, however, the Court did just that by basing its further assessment on Nicaragua's itemized 'corrected analysis', which proposed to evaluate the overall damage by referring to only four categories of environmental goods and services.[257] Thus, although the Court claimed to look at the bigger picture, it was in fact only watching some of the brush strokes.[258]

Subsequently, the Court then explained in detail why it found that the corrected analysis underestimated the value of three out of the four cat-

252 ICJ, Certain Activities (Compensation) (n. 13), Separate Opinion of Judge Cançado Trindade, para. 2.
253 *Ibid.*, Separate opinion of Judge Cançado Trindade, para. 55.
254 *Kindji/Faure* (n. 248), 26–27.
255 *Sendut* (n. 127), 22.
256 Cf. ICJ, Certain Activities (Compensation) (n. 13), para. 78.
257 Cf. *ibid.*, para. 84.
258 This view is shared, *inter alia*, by *ibid.*, Dissenting Opinion of Judge ad hoc Dugard, para. 15.

egories of goods and services.[259] It had already indicated that it considered the removal of trees to be the most significant damage out of the four categories.[260] All of this suggested that the Court would explain how the values assigned to the individual categories of goods and services would need to be adjusted in order to reflect the actual damage.[261] But the Court just went straight to announcing the final sum without giving any further explanation.[262] The Court's reasoning in this respect is rather opaque.

After all, it may be questioned whether the Courts 'overall approach' is an evidence-based valuation method or rather an exercise of judicial discretion. Tellingly, to justify its result on the amount of compensation, the Court stated that

> *'the absence of certainty as to the extent of damage does not necessarily preclude it from awarding an amount that it considers approximately to reflect the value of the impairment or loss of environmental goods and services.'*[263]

The first part of this sentence refers to the *Trail Smelter* award already quoted earlier in the judgment,[264] in which the tribunal concluded that uncertainty in the ascertainment of the amount of damages should not preclude the compensability of injury.[265] It also refers indirectly to the ICJ's judgment on compensation in the *Diallo* case. In that case, the Court had awarded, *inter alia*, compensation for the loss of personal property.[266] As the value of the lost items could no longer be established, the Court had relied on 'equitable considerations' to determine the amount of compensation, arguing that other courts, including the *European Court of Human Rights* and the *Inter-American Court of Human Rights*, had followed the same approach where warranted.[267]

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259 Cf. *ibid.*, para. 85.
260 *Ibid.*, para. 79.
261 *Rudall* (n. 84), 292–293.
262 Cf. ICJ, Certain Activities (Compensation) (n. 13), para. 86.
263 *Ibid.*
264 Cf. *ibid.*, para. 35.
265 Cf. Trail Smelter Case, Decision of 1941 (n. 60), 1920; see *supra* n. 138 and accompanying text.
266 Cf. ICJ, Diallo (Compensation) (n. 133), para. 29.
267 *Ibid.*, para. 33 quoting ECtHR, Lupsa v. Romania, Judgment of 08 June 2006, Application no. 10337/04, paras. 70–72; and IACtHR, Chaparro Álvarez and Lapo Íñiguez v. Ecuador, Judgment of 21 November 2007, IACtHR Ser. C, No. 170, paras. 240 and 242.

It appears that the ICJ has, although without admitting it, relied on considerations of equity to determine the amount of compensation.[268] It could even be argued that by referring to the *Diallo* case, the ICJ has transferred a principle originating in international human rights law[269] to the field of international environmental responsibility: Where compensation is due but cannot be quantified by relying on facts, judges may rely on 'equitable considerations', i.e. determine the amount of compensation at their own discretion.[270] Interestingly, this development was already anticipated in 1997 by the *Institut de Droit International*, which declared that 'equitable assessment and other criteria developed under international conventions and by decisions of tribunals should also be considered' in the development of regimes on environmental responsibility and liability.[271] Nevertheless, it remains unclear why the ICJ 'did not clearly state that it reached its decision on quantum based on equitable considerations'.[272] At the same time, the reliance on equitable considerations doubtlessly engages normative principles.[273] For instance, in the human rights context, compensation is determined by referring to the seriousness of the violation, the applicant's position (such as age, social status or contributory

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268 ICJ, Certain Activities (Compensation) (n. 13), Dissenting Opinion of Judge ad hoc Dugard, para. 29.

269 On the use of equity in determining compensation for human rights violations by international human rights bodies, see *Szilvia Altwicker-Hámori* et al., Measuring Violations of Human Rights, 76 (2016) ZaöRV 1, 15–21; International Commission of Jurists, The Right to a Remedy and Reparation for Gross Human Rights Violations: A Practitioners' Guide, Revised Edition (2018), 181–189.

270 See ICJ, Certain Activities (Compensation) (n. 13), Dissenting Opinion of Judge ad hoc Dugard, para. 20.

271 IDI, Resolution on Responsibility and Liability for Environmental Damage (n. 142), Article 24. Also see *Sands/Stewart* (n. 86), 294, who suggested that instead of relying on economic methodologies to determine the loss caused by environmental injury in particular cases, 'judges or members of an administrative tribunal could use their best judgment to assign a monetary value to environmental damage on a case-by-case basis'.

272 ICJ, Certain Activities (Compensation) (n. 13), Separate Opinion of Judge Bhandari, para. 11, who argued that the Court 'could have been more explicit concerning its approach to determining the quantum of compensation, with particular regard to equitable considerations in cases in which the available evidence is not adequate as to the exact amount to be awarded to an injured State' (*ibid.*, para. 12); a similar view was taken by Judge Cançado Trindade (*ibid.*, para. 47), who argued that the Court was 'far more assertive as to the considerations of equity' in the Diallo case and 'could and should have been as forward-looking' in the present case.

273 *Sendut* (n. 127), 24.

negligence) and the overall context in which the breach occurred (such as the local economic circumstances).[274] Therefore, the reference to equitable considerations should not be used to 'mask judicial decisions untethered to any attempt at objective quantification of damage'.[275]

After all, the Court's refusal to justify how its overall approach led to the adoption of the (rather limited) amount of USD 120,000, and its reference to equitable considerations, may lead to important components of environmental losses being overlooked when the overall approach is applied in future disputes.[276] In sum, it is therefore doubtful whether the ICJ's judgment can serve as a precedent in future cases on the question of how compensation for damage to the environment shall be quantified.[277] While it is to be welcomed that the ICJ has not committed itself to any particular valuation method (as it depends on the circumstances of each case which method is appropriate), it is regrettable that the Court failed to give any explanation on how it reached its result. For this reason, it has rightfully been pointed out that the judgment provides 'no authoritative touchstone for other international courts or tribunals dealing with similar issues'.[278]

C. Summary

It is now generally accepted that damage to the environment constitutes a category of damage for which reparation must be served under international law. This includes at least the costs incurred by the injured state in assessing the damage, preventing further injury and restoring the environment to its *status quo ante*,[279] provided that the measures taken are appropriate and reasonable in light of the circumstances of the case and the state of science.[280] Compensation is generally served by reimbursing the affected state for the expenses incurred in implementing these measures.[281] These

274 See, with references to the jurisprudence of the European Court of Human Rights, *Altwicker-Hámori* et al. (n. 269), 15–21.
275 *Sendut* (n. 127), 24.
276 Cf. *Kindji/Faure* (n. 248), 27.
277 Cf. *Rudall* (n. 84), 292.
278 *Ibid.*; see *Rudall* (n. 1), 30.
279 See *supra* section A.I.
280 See *supra* section A.II.
281 See *supra* section A.I.2.

principles apply to all types of environmental damage, including potential transboundary damage caused by products of biotechnology.

Compensation must also be made for 'damage to the environment *per se*', i.e. temporary or permanent impairments of the environment. While international law appears to favour restoration over the mere payment of monetary compensation,[282] payment of financial compensation is an accepted remedy for damage that cannot be restored.[283]

The impairment of environmental goods and services that are commercial assets, such as timber or agricultural productivity, is usually compensated according to the market value of those assets.[284] While it is generally recognized that reparation must also be served for injury to elements of the environment that have no (clear) economic value, it is controversial how the type and quantum of such reparation shall be determined. One approach is *compensatory restoration*, which refers to measures aimed at preserving or improving elements of the environment equivalent to those injured.[285] Other approaches seek to establish a monetary value of the impaired environmental goods and services by referring to *non-market valuation techniques*.[286] However, these techniques are being criticized as anthropocentric and unable to capture complex ecosystem interdependencies and long-term effects.[287] These difficulties become greater the more complex and widespread the damage is.

After all, international practice has not yet yielded a generally accepted technique for determining the form and quantum of compensation for environmental damage. Thus, cases of transboundary damage caused by self-spreading biotechnology will not only entail difficult legal and evidentiary questions about causation but also concerning the proof and valuation of the damage. The ICJ's first judgment on the issue has provided little clarity because its 'overall valuation' approach appears to be mainly based on judicial discretion.[288] Thus, there is currently no clear way to quantify compensation for damage caused by the application of self-spreading biotechnology, especially when damage is caused to common goods and values such as global biodiversity.

282 *Kindji/Faure* (n. 248), 16; Synthesis Report on Article 14(2) CBD (n. 86), para. 59.
283 See *supra* section B.I.
284 See *supra* section B.II.2.a).
285 See *supra* section B.II.1.
286 See *supra* section B.II.2.b).
287 *Hanley* (n. 167), 33; see *supra* section B.II.3.
288 See *supra* section B.III.5.

Concluding Remarks

> *'The liability of the operators of aircraft, liability for pollution, nuclear liability, space liability, liability for weather modification, and so forth, can no longer be regarded as distinct branches of the law, […] but they are all aspects of the broader problem of the role of law, internationally as well as nationally, in the social control of the new relationship between man and his environment created by contemporary scientific and technological progress.'*
> *– C. Wilfried Jenks*[1]

The emergence of self-spreading biotechnology is a megatrend that will vastly change the *modus operandi* of molecular biotechnology. Genetic engineering is no longer confined to the laboratory but will be carried out directly in the environment. Engineered gene drives and other *genetic alteration agents* make it possible to perform genetic modifications in natural populations of species, virulent pathogens, or crop plants in already-planted fields. In this way, self-spreading biotechnology will 'allow to remotely rewrite the code that determines the shape and function of the living world'.[2]

While self-spreading biotechnology potentially brings about new options to address pressing environmental, agricultural, and public health problems, it also entails considerable challenges and risks. Although there are no known cases in which biotechnology has given rise to significant transboundary harm until today, the advent of self-spreading biotechnology justifies the assertion that such harm could well be caused in the future. In fact, the potential of engineered gene drives and similar techniques to spread across political borders is widely recognized in the scientific community, even among researchers developing these techniques.[3]

However, international law is currently not capable of preventing unilateral releases of self-spreading biotechnology that might traverse political borders. In principle, the general rules on the prevention of transboundary harm apply to risks arising from self-spreading biotechnology just as they

1 Liability for Ultra-Hazardous Activities in International Law, 117 (1966) RdC 99, 170.
2 *Bernd Giese*, The Viral Era, 22 (2021) EMBO Reports e53229, 3.
3 See chapter 1, section C.IV.4.

apply to other forms of transboundary environmental risks. However, the mere unsolicited presence of a modified organism in the environment of another state may not necessarily be perceived as reaching the threshold of 'significant' harm, which is a prerequisite for the obligation to prevent such harm to apply. At the same time, the due diligence standard of the obligation to prevent transboundary harm may serve as a convenient buffer against legitimate claims not only before, but even after such harm has occurred.

Before harm has occurred, states will argue that the due diligence standard neither implies a sweeping prohibition to carry out hazardous activities nor requires specific action to make sure that no harm is caused. Although it is generally recognized that states must ensure that the best available technologies are used, there are no agreed standards of what these technologies are in the context of biotechnology, as aptly shown by the lack of binding international standards on laboratory biosafety. Moreover, since international jurisprudence views the occurrence of transboundary harm as a *conditio sine qua non* for a breach of the obligation to prevent such harm, claims of alleged violations will likely be unsuccessful until harm has actually occurred. The same applies to violations of procedural obligations, such as the duty to conduct environmental impact assessments, which, according to international jurisprudence, are almost completely severed from the substantive obligation to prevent harm. This misguided view should be corrected in future cases, because non-compliance with procedural obligations often directly affects the performance of the substantive branch of the obligation to prevent transboundary harm.

After harm has occurred, a responsible state will claim that the due diligence standard requires best efforts but does not guarantee that significant harm is totally prevented despite these efforts. Consequently, the mere causation of transboundary harm does not indicate that a state has violated its obligations to prevent such harm. Instead, an injured state would have to demonstrate that the state of origin has not taken all appropriate measures to prevent harm in the particular circumstances and that this breach was responsible for the harm to be caused. In many cases, this will require an *ex post* determination of what measures would have been appropriate in the individual case from an *ex ante* perspective. As a consequence, establishing a breach of the obligation to prevent transboundary harm is likely to be an uphill battle even after harm has been caused.

The precautionary principle is often invoked in the present context, but its normative value remains ambiguous. Although it clearly militates for restraint in the use of self-spreading techniques rather than their premature deployment, it remains questionable whether the precautionary principle can be successfully invoked to require a state to refrain from releasing organisms containing self-spreading biotechnology. Apart from the persisting uncertainties over the exact meaning and scope of precaution as a rule of international law, in practice, it will most likely be controversial whether there *is* in fact scientific uncertainty about the potential adverse effects involved with a particular release. Moreover, precaution does not require the absence of risk, but rather that the residual risks of a technique are outweighed by its perceived social or environmental benefits. Finally, while the precautionary principle can lower the evidentiary threshold when there is a risk of harm, it cannot be used to ease evidentiary burdens once harm has been caused.

In the context of engineered gene drives, the decision adopted by the parties to the CBD in 2018 is of limited value. While it is notable for confirming the applicability of established principles of international environmental law, the decision neither imposed a moratorium on engineered gene drives nor provided a comprehensive 'checklist' of requirements under which states may proceed with releases. On the contrary, by not even mentioning potential transboundary spreads, the parties to the CBD even failed to address the issue that most naturally should be addressed by an intergovernmental forum. In fact, there are good reasons to presume that proposed uses of self-spreading biotechnology to eradicate a species in its native habitat range are incompatible with the CBD altogether. Self-spreading modified organisms could also become *invasive alien species*, which all parties to the CBD undertook to prevent, control, and eradicate. Future meetings of the parties to the CBD should clarify the scope and potential consequences of these obligations.

Besides uncontrolled and unintentional transboundary spreads, the issue of *intentional* transboundary movements of modified organisms is even less regulated by international law. The *Advance Informed Agreement* mechanism laid down in the Cartagena Protocol establishes nothing more than a procedural framework for obtaining the prior consent of states into imports of LMOs, but it does not contain any substantive rules as to in which cases a state may refuse or must allow such imports. The primary purpose of the AIA mechanism is to protect the sovereign policies of each state concerning the import and use of LMOs on its territory. However, international trade law significantly limits the liberty of states to deny imports of commercial biotechnology products into their territory. Moreover, recent examples have demonstrated that the AIA mechanism is at risk of being undermined by both genuine and disguised changes of the 'intended use' declared at the time of import.[4] Nevertheless, the AIA mechanism could provide an instrument to address unilateral releases of self-spreading biotechnology that is likely to cross political borders. Parties to the Cartagena Protocol should clarify that if there is a known probability of an uncontrolled transboundary spread, releases are regarded as intentional transboundary movements that require the prior consent of all potentially affected states.

In the event that biotechnology gives rise to transboundary harm, all eyes will be on the *Nagoya – Kuala Lumpur Supplementary Protocol*. The instrument is widely perceived to be the key reference on international liability for damage caused by LMOs, including those with the capacity for self-dispersion.[5] It clearly recognizes that LMOs can cause damage to biological diversity as well as to human health and property. It also recognizes that damage to the environment *per se*, in this case to biological diversity, is subject to reparation. By providing for the implementation of practical remediation measures rather than mere payment of financial compensation, the Supplementary Protocol takes an innovative approach and reflects an emerging trend in international environmental law. However, hopes that this approach represents a much-needed 'paradigm shift' that could also revive other areas of environmental liability law have largely diminished since the ratification process of the second global instrument providing for administrative liability, the Antarctic Liability Annex, has stalled.

Moreover, doubts remain that the Supplementary Protocol is fully 'fit for purpose'. It fails to provide a satisfactory answer to the central question of *who* should be liable. Considering that damage caused by LMOs will usually have a slow onset, identifying the 'operator which has caused the damage' will often be fraught with difficulties. For the sake of a just risk allocation, a distinction should be made between damage caused by 'development risks' and damage caused by a particular application or release. But the Supplementary Protocol remains silent on these issues.

While the Supplementary Protocol only applies to LMOs that have been subject to a transboundary movement, it does not address the private international law issues that naturally arise in these situations, such as

4 See chapter 3, section A.II.1.g).
5 See, e.g., *Stephanie James* et al., Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group, 98 (2018) Am. J. Trop. Med. Hyg. 1, 13; *Kenneth A. Oye* et al., Regulating Gene Drives, 345 (2014) Science 626, 628; *Hung-En Lai* et al., Synthetic Biology and the United Nations, 37 (2019) Trends in Biotechnology 1146, 1147; and the references in chapter 6.

jurisdiction, applicable law, as well as recognition and enforcement of judgments. It is hard to envisage how an operator situated abroad could be successfully held liable under the terms of the Supplementary Protocol. In many cases, victims of transboundary harm will have to seek remedies in the domestic legal system of the state where the harm originated – or in third states, depending on where the tortfeasor resides or has seizable assets. However, although it only applies to transboundary situations, the Supplementary Protocol treats liability in these situations as if it were a purely domestic matter. It even fails to confirm fundamental principles of civil liability for transboundary harm, which, it is argued here, have now become part of universal customary international law – namely, that the state of origin must ensure that foreign victims can obtain prompt and adequate compensation, and have non-discriminatory access to its domestic judiciary.[6]

Taken together, the Supplementary Protocol leaves many key questions unresolved: who should be ultimately liable for damage caused by a particular LMO? How can such liability be enforced in transboundary and transnational situations? What role is to be played by states who authorize the development or release of self-spreading, potentially hazardous organisms? Arguably, the meagre substantive content of the Protocol represents the low level of agreement among states on their own role in the management of adverse transboundary effects arising from hazardous activities. However, it also begs the question as to the sense of concluding international agreements on liability that fail to establish any substantive standards in this regard. After all, the Supplementary Protocol runs the risk of creating an 'illusion' of international law that will not hold up in real cases of harm.

In principle, the law of state responsibility provides far-reaching consequences when states breach their obligations under international law. However, states are not generally responsible for the conduct of individuals within their jurisdiction. The conduct of natural or legal persons is only attributed to a state under certain limited conditions; there is no 'vicarious responsibility' of states for the conduct of private actors within their jurisdiction. Therefore, in the context of transboundary environmental interference, the focus is on the obligations of states to adequately regulate hazardous activities and, in the event of damage, to provide for liability and redress. In any event, establishing a causal link between acts

6 *René Lefeber*, Transboundary Environmental Interference and the Origin of State Liability (1996), 230.

or omissions attributable to a state and actual injury will often be difficult. After all, state responsibility is important not so much because it may provide for compensation, but because it ensures the compliance of states with their 'primary' obligations by imposing 'secondary' obligations of reparation in the event of a breach. Consequently, the effectiveness of state responsibility can only be improved by strengthening the corpus of primary obligations in the context of prevention and liability.

Due to the limited scope of state responsibility, there may well be cases in which adverse effects caused by LMOs in a transboundary context are not sufficiently redressed. In the overwhelming majority of past cases, the source states have stepped in and compensated foreign victims of transboundary harm. Nevertheless, states consistently refuse to accept a legal obligation to do so, which has successfully prevented the development of a customary rule of 'strict state liability'. A notable exception can be seen in Article 25(2) of the Cartagena Protocol, which arguably imposes a strict obligation on the state of origin to dispose of an LMO illegally imported into another state. As the lawfulness of the import depends solely on the domestic legal regime of the receiving state, this obligation is independent of any wrongdoing on the part of the state of origin. However, it remains questionable how this obligation can be implemented, especially when a – potentially self-spreading – LMO has already been released into the environment of the receiving state.

After all, the rules of international law on liability for damage caused by biotechnology in a transboundary context remain incomplete and incoherent. To date, international law has not provided a clear and uniform pathway to redress. States persistently refuse to accept liability for transboundary harm caused by private operators under their jurisdiction, but fail to adequately harmonize their domestic laws in order to provide for consistent liability of those private actors. As long as biotechnology has not yet given rise to cases of transboundary harm on a significant scale, these questions remain theoretical and the need to address them is not self-evident. But the emergence of self-spreading biotechnology has created a renewed focus on the need to pre-emptively address possible cases of harm. In addition, the COVID-19 pandemic has shown the need to strengthen the global biosafety regimes as a matter of urgency. The current attention on these issues could and should be used to develop further standards for the release of self-spreading biotechnology and to strengthen the rules on response measures and redress for transboundary harm in case it occurs.

Summary of Results

Chapter 1: The Emergence of Self-Spreading Biotechnology

1. Molecular biotechnology has made significant advances in the last decade, especially because of the emergence of *genome editing* techniques like CRISPR, which make it possible to modify the genome of living organisms on the level of individual *base pairs* (or 'letters') of DNA. Compared to conventional techniques of genetic engineering, genome editing is not only more precise, versatile, and cheaper to apply, but also allows inducing genetic modifications without inserting foreign genetic material into the target organisms.[1]
2. Genome editing techniques also enable the development of various types of *self-dispersing* biotechnology, which refers to modified organisms capable of quickly dispersing through populations of wild species or crop plants in already-planted fields. This includes engineered gene drives, which bias the Mendelian rules of inheritance in favour of the genetic modification they confer. Gene drives could be used to confer new traits to natural populations, but can also be used to inhibit the reproductivity of organisms and thereby suppress populations of species, potentially to the point of extinction.[2]
3. So-called *horizontal environmental genetic alteration agents* (HEGAAs) might even be capable of genetically modifying organisms within the same generation, which would make it possible to confer new traits on existing crop plants.[3] Besides, genetically modified viruses can be used for many different interventions, including the suppression of plant pests or as 'transmissible vaccines', which move through populations like pathogens but confer immunity rather than causing disease.[4]
4. The emergence of self-dispersing techniques is likely to signify a megatrend that will vastly change the *modus operandi* of biotechnology. In contrast to conventional genetic engineering, where modifications are made under controlled conditions in a laboratory, the emergence

1 Chapter 1, section B.
2 Chapter 1, section C.
3 Chapter 1, section D.
4 Chapter 1, sections E.I. and E.II.

of self-dispersing biotechnology implies that genetic modifications are carried out directly in the living target organism without human intervention. However, the ecological effects of these techniques have not yet been sufficiently scrutinized, and there is a substantial likelihood that they will be released into the environment before the risks are fully understood. This poses considerable challenges to existing scientific conventions, but also to the law.[5]

Chapter 2: Concepts and Terms Relevant to Transboundary Harm Caused by Biotechnology

5. While most national biosafety regimes apply to 'genetically modified organisms' (GMOs), international law generally refers to 'living modified organism' (LMOs). It is widely assumed that both terms are synonymous, although more recent genome editing techniques challenge the existing definitions of both terms under the various instruments.[6]
6. Generally, LMOs can give rise to personal injury, property damage, and economic loss, which is often referred to as 'traditional damage' because its compensability is universally accepted. In addition, damage may also be caused to common goods, such as the environment itself and biological diversity. While it is widely accepted that expenses incurred to mitigate environmental damage are recoverable, it is controversial whether any sustaining damage to the environment *per se* is subject to financial compensation. Besides, uncontrolled transboundary movements of LMOs must be distinguished from harm that occurs after an organism was deliberately imported into the receiving state and subsequently released there.[7]
7. The terms *responsibility* and *liability* are used inconsistently in international law dealing with the consequences of transboundary harm. The present study refers to 'responsibility' as the legal consequences that arise from unlawful conduct, whereas 'liability' is used to denote an obligation to rectify damage, regardless of whether this obligation results from responsibility or from a legal rule providing for liability regardless of wrongdoing.[8]

5 Chapter 1, section F.
6 Chapter 2, section A.
7 Chapter 2, section B.
8 Chapter 2, section C.

8. The 'polluter-pays principle' provides that the costs of pollution or environmental degradation shall be allocated to the actor who causes the harm and draws the benefits from the harmful activity. However, from the perspective of international law it is not entirely clear whether the principle directs liability only to the *operators*, which means the person in actual control of a hazardous activity, or also to the state under which jurisdiction the activity is conducted.[9]
9. Since states are generally reluctant to accept liability for hazardous conduct carried out by private actors within their jurisdiction, international law often provides for *operator liability*, which denotes the liability of private actors implemented under national law adopted in accordance with international treaty obligations and enforced by national judicial and administrative systems.
10. Operator liability usually takes the form of 'civil liability', which denotes a legal obligation to pay monetary compensation. In contrast, 'administrative liability' refers to requiring the operator to take 'response measures', which means tangible action to contain, mitigate and remediate the damage.[10] Most liability regimes usually distinguish between 'fault-based liability', which attaches to some form of wrongful or negligent conduct, and 'strict liability', which arises regardless of such fault and is often imposed because of the inherent hazardousness of an activity or substance.[11] However, since non-state operators are not subjects of public international law, their liability must usually be implemented by states. This may pose obstacles in a transboundary context since states are under no general obligation to recognize and enforce foreign judgments.[12]
11. Besides the operator, accountability for transboundary harm may also be imposed on the so-called *state of origin* (or *source state*), which refers to the state under whose jurisdiction the activity that has caused the damage is carried out. In principle, it is undisputed that a state is internationally responsible for transboundary harm that results from a breach of its international obligations aimed at preventing such harm. Arguably, international responsibility may also be incurred by a failure to implement international obligations to provide for the liability of the respective operators which have caused the damage. Beyond that,

9 Chapter 2, section D.
10 Chapter 2, section D.
11 Chapter 2, section E.
12 Chapter 2, section F.

however, it is controversial whether the state should also be *liable* for transboundary harm for which it is not *responsible*.[13]

Chapter 3: The Regulation of Biotechnology in International Law

12. At the global level, the most relevant instrument regulating the development and transboundary movement of LMOs is the Cartagena Protocol on Biosafety. The Cartagena Protocol is wide in scope and applies to organisms modified with genome editing techniques even when the technique employed does not – unlike conventional methods of genetic engineering – involve the (permanent) insertion of foreign genetic material into the target organism.[14]
13. The Cartagena Protocol is primarily concerned with ensuring that products of modern biotechnology that are permitted under the jurisdiction of one state and that are, in principle, freely available in international markets, do not cause harm to the environment of other states. To this end, the Cartagena Protocol establishes a detailed procedural framework for ensuring that each party can take sovereign decisions on whether to allow the import and environmental release of LMOs in its territory. At the same time, the Cartagena Protocol contains no material provision outlining under what circumstances an import should be allowed, subjected to conditions, or denied entirely.[15]
14. A significant challenge to the effectiveness of the Cartagena Protocol's consent mechanism is the fact that its applicability depends on the exporter's (stated) intentions about whether or not an LMO will be released into the environment once it has been imported into the receiving state. Apart from situations of a genuine subsequent change to the intended use, importers may exploit the 'contained use' exception to circumvent the AIA procedure. While this would not affect any domestic regulations applicable to a later release in the receiving state, a plausible motive could be to avoid more stringent requirements that apply in the state of origin. The responsibility to prevent such behaviour is shared by exporting and importing parties to the Cartagena Protocol alike. Exporting parties must ensure that statements about

13 Chapter 2, section D.
14 Chapter 3, section A.I.
15 Chapter 3, section A.II.1.

the intended use are accurate, whereas importing parties should insist on the application of the AIA procedure – as implemented in their domestic law – whenever it appears possible or likely that an LMO initially imported for contained use will subsequently be released into the environment.[16]

15. The Cartagena Protocol also contains a range of provisions that apply regardless of whether an LMO is subject to a (deliberate) transboundary movement and thus regulated by the AIA mechanism, although they are largely free to decide how to regulate the development and use of LMOs in their own territory.[17] Moreover, states are required to cooperate, especially in sharing information about potential hazards originating from LMOs.[18]
16. In sum, the Cartagena Protocol is insufficient to regulate the use of modified organisms capable of self-propagation, including engineered gene drives and modified viruses, that have a high likelihood of spreading across political borders.[19] Article 25(2) is a notable exception because it imposes a strict obligation on the state of origin to dispose of an LMO illegally imported into another state. As the lawfulness of the import depends on whether the AIA mechanism, as well as the domestic laws of the receiving state, have been observed, this obligation is independent of any wrongdoing on the part of the state of origin. However, it remains questionable how this obligation can be implemented, especially when a (potentially self-dispersing) LMO has already been releaseed into the environment of the receiving state.[20]
17. The liberty of states to decide for themselves whether they allow the import of LMOs into their territory may be considerably limited by international trade law, which provides that any restriction on international trade for the purpose of protecting the environment or human health must be based on scientific evidence about the risks that are to be averted. In contrast to the Cartagena Protocol, states are not allowed to invoke scientific uncertainty about risks as a reason to restrict trade, but only insufficient scientific information that prevents a scientifically sound risk assessment altogether. How WTO law can

16 Chapter 3, section A.II.1.g).
17 Chapter 3, section A.II.2.
18 Chapter 3, section A.II.3.
19 Chapter 3, section A.II.2.a)cc).
20 Chapter 3, section A.III.2.c)bb).

be integrated into the wider body of international law is still an unresolved question.[21]

18. Besides the Cartagena Protocol, the provisions on biotechnology contained in the Convention on Biological Diversity remain relevant, particularly for those states which have not ratified the Cartagena Protocol. At the same time, many of the obligations stipulated by the CBD are broad and unspecific, which makes it difficult to assess compliance. However, programmes aimed at completely eradicating a species within its native habitat range may be in breach of the CBD and thus be prohibited by international law altogether.[22] Moreover, the CBD and several other instruments require to prevent the spread of invasive species. It appears to be widely recognized that LMOs which may become invasive are covered by those provisions.[23]
19. Despite the widespread and persisting disagreement about whether LMOs are – as such and inherently – hazardous, the international instruments concerned with plant and animal health, food safety, and international transport of hazardous goods recognize that LMOs (or GMOs) may indeed pose certain risks. Yet, these instruments take a more practical approach than the Cartagena Protocol by providing specific guidance on how to assess potential risks of LMOs in their specific context and on how to handle LMOs in ways that minimize these risks.[24]
20. When a modified organism or pathogen causes a transmissible disease in humans, the WHO's *International Health Regulations* require the state where the outbreak occurs to speedily inform the WHO, which can then issue recommendations to the affected states on how to mitigate the outbreak, and to non-affected states on how to prevent an international spread. However, the recent experience of the COVID-19 pandemic has shown that compliance of both affected and non-affected states is still insufficient and inconsistent.[25]
21. International law on biological weapons and the military use of environmental modification techniques as well as international humanitarian law also applies to recent advances in biotechnology, includ-

21 Chapter 3, section C.III.
22 Chapter 3, section B.VIII.
23 Chapter 3, sections B.V, D, E, and G.
24 Chapter 3, sections D to H.
25 Chapter 3, section I.

ing self-dispersing modified organisms, although ensuring compliance with these provisions involves significant challenges.[26]

Chapter 4: Prevention of Transboundary Harm from Biotechnology Under Customary International Law

22. The general customary obligation of states to prevent significant transboundary harm applies to adverse transboundary adverse effects of LMOs in the same manner as it applies to other forms of transboundary environmental interference.[27] However, it only applies to unintended or accidental transboundary effects of LMOs but not to intentional transboundary movements. A general obligation to ensure that the prior consent of the receiving state is obtained prior to exporting an LMO, as set out in the Cartagena Protocol, is currently not part of customary international law.[28]
23. International responsibility for transboundary harm requires such harm to be 'significant', but it is doubtful whether this threshold is reached by the mere presence of an LMO in the territory of another state. It must be shown that the LMO causes 'real detriment' in the form of damage to persons, property or the environment. A large-scale influx of LMOs, e.g. caused by an invasive gene drive, is likely to be regarded as significant, especially when it has adverse effects on local ecosystems. Moreover, when the release of a particular LMO (or of LMOs generally) is illegal under the national laws of a state, that state cannot argue that an unintentional spread of that LMO into the environment of another state was insignificant.[29]
24. The obligation to prevent transboundary harm is only an obligation of 'due diligence', which means that a state must make reasonable efforts to inform itself about the factual and legal circumstances that relate to a proposed activity and take appropriate preventive measures in due time.[30] Hence, in order to establish a violation, a claimant would need to demonstrate that the responsible state has failed to employ due diligence and that this failure caused the occurrence of transboundary

26 Chapter 3, section J.
27 Chapter 4, section B.II.
28 Chapter 4, sections B.III. and B.VII.2.
29 Chapter 4, sections B.IV. and B.VII.
30 Chapter 4, section C.

harm. Ultimately, this will require an *ex post* determination of what measures would have been appropriate in the individual case from an *ex ante* perspective.

25. When knowledge is insufficient, the precautionary approach lowers the evidentiary threshold for requiring preventive measures. As a result, states can be required to take preventive action already when there are indications, albeit no proof (or scientific certainty), that an activity might lead to significant transboundary harm. However, the precautionary approach does not result in a reversal of the burden of proof; a state invoking the precautionary principle still must adduce enough evidence to establish at least a *prima facie* case.[31]
26. While the substantive content of due diligence remains rather vague, the corollary procedural obligations are more specific. In particular, the obligation to carry out an environmental impact assessment is universally recognized, and the adequacy of such assessments is increasingly subject to legal review by international courts and arbitral tribunals.[32] The documentation prepared during an EIA procedure can be regarded as written evidence of the exercise of due diligence, as it commonly includes a description of the potential impacts of the proposed activity as well as of the required prevention and mitigation measures. At the same time, the greater level of detail in the procedural manifestations of prevention has often led international jurisprudence to focus on procedural aspects while applying less scrutiny to the question of whether the substantive obligation to prevent harm has been observed.
27. Because the obligation to act with due diligence is not an 'obligation of result', the mere occurrence of transboundary harm does not *per se* indicate a violation.[33] *Vice versa*, however, international jurisprudence seems to consider it a prerequisite of a breach that harm has actually occurred.[34] Nor are violations of procedural duties, in the view of international jurisprudence, evidence *per se* of a breach of the substantive obligation to prevent transboundary harm. However, procedural duties should be seen not only as independent obligations but also as expressions of the substantive obligation to prevent harm. That is, breaches of procedural duties imply that a state has also disregarded its

31 Chapter 4, section B.VI.
32 Chapter 4, section D.II.
33 Chapter 4, sections E.I.
34 Chapter 4, sections E.II.

substantive obligation to employ due diligence, regardless of whether harm has already been caused.[35]

28. To date, no state has ever claimed a breach of international law for adverse transboundary effects caused by LMOs uncontrolledly entering its territory. In light of recent advances in developing self-dispersing biotechnology such as engineered gene drives, such claims are likely to arise in the future. However, it is doubtful whether customary international law is capable of preventing unilateral releases when the potential for a transboundary spread of the organism is controversial.[36]

Chapter 5: The International Governance of Engineered Gene Drives

29. Since the first releases of engineered gene drives are expected to occur as soon as 2023, the debate about the international regulation of this emerging technology has gained speed and culminated in a first substantive decision on this matter by the parties to the CBD in 2018.[37]
30. The fact that the decision was carried by consensus by all states (except for the United States) gives the decision a high degree of normative authority. This is also because the decision does not attempt to establish new principles, but rather endorses the application of certain established rules of international law to the issue of gene drives.[38]
31. The decision calls on states to observe the precautionary principle. Contrary to what a few authors have contended, this cannot be used to justify premature releases in order to address other environmental threats that require rapid action. Instead, the precautionary principle calls for restraint in using gene drive techniques as long as their risks and benefits cannot be fully evaluated.[39]
32. The decision calls on states to consider releasing engineered gene drives only when three conditions are met: a scientifically sound risk assessment has been carried out; appropriate risk management measures are in place; and the free and informed prior consent of indigenous peoples and local communities has been obtained (where applicable).

35 Chapter 4, sections E.III.
36 Chapter 4, section F.
37 Chapter 5, section A.
38 Chapter 5, section B.
39 Chapter 5, section C.I.

33. While these criteria had previously been recognized by the parties to the CBD, many questions remain regarding their consequences in the context of gene drives, and the benchmark for what constitutes the 'best available technologies' is currently not defined by the states but rather by the researchers involved in the development of gene drives. The same is true for the call to ensure the safety of gene drive in contained use, where the decision even suggests a level of international harmonization that actually does not exist.[40]
34. An issue left unaddressed by the decision is the potential of engineered gene drives to spread across borders. While the problem is broadly recognized in principle, the likeliness of such spreads will often create controversy between the state planning a release and potentially affected neighbouring states, which makes it difficult to agree on general rules.[41] Parties to the Cartagena Protocol should clarify that releases likely to result in a transboundary spread constitute 'intentional transboundary movements' that require the Advance Informed Agreement of the likely affected states prior to the release.[42]
35. The decision neither results in a moratorium of gene drive releases nor provides a comprehensive 'checklist' for future releases. Therefore, the decision should be seen as a carefully balanced compromise between both ends of the spectrum, which does not answer the question as to whether responsible gene drive releases are permissible under the current rules of international law.[43]

Chapter 6: The Nagoya – Kuala Lumpur Supplementary Protocol on Redress and Liability

36. The Supplementary Protocol is the first global agreement on liability for damage to a global common and the first global agreement providing for an administrative approach to liability, and the first global agreement dealing with environmental liability outside the context of maritime oil pollution and nuclear damage that has ever entered into force.[44]

40 Chapter 5, section C.II.
41 Chapter 5, section D.
42 Chapter 5, section D.I.2.
43 Chapter 5, section E.
44 Chapter 6, section A.

37. The Supplementary Protocol provides for 'administrative liability'. Instead of providing simply for the payment of monetary compensation by the responsible operators, the Supplementary Protocol stipulates that damage shall be prevented, mitigated and restored by implementing response measures. However, parties to the Supplementary Protocol enjoy too much leeway in implementing the administrative approach in their domestic legal and administrative systems. Apart from stipulating the primacy of prevention over restoration, and the primacy of restoration over compensation,[45] it does not define any specific criteria for what constitutes damage to biological diversity,[46] how to identify the liable actor, and what kinds of response measures should be taken. At the same time, it might be an inherent necessity of the 'administrative liability' approach to grant states a certain margin of appreciation, as it is not possible to pre-emptively regulate what measures will be required in individual cases of damage.[47]
38. With respect to personal injury and property damage, the Supplementary Protocol does not even attempt to harmonize substantive and procedural rules on civil liability. This takes account of the fact that states widely refuse to accept the harmonization approach, as aptly demonstrated by the numerous civil liability treaties that have failed to enter into force. Consequently, the Supplementary Protocol does not commit the parties to particular standards on civil liability but only stipulates a procedural duty requiring states to 'aim' for 'appropriate rules and procedures' in their domestic law.[48]
39. One of the most striking omissions of the Supplementary Protocol is its failure to address the transnational implementation of liability. Although it only applies to damage resulting from LMOs that find their origin in a transboundary movement, it remains silent on how to deal with situations in which the responsible operator is located in one state and biodiversity damage occurs in another. The Supplementary Protocol fails to address the issues that naturally arise in these situations, including jurisdiction, applicable law, and recognition and enforcement of judgments. Thus, the Supplementary Protocol only ap-

45 Chapter 6, section C.IV.
46 Chapter 6, section B.
47 Chapter 6, section C.VI.
48 Chapter 6, section D.

plies to transboundary situations but treats liability in these situations as if they were a purely domestic matter.[49]

40. It is doubtful that the Supplementary Protocol will be of particular use when self-dispersing biotechnology causes adverse transboundary effects. Although the Supplementary Protocol expressly applies to unintentional transboundary movements, it does not provide any means to deal with such situations. Unless the 'operator which has caused the damage' has assets in the affected state that can be seized to enforce liability, and in the absence of other instruments, a state facing adverse effects of an LMO that uncontrolledly entered its territory has no remedies to enforce the civil or administrative liability of foreign operators. In such situations, the only options are seeking civil law remedies in states where the responsible operator is situated or has assets, or invoking the international responsibility of the state that has authorized the release, provided it has breached preventive obligations under international law.[50]
41. While the lack of harmonization is a major shortcoming of the Supplementary Protocol, it is arguably also an important factor that allowed it to enter into force. However, it also demonstrates the low level of agreement among states about substantive standards for environmental liability in an international context. In any event, adopting instruments on transboundary environmental liability that do not actually address the challenges arising from transboundary situations will likely prove to be a Pyrrhic victory.[51]

Chapter 7: A Private Liability Scheme: The 'Biodiversity Compact'

42. The Biodiversity Compact is a voluntary private compensation scheme under which six agricultural biotechnology corporations assume liability for biodiversity damage caused by any of their LMOs.[52] The Compact adopts the 'administrative approach' to liability followed by the Supplementary Protocol but specifies the modalities of liability in much greater detail.[53] It channels liability to a clearly identifiable ac-

49 Chapter 6, section F.I.
50 Chapter 6, section H.
51 Chapter 6, section H.
52 Chapter 7, sections A and B.
53 Chapter 7, section E.

tor, and its binding arbitration mechanism provides means to enforce liability even when the liable party is situated outside of the state's jurisdiction.[54] Furthermore, due to its nature as a third-party beneficiary contract, the Compact also benefits those states which have not ratified the Supplementary Protocol or do not have in place adequate liability rules in their domestic law.

43. Like the Supplementary Protocol, the Compact suffers from limited participation and representativeness. The shortcomings in participation are likely to become more pronounced, seen as the emergence of genome editing techniques has led to a substantial increase in bio-enterprise investment. Many new companies have emerged and have begun to commercialize these techniques. Furthermore, engineered gene drive techniques are mainly pursued not by the biotechnology industry but rather by research institutions and philanthropic organizations. It currently seems unlikely that these actors will feel compelled to sign the Compact.[55]
44. Besides its limited participation, the Compact's most significant shortcoming is its exclusion of damage resulting from risks that were already known when the LMO was authorized for marketing or release; such a one-sided risk allocation is uncommon for liability regimes addressing activities or substances that are deemed hazardous but socially beneficial.[56] Due to the Compact's complex definition of damage, evidentiary requirements, provisions on determining the adequate response, and claims process, it seems unlikely that potential claims would be successful.[57]
45. Although presented as a confidence-building measure, the Compact must rather be seen as a (failed) attempt to avert the adoption of a legally binding international regime on liability for damage caused by LMOs. At the same time, the considerable complexity of the Compact's text demonstrates the challenges involved in implementing the Supplementary Protocol into specific legislation at the domestic level.[58]

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54 Chapter 7, section G.
55 Chapter 7, section H.
56 Chapter 7, section D.
57 Chapter 7, sections C to G.
58 Chapter 7, section H.

Chapter 8: A Customary Obligation to Ensure Prompt and Adequate Compensation for Transboundary Damage?

46. When activities under their jurisdiction cause transboundary harm, states are obliged by customary international law to ensure that foreign victims have access to non-discriminatory remedies and can obtain prompt and adequate compensation.[59] States must also take response measures to prevent and mitigate further damage, including by notifying and cooperating with all other states likely to be affected.[60]
47. The state of origin is neither required nor generally allowed to take response measures in the territory of affected states.[61] Affected states, however, do not bear a general obligation to take response measures under general customary international law, although such an obligation arises from Article 8(h) of the CBD in case a self-dispersing LMO spreads beyond its intended target range and becomes an 'invasive alien species' threatening biodiversity. If an affected state takes reasonable mitigation and reinstatement measures, the expenses incurred in doing so become part of the damage for which the state of origin must ensure prompt, adequate and effective remedies under its domestic legal system.[62]

Chapter 9: State Responsibility for Transboundary Harm Caused by Biotechnology

48. The law of state responsibility provides far-reaching consequences for breaches of international law, including unlimited responsibility for any injury caused. However, state responsibility is also subject to several limitations and caveats.
49. States are not generally responsible for the conduct of individuals within their jurisdiction. The conduct of natural or legal persons is only attributed to the state under certain limited conditions; there is no 'vicarious responsibility' of states for the conduct of private actors within their jurisdiction.[63] Therefore, in the context of transboundary

59 Chapter 8, section B.
60 Chapter 8, section C.
61 Chapter 8, section F.
62 Chapter 8, sections C and F.
63 Chapter 9, section A.II.

environmental interference, the focus is on the obligations of states to adequately regulate hazardous activities and, in the event of damage, to provide for the liability and redress.[64] However, hazardous conduct can become directly attributable when the state itself engages in such conduct or effectively controls such conduct carried out by non-state actors.[65]

50. To implement state responsibility, it must be shown that the state's conduct was not in conformity with its obligations under international law. However, proving the relevant facts, including what the responsible state *could* and *should* have done to prevent damage, will often involve difficult evidentiary questions.[66] Similar difficulties may arise regarding the proof of causation, especially when the damage only manifests in the long term or when there is more than one possible pathway or multiple states that are jointly responsible for the damage. International courts and tribunals are reluctant to lower the standard of proof required to establish the existence of a causal link between the responsible state's failure to adequately regulate a hazardous activity or organism, and the resulting damage.[67]
51. When a breach can be established, the responsible state must cease the wrongful conduct and make reparation for any injury caused by it.[68] In principle, the obligation to make full reparation applies not only to 'traditional' damage such as personal injury, property damage, and economic loss, but also to damage to the environment *per se.*[69] This will become particularly relevant when self-spreading LMOs cause damage to native species, ecosystems or biological diversity at large.
52. A state's international responsibility can only be invoked by other states. In the absence of dedicated treaties, foreign private actors cannot directly make claims against the state of origin but need to be represented by their respective states. However, unlike conventional cases of *diplomatic protection*, there is no requirement that the private actor must exhaust *local remedies* because the victims have not voluntarily subordinated themselves to the jurisdiction of the source state.[70]

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64 Chapter 9, section A.II.6.
65 Chapter 9, section A.II.2.
66 Chapter 9, section A.III.
67 Chapter 9, section B.II.2.
68 Chapter 9, section B.
69 Chapter 9, section B.II.3.
70 Chapter 9, section C.II.2.

53. Since states are not bound to accept the jurisdiction of any international court or tribunal, there will be no adequate legal mechanism to enforce the liability of the state of origin in many cases; this may well prove to be the biggest obstacle to enforcing state responsibility for transboundary damage caused by biotechnology.[71] Compliance mechanisms established by multilateral environmental agreements such as the Cartagena Protocol may be better equipped to promote adherence to international rules.[72] Yet, they fulfil different functions. While compliance mechanisms are 'forward-looking' and aim to ensure the future compliance of states with their obligations, state responsibility remains the relevant regime to rectify injury that has already been caused by breaches of international obligations.[73]
54. Despite its difficulties, the relevance of state responsibility in the context of transboundary harm should not be underestimated because the perspective of being held responsible for non-compliance ensures the effectiveness of all primary rules on prevention and operator liability. This is even more true when states proceed with releasing modified organisms capable of self-dispersion unilaterally rather than in internationally coordinated efforts.[74]

Chapter 10: Strict State Liability for Transboundary Harm?

55. Although it is widely acknowledged in legal scholarship that, *de lege ferenda*, there should be a form of subsidiary state liability for significant transboundary harm caused by hazardous activities, the pertinent state practice currently does not provide sufficient ground to presume the existence of a customary rule providing for strict state liability for transboundary harm caused by self-spreading biotechnology. While there are only a few cases in which transboundary harm was left entirely unanswered by the state of origin, most payments were made explicitly on an *ex gratia* basis, and states insisted on not accepting a *legal* responsibility or liability for the damage.[75]

71 Chapter 9, section C.III.2.
72 Chapter 9, section C.III.3.a).
73 Chapter 9, section C.III.3.b).
74 Chapter 9, section D.
75 Chapter 10, section B.

56. Consequently, a state is not generally liable for transboundary harm caused by self-spreading biotechnology unless in cases of a breach of international law.[76] Thus, if a state has taken all measures deemed 'appropriate' to prevent adverse transboundary effects, it is under no obligation to compensate for damage that occurs nevertheless. This demonstrates, again, the need to strengthen the preventive obligations and, since a moratorium seems difficult to achieve, to agree on clear conditions for environmental releases of engineered gene drives and other forms of self-spreading biotechnology.

Chapter 11: Compensation for Environmental Damage in International Law

57. It is now generally accepted that damage to the environment constitutes a category of damage for which reparation must be served under international law. This includes at least the costs incurred by the injured state in assessing the damage, preventing further injury and restoring the environment to its *status quo ante*,[77] provided that the measures taken are appropriate and reasonable in light of the circumstances of the case and the state of science.[78] Compensation is generally served by reimbursing the affected state for the expenses incurred in implementing these measures.[79] These principles apply to all types of environmental damage, including potential transboundary damage caused by products of biotechnology.
58. Compensation must also be made for 'damage to the environment *per se*', i.e. temporary or permanent impairments of the environment. While international law appears to favour restoration over the mere payment of monetary compensation, payment of financial compensation is an accepted remedy when the damage cannot be restored.[80]
59. The impairment of environmental goods and services used commercially is compensated according to their 'use value', which is usually the market value of the affected natural resources.[81]

76 Chapter 10, section E.
77 Chapter 11, section A.I.
78 Chapter 11, section A.II.
79 Chapter 11, section A.I.2.
80 Chapter 11, section B.I.
81 Chapter 11, section B.II.2.a).

60. While it is generally recognized that reparation must also be served for injury to elements of the environment with no clear economic value, it is controversial how the type and quantum of such reparation shall be determined.[82] One approach is *compensatory restoration*, which denotes replacing lost environmental assets by preserving or improving other elements of the environment capable of providing environmental goods and services similar to those lost.[83] Other approaches seek to establish a monetary value of the impaired environmental goods and services by referring to *non-market valuation techniques*, including 'stated preference' and 'revealed preference' methods.[84] Besides, 'benefit' transfer methods[85] and the costs of 'hypothetical' response measures can be used to quantify compensation.[86]
61. The international practice has not yet yielded a generally accepted technique for determining the form and quantum of compensation for environmental damage. Thus, cases of transboundary damage caused by biotechnology will not only pose difficult legal and evidentiary questions about causation but also concerning the establishment and valuation of the damage. The ICJ's first judgment on the issue has provided little clarity on the issue, because its 'overall valuation' approach appears to be mainly based on judicial discretion.[87] Thus, there is currently no clear way to quantify compensation for damage caused by the application of biotechnology, especially when damage is caused to common goods and values, such as global biodiversity.

82 Chapter 11, section B.II.
83 Chapter 11, section B.II.1.
84 Chapter 11, section B.II.2.b).
85 Chapter 11, section B.II.2.c).
86 Chapter 11, section B.II.2.d).
87 Chapter 11, section B.III.

Zusammenfassung in deutscher Sprache

Die vorliegende Arbeit untersucht die völkerrechtlichen Regeln über die Verantwortlichkeit und Haftung für grenzüberschreitende Schäden, die durch den Einsatz neuartiger biotechnologischer Verfahren verursacht werden können. Die Notwendigkeit, sich mit möglichen grenzüberschreitenden Auswirkungen der Biotechnologie auch aus völkerrechtlicher Perspektive zu befassen, ist spätestens durch die COVID-19-Pandemie offenkundig geworden. Wenngleich das Coronavirus SARS-CoV-2 nach derzeitigem wissenschaftlichem Erkenntnisstand nicht das Produkt einer gezielten genetischen Veränderung ist, gilt ein Laborausbruch weiterhin als möglicher Ursprung des Virus.

Allerdings begründet nicht nur COVID-19 die Annahme, dass biotechnologische Verfahren in Zukunft grenzüberschreitende Schäden verursachen könnten. Die im vergangenen Jahrzehnt entwickelten Verfahren zum *Genome Editing* ermöglichen nicht nur das präzise Verändern von Erbgut, sondern auch die Entwicklung von *sich selbst ausbreitender Biotechnologie* („self-spreading biotechnology“). Mit *Gene Drives* und ähnlichen molekularbiologischen Verfahren wird es bald möglich sein, wild lebende Arten, Keime und Nutzpflanzen direkt in der Umwelt – und in einer unbestimmten Zahl von Individuen – gezielt genetisch zu modifizieren. Allerdings ist allgemein anerkannt, dass mit diesen Verfahren das Risiko unkontrollierter, potenziell auch grenzüberschreitender Ausbreitungen einhergeht.

Die Arbeit untersucht diese Herausforderungen aus den Perspektiven der *Prävention*, der *Verantwortlichkeit* sowie der *Haftung.* Allgemein kommt dem Haftungsrecht primär eine *reparative* Funktion zu, indem es *ex post* die Wiedergutmachung eingetretener Schäden anordnet. Darüber hinaus hat das Haftungsrecht aber auch eine *präventive* Funktion, da die Aussicht, für eingetretene Schäden in Haftung genommen zu werden, die verantwortlichen Akteure schon *ex ante* zur Vermeidung solcher Schäden anhält.

Die Arbeit ist in drei Teile gegliedert. Der erste Teil gibt in Kapitel 1 zunächst einen Überblick über die oben angerissenen Fortschritte in der Biotechnologie und die damit verbundenen Risiken. Anschließend werden in Kapitel 2 Schlüsselbegriffe und Konzepte eingeführt, die für die nachfolgende Untersuchung grundlegend sind.

Der zweite Teil der Arbeit befasst sich mit der Prävention grenzüberschreitender Schäden im Kontext der molekularen Biotechnologie. In Kapitel 3 werden die einschlägigen völkerrechtlichen Verträge untersucht, allen voran das *Cartagena-Protokoll über die biologische Sicherheit*. In Kapitel 4 werden Reichweite und Inhalt der völkergewohnheitsrechtlichen Pflicht der Staaten zur Prävention erheblicher grenzüberschreitender Schäden beleuchtet. In Kapitel 5 werden die laufende Debatte über die völkerrechtliche Regulierung von Gene Drives sowie die erste substanziellen Entscheidung zu diesem Thema aus dem Jahr 2018 analysiert.

Im dritten Teil wird die sog. *Betreiberhaftung* untersucht, d.h. die Haftung staatlicher und nicht-staatlicher Akteure, die schadensgeneigte Tätigkeiten ausüben. Das *Zusatzprotokoll von Nagoya/Kuala Lumpur*, das dedizierte Regeln für die Betreiberhaftung im Kontext der Gentechnik aufstellt, ist Gegenstand des Kapitels 6. In Kapitel 7 wird ein privatrechtliches Haftungsinstrument besprochen, das als Alternative zu den Regeln des Zusatzprotokolls entwickelt wurde. In Kapitel 8 wird geklärt, ob Staaten völkergewohnheitsrechtlich verpflichtet sind, in grenzüberschreitenden Schadensfällen die Haftung der ihrer Hoheitsgewalt unterstehenden Betreiber sicherzustellen.

Im vierten Teil wird schließlich die Verantwortlichkeit und Haftung von Staaten untersucht. Das Kapitel 9 ist dem Recht der Staatenverantwortlichkeit gewidmet, welches die Folgen völkerrechtswidrigen Verhaltens regelt. In Kapitel 10 wird herausgearbeitet, ob es darüber hinaus eine völkerrechtliche Gefährdungshaftung der Staaten für grenzüberschreitende Schäden gibt. In Kapitel 11 wird schließlich die Frage beleuchtet, ob und inwiefern Schäden an der Umwelt im Völkerrecht als ersatzfähig anerkannt sind.

Insgesamt zeigt die vorliegende Arbeit, dass das derzeit geltende Völkerrecht zur Haftung für grenzüberschreitende Schäden im gegenwärtigen Kontext lückenhaft und daher nur beschränkt dazu in der Lage ist, sachgerechte Antworten auf die Herausforderungen zu liefern, die sich durch das Aufkommen neuartiger biotechnologischer Verfahren mit der Möglichkeit zur Selbstausbreitung stellen.

Kapitel 1: Das Aufkommen von sich selbst ausbreitender Biotechnologie

Im Jahr 2012 wurde mit der „Genschere" CRISPR/Cas9 eine neuartige molekularbiologische Methode entwickelt, mit der das Erbgut lebender Organsimen mit hoher Präzision modifiziert werden kann. Die auch als

Genome Editing bezeichneten Verfahren ermöglichen es, DNA gezielt zu schneiden und somit auf der Ebene einzelner Basenpaare (oder „Buchstaben“) zu verändern. Im Vergleich zu konventionellen gentechnischen Methoden gilt Genome Editing nicht nur als präziser, vielseitiger und kostengünstiger in der Anwendung, sondern ermöglicht es auch erstmals, genetische Veränderungen vorzunehmen, ohne dass Erbinformationen anderer Arten, sog. *Transgene*, in den Zielorganismus eingefügt werden. Dies bringt erhebliche Herausforderungen für die bestehenden Regulierungsinstrumente für gentechnische Anwendungen auf nationaler wie internationaler Ebene mit sich, deren Anwendbarkeit nach überkommenem Verständnis von der Präsenz von Transgenen in den daraus hervorgebrachten Organismen abhängt.

Genome Editing ermöglicht auch die Entwicklung von Verfahren zur beschleunigten Ausbreitung genetischer Veränderungen in natürlichen Tier- und Pflanzenpopulationen, insbesondere sog. *Gene Drives*. Während sich genetische Veränderungen nach den Gesetzmäßigkeiten der chromosomalen Vererbung nur langsam in natürlichen Beständen verbreiten, kann mithilfe von Gene Drives eine *überproportionale Vererbung* und damit eine beschleunigte Verbreitung erreicht werden. Auf diese Weise können natürliche Populationen – insbesondere solche mit kleinem Generationenabstand – in kürzester Zeit genetisch verändert werden. Neben der Verbreitung neuer genetischer Eigenschaften können Gene Drives auch dazu eingesetzt werden, in die Reproduktionsfähigkeit oder das Geschlechterverhältnis einer Population einzugreifen und diese dadurch gezielt zu dezimieren oder gar zum (lokalen oder globalen) Aussterben zu bringen.

Für Gene Drives bestehen zahlreiche potenzielle Anwendungsfelder: So sollen etwa Malaria übertragende Moskitoarten entweder ausgerottet oder zumindest derart genetisch verändert werden, dass sie die Krankheit nicht mehr übertragen können. In der Landwirtschaft könnten Gene Drives eingesetzt werden, um Herbizid- oder Pestizidresistenzen, die Schädlingsarten im Laufe der Zeit entwickelt haben, wieder zu entfernen oder Schädlinge erstmals anfällig gegen bestimmte Substanzen zu machen und so den Einsatz ungiftiger Pestizide zu ermöglichen. Auch im Naturschutz werden Einsatzmöglichkeiten gesehen, etwa bei der Bekämpfung invasiver Arten oder zum Schutz bedrohter Arten.

Genome Editing ermöglicht auch die Entwicklung übertragbarer Agenzien zur *horizontalen Genmodifikation* (sog. „horizontal environmental genetic alteration agents“, kurz HEGAAs). Im Gegensatz zu Gene Drives wird dabei nicht nur eine überproportionale Vererbung angestrebt, sondern eine Vielzahl von Individuen einer Art derselben Generation parallel genetisch verändert. Dazu werden ansteckende Viren genetisch so programmiert, dass sie selbst das Erbgut der von ihnen infizierten Organismen modifizieren. Dies könnte beispielsweise dazu genutzt werden, bereits angebaute Nutzpflanzen im Freiland kurzfristig resistent gegen unerwartete Umwelteinflüsse wie Krankheiten oder Dürre zu machen. Ein vom US-Verteidigungsministerium finanziertes Forschungsprogramm zielte zudem darauf ab, HEGAAs mittels Insekten auf die Zielorganismen zu verbreiten.

Darüber hinaus kommen genetisch veränderte Viren für eine Vielzahl weiterer Einsatzzwecke in Betracht, etwa zur Unterdrückung von Pflanzenschädlingen. So hat beispielsweise ein US-Unternehmen ein harmloses, in Zitrusbäumen bereits weit verbreitetes Virus mit bestimmten Genen aus Spinat versehen, die diese Bäume resistent gegen schädliche Bakterien machen sollen. Schließlich könnten genetisch veränderte Viren als „ansteckende Impfstoffe" zum Einsatz kommen, die sich zwar wie Krankheitserreger verbreiten, dabei jedoch keine Erkrankungen verursachen, sondern Immunität gegen andere, schwerere Krankheiten verleihen.

Das Aufkommen selbstausbreitender biotechnologischer Verfahren stellt einen *Megatrend* dar, der die Funktionsweise der molekularen Biotechnologie grundlegend verändern wird. Im Gegensatz zur konventionellen Gentechnik, bei der Veränderungen unter kontrollierten Bedingungen im Labor vorgenommen werden, haben die neuen Verfahren gemein, dass genetische Veränderungen ohne menschliches Zutun direkt im lebenden Zielorganismus vorgenommen werden können. Die ökologischen Auswirkungen dieser Techniken sind jedoch bislang kaum erforscht. Zugleich besteht eine nicht unerhebliche Wahrscheinlichkeit, dass sie in der Umwelt zum Einsatz kommen, bevor ihre Risiken vollständig verstanden wurden.

Kapitel 2: Relevante Konzepte und Begriffe im Kontext grenzüberschreitender Schäden durch Biotechnologie

Die regulatorischen Systeme zur Biotechnologie und biologischen Sicherheit auf nationaler Ebene sowie im Europarecht betreffen die Entwicklung und Verbreitung von *genetisch* bzw. *gentechnisch veränderten Organismen* (GVO/GMO). Auf völkerrechtlicher Ebene beziehen sich die meisten Instrumente dagegen auf *lebende veränderte Organismen* („living modified organisms", kurz LMO). Mit Blick auf die konventionelle Gentechnik wurde bislang meist davon ausgegangen, dass beide Begriffe weitestgehend synonym sind. Aufgrund der teils sehr unterschiedlichen Legaldefinitionen kann dies mit Blick auf die oben genannten neueren Verfahren jedoch nicht mehr pauschal angenommen werden.

Grundsätzlich können schädliche Folgewirkungen von LMO zur Verletzung von Personen, Sachschäden und wirtschaftlichen Verlusten führen. Diese Schadensarten werden im völkerrechtlichen Diskurs häufig als *herkömmliche Schäden* („traditional damage") bezeichnet, da ihre Ersatzfähigkeit allgemein anerkannt ist. Darüber hinaus können LMO jedoch auch Schäden an Gemeinschaftsgütern wie der Umwelt und der biologischen Vielfalt verursachen. Mit Blick auf die schädlichen Folgewirkungen von LMO müssen Schäden infolge einer unabsichtlichen grenzüberschreitenden Verbringung oder Ausbreitung von LMO von solchen Schäden unterschieden werden, die entstehen, nachdem ein Organismus absichtlich in den Aufnahmestaat eingeführt und dort anschließend freigesetzt wurde.

Im völkerrechtlichen Diskurs zu den Folgen grenzüberschreitender Schäden werden die Begriffe *Verantwortlichkeit* („responsibility") und *Haftung* („liability") uneinheitlich verwendet. Die vorliegende Arbeit bezeichnet mit *Verantwortlichkeit* die Rechtsfolgen, die sich aus einem rechtswidrigen Verhalten bzw. einer Pflichtverletzung ergeben. Demgegenüber bezeichnet der Begriff der *Haftung* eine Pflicht zum Schadensersatz, unabhängig davon, ob sie die Folge einer Pflichtverletzung ist oder als Gefährdungshaftung verschuldensunabhängig eintritt.

Nach dem umweltrechtlichen *Verursacherprinzip* („polluter pays principle") sollen die Kosten für die Vermeidung, Beseitigung und den Ausgleich von Umweltschäden jenem Akteur zugewiesen werden, der den Schaden verursacht bzw. den Nutzen aus der schädlichen Tätigkeit gezogen hat. Aus völkerrechtlicher Sicht ist jedoch nicht endgültig geklärt, ob das Verursacherprinzip die Haftung nur auf den *Betreiber* richtet, d.h. jene natürliche oder juristische Person, die die tatsächliche Kontrolle über die gefährliche oder schadensverursachende Tätigkeit ausübt, oder auch auf den *Staat*, unter dessen Hoheitsgewalt die betreffende Tätigkeit durchgeführt wird. Aus diesem Grund müssen Betreiber- und Staatenhaftung parallel und als potenziell konkurrierend betrachtet werden.

Ferner muss unterschieden werden zwischen der Haftung von Staaten nach dem Völkerrecht und der Haftung nichtstaatlicher Akteure, die sich mangels deren völkerrechtlicher Subjektivität in der Regel nach nationalem – gegebenenfalls durch völkerrechtliche Regeln harmonisiertem – Recht richtet und durch nationale Organe durchgesetzt werden muss.

Da Staaten eine eigene Haftung für grenzüberschreitende Schäden infolge gefährlicher Aktivitäten nichtstaatlicher Akteure meist ablehnen, kommt der völkerrechtlich harmonisierten *Betreiberhaftung* große Bedeutung zu. In grenzüberschreitenden Sachverhalten stellt sich zudem häufig das Problem der Anerkennung und Vollstreckung ausländischer Gerichtsurteile, da Staaten hierzu nach allgemeinem Völkerrecht nicht verpflichtet sind.

Die meisten Instrumente des internationalen Umwelthaftungsrechts harmonisieren die Betreiberhaftung in Form einer *zivilrechtlichen Haftung* („civil liability"), womit eine rechtliche Verpflichtung zur Zahlung einer Geldentschädigung an einen oder mehrere Geschädigte gemeint ist. Während dieser Ansatz problemlos dazu geeignet ist, herkömmliche Personen- und Sachschäden sowie wirtschaftliche Verluste zu ersetzen, stößt er bei Schäden an Gemeingütern wie der biologischen Vielfalt oder der Umwelt häufig an seine Grenzen. In diesen Fällen fehlt es oft an einem Gläubiger, der eine individuelle Rechtsverletzung behaupten und den Ersatz eines konkreten Schadens verlangen kann.

Aus diesem Grund sehen einige jüngere Instrumente eine *administrative Haftung* („administrative liability") vor. Diese zeichnet sich dadurch aus, dass der Verursacher nicht zu Schadensersatz in Geld, sondern zum Ergreifen von *Gegenmaßnahmen* („response measures") verpflichtet wird. Dabei handelt es sich um ein tatsächliches Tätigwerden mit dem Ziel, den Schaden soweit wie möglich zu verhindern, zu begrenzen und die geschädigte Umwelt soweit wie möglich wiederherzustellen. Art und Umfang der erforderlichen Maßnahmen werden in der Regel durch eine staatliche Behörde festgelegt. Sofern der Verursacher die Maßnahmen nicht selbst durchführt, muss er die Kosten einer Ersatzvornahme durch andere staatliche oder nichtstaatliche Akteure erstatten.

Schließlich unterscheiden praktisch alle Rechtsordnungen zwischen *verschuldensabhängiger Haftung*, die auf ein unrechtmäßiges oder fahrlässiges Verhalten abstellt, und *verschuldensunabhängiger Gefährdungshaftung*, die allein an die Schadensverursachung anknüpft und dem Verursacher meist aufgrund der inhärenten Gefährlichkeit einer Tätigkeit oder Substanz auferlegt wird.

Kapitel 3: Die völkerrechtliche Regulierung der Biotechnologie

Die Verletzung von Präventionspflichten stellt eine der Hauptquellen der völkerrechtlichen Haftung für grenzüberschreitende Schäden dar. Aus diesem Grund werden im dritten Kapitel zunächst die völkerrechtlichen

Rahmenbedingungen für den Einsatz von konventionellen und sich selbst ausbreitenden Anwendungen der Biotechnologie untersucht, wie sie in völkerrechtlichen Verträgen niedergelegt sind. Auf globaler Ebene kommt dem *Cartagena-Protokoll über die biologische Sicherheit* dabei eine zentrale Rolle zu. Entgegen teilweise vertretener Auffassungen ist die Legaldefinition des Begriffs „lebender veränderter Organismus" im Cartagena-Protokoll bewusst weit gefasst und umfasst neuartige Methoden des Genome Editing auch dann, wenn sie nicht das (dauerhafte) Einfügen von Transgenen in den Zielorganismus zum Gegenstand haben.

Durch das Cartagena-Protokoll soll in erster Linie sichergestellt werden, dass Produkte der modernen Biotechnologie, die im Hoheitsgebiet eines Staates zugelassen sind und prinzipiell international gehandelt werden (können), keine Schäden an der Umwelt anderer Staaten verursachen. Zu diesem Zweck legt das Protokoll ein Verfahren der *vorherigen Zustimmung in Kenntnis der Sachlage* („advance informed agreement", kurz AIA) fest. Danach soll jede Vertragspartei eine souveräne und informierte Entscheidung darüber treffen können, ob ein zur Freisetzung bestimmter LMO in sein Staatsgebiet eingeführt werden darf. Das Cartagena-Protokoll enthält jedoch keine materiellen Bestimmungen darüber, unter welchen Umständen eine Einfuhr erlaubt, an Bedingungen geknüpft oder ganz verweigert werden darf oder muss.

Das AIA-Verfahren findet nur Anwendung auf LMO, die in den Empfängerstaat zum Zweck der absichtlichen Einbringung in die Umwelt eingeführt werden; die Einfuhr von zur Anwendung in geschlossenen Systemen bestimmten LMO ist vom Anwendungsbereich des Verfahrens ausdrücklich ausgenommen. Dies bringt ein erhebliches Missbrauchsrisiko mit sich, da die Anwendbarkeit des Verfahrens im Wesentlichen von den (erklärten) Absichten zum Zeitpunkt der Einfuhr abhängt und Zweckänderungen nach erfolgter Einfuhr nicht erfasst sind. Abgesehen von tatsächlichen Änderungen der Verwendungsbestimmungen kann die Ausnahme zur Umgehung des AIA-Verfahrens missbraucht werden, indem bei der Einfuhr falsche oder unvollständige Angaben über die beabsichtigte Verwendung des LMO gemacht werden. Zwar hätte dies keine Auswirkung auf innerstaatliche Vorschriften über die Freisetzung in die Umwelt des Einfuhrstaates. Ein plausibles Motiv für die Umgehung des AIA-Verfahrens kann jedoch in der Vermeidung ggfs. strengerer Vorschriften im Herkunftsstaat gesehen werden. So ist etwa nach europäischem Recht für auszuführende LMO im Rahmen des AIA-Verfahrens eine Risikoprüfung nach denselben strengen Anforderungen durchzuführen, die auch für die Freisetzungsgenehmigung innerhalb der EU gelten. Da die Vertragsparteien zur effektiven Umsetzung des Cartagena-Protokolls völkerrechtlich verpflichtet sind, müssen sie jedoch sicherstellen, dass die von Exporteuren gemachten Angaben über die beabsichtigte Verwendung wahrheitsgemäß und plausibel sind. Einführende Vertragsparteien sollten demgegenüber auf die Anwendung des AIA-Verfahrens bestehen, wann immer es wahrscheinlich erscheint, dass ein LMO, der als zur Verwendung in geschlossenen Systemen bestimmt deklariert wurde, später in die Umwelt freigesetzt wird.

Neben dem AIA-Verfahren enthält das Cartagena-Protokoll auch eine Reihe von Bestimmungen, die unabhängig davon gelten, ob ein LMO einer absichtlichen grenzüberschreitenden Verbringung unterliegt. Insbesondere müssen die Staaten geeignete Maßnahmen ergreifen, um die unabsichtliche grenzüberschreitende Verbringung von LMO zu verhindern. Zudem bestehen Pflichten zur Kooperation und zum Austausch von Informationen, insbesondere über mögliche Gefahren. Die übrigen Bestimmungen bleiben jedoch vage und unspezifisch, sodass es den Vertragsparteien weitgehend freigestellt bleibt, wie sie die Entwicklung und Verwendung von LMO in ihrem Hoheitsbereich regulieren.

Im Ergebnis ist daher festzuhalten, dass das Cartagena-Protokoll keine zureichenden Regelungen für die Nutzung selbstausbreitender Biotechnologie mit dem Potenzial grenzüberschreitender Verbreitung, wie etwa Gene Drives und modifizierte Viren, enthält. Eine Ausnahme hiervon kann in Artikel 25(2) gesehen werden, der im Fall der vorsätzlichen und illegalen grenzüberschreitenden Verbringung eines LMO den Herkunftsstaat ohne Rücksicht auf sein Verschulden dazu verpflichtet, den LMO auf eigene Kosten zurückzunehmen oder zu vernichten. Unklar bleibt jedoch, wie diese Verpflichtung umgesetzt werden kann; dies gilt insbesondere dann, wenn ein – potenziell sich selbst ausbreitender – LMO bereits in die Umwelt des Empfängerstaates gelangt ist.

Die durch das Cartagena-Protokoll geschützte Freiheit der Staaten, selbst über die Einfuhr von LMO in ihr Hoheitsgebiet zu entscheiden, wird durch das Welthandelsrecht wesentlichen Einschränkungen unterworfen. Dieses sieht vor, dass jede Beschränkung des internationalen Handels zum Schutz der Umwelt oder der menschlichen Gesundheit auf wissenschaftlichen Erkenntnissen über die abzuwehrenden Risiken beruhen muss. Im Gegensatz zum Cartagena-Protokoll können unzureichende wissenschaftliche Erkenntnisse über Art und Umfang der Umwelt- und Gesundheitsrisiken im Welthandelsrecht nur unter sehr strengen Voraussetzungen angeführt werden, um Handelsbeschränkungen zu rechtfertigen. Bislang ungeklärt ist die Frage, wie sich das Welthandelsrecht mit seinen strengen Anforderungen an wissenschaftliche Evidenz in Einklang mit dem allgemeinen Völkerrecht bringen lässt, das insoweit – insbesondere mit Blick auf das Vorsorgeprinzip – wesentlich nachgiebiger ist.

Neben dem Cartagena-Protokoll bleibt auch dessen Rahmeninstrument, das *Übereinkommen über die biologische Vielfalt* (CBD), im Kontext der Biotechnologie relevant; dies gilt besonders mit Blick auf jene Staaten, die das Cartagena-Protokoll nicht ratifiziert haben. Zwar sind viele der in der CBD niedergelegten Verpflichtungen weit und unspezifisch formuliert, wodurch die Überprüfung ihrer Einhaltung erschwert wird. Allerdings dürften Vorhaben, die auf die vollständige Ausrottung einer Art in ihrem herkömmlichen Verbreitungsgebiet gerichtet sind, mit der CBD nicht in Einklang zu bringen und daher *per se* völkerrechtswidrig sein. Selbstausbreitende modifizierte Organismen könnten zudem von der in der CBD und mehreren anderen Instrumenten niedergelegten Verpflichtung erfasst sein, die Ausbreitung invasiver Arten zu verhindern. Es ist allgemein anerkannt, dass diese Bestimmungen auch auf LMO anwendbar sind, die sich invasiv ausbreiten.

Trotz der anhaltenden Kontroversen darüber, ob die moderne Gentechnik bzw. ihre Produkte inhärent risikobehaftet sind, ist in verschiedenen internationalen Instrumenten zur Pflanzen- und Tiergesundheit, Lebensmittelsicherheit und betreffend den grenzüberschreitenden Transport gefährlicher Güter anerkannt, dass von LMO (oder GMO) Gefahren ausgehen können. Insoweit verfolgen diese Instrumente einen pragmatischeren Ansatz als das Cartagena-Protokoll, da sie – jeweils in ihrem spezifischen Kontext – konkrete Maßgaben zur Ermittlung und Bewertung potenzieller Risiken aufstellen und Verfahrensweisen vorschreiben, die diese Risiken minimieren. Die Einhaltung dieser Vorschriften ist auch und insbesondere im Kontext selbstausbreitender Biotechnologie relevant.

Wenn ein genetisch veränderter Organismus oder ein genetisch verändertes Pathogen eine auf den Menschen übertragbare Krankheit verursacht, ist der betroffene Staat nach den *International Health Regulations* der Weltgesundheitsorganisation (WHO) verpflichtet, die WHO unverzüglich zu informieren. Die WHO soll dann einerseits Empfehlungen an die betroffenen Staaten richten, um den Ausbruch einzudämmen, und andererseits Empfehlungen an noch nicht betroffene Staaten geben, um eine internationale Ausbreitung zu verhindern. Die jüngsten Erfahrungen der COVID-19-Pandemie haben jedoch gezeigt, dass sich sowohl betroffene als auch nicht oder nur indirekt betroffene Staaten häufig nur unzureichend und uneinheitlich an die Empfehlungen der WHO halten.

Schließlich unterfallen Verfahren der selbstausbreitenden Biotechnologie auch den völkerrechtlichen Vorschriften in Bezug auf biologische Waffen und die militärische Nutzung umweltverändernder Techniken wie auch dem humanitären Völkerrecht. Aufgrund des erheblichen *Dual-Use*-Potenzials dieser Verfahren begegnet die Gewährleistung der Einhaltung dieser Bestimmungen jedoch bereits jetzt erheblichen Herausforderungen.

Kapitel 4: Verhütung grenzüberschreitender Schäden durch Biotechnologie im Rahmen des Völkergewohnheitsrechts

Neben völkerrechtlichen Verträgen sind auch die allgemeinen Regeln des Völkergewohnheitsrechts zur Vermeidung von grenzüberschreitenden Schäden von hoher Relevanz für die Haftung für solche Schäden. Dies ist nicht zuletzt deshalb der Fall, weil eine Reihe von Staaten, die wesentliche Rollen bei der Entwicklung selbstausbreitender Biotechnologie spielen, das Cartagena-Protokoll nicht ratifiziert haben.

Im vierten Kapitel wird gezeigt, dass die allgemeine völkergewohnheitsrechtliche Pflicht der Staaten zur Prävention erheblicher grenzüberschreitender Umweltschäden auf schädliche Folgewirkungen von LMO in der gleichen Weise Anwendung findet wie auf andere Formen grenzüberschreitender Umweltbeeinträchtigungen. Sie gilt jedoch nur für *unbeabsichtigte* und *unkontrollierte* grenzüberschreitende Auswirkungen von LMO, nicht aber für *absichtliche* grenzüberschreitende Verbringungen. Eine dem Cartagena-Protokoll entsprechende Verpflichtung, vor der Einfuhr eines LMO die vorherige Zustimmung des Empfängerstaates einzuholen, ist derzeit nicht Bestandteil des Völkergewohnheitsrechts.

Die Pflicht zur Prävention grenzüberschreitender Schäden gilt nur für solche Schäden, die *erheblich* („significant“) sind. Nach allgemeiner Auffassung setzt dies voraus, dass tatsächliche Nachteile in Gestalt von Personen-, Sach- oder Umweltschäden verursacht werden. Aus diesem Grund ist zweifelhaft, ob die Erheblichkeitsschwelle bereits durch die bloße Präsenz eines LMO in der Umwelt eines anderen Staates erreicht wird. Ein erheblicher grenzüberschreitender Schaden wird jedoch jedenfalls dann anzunehmen sein, wenn es zu einem großflächigen Eintrag von LMO in die Umwelt eines anderen Staates oder zu einer Kontamination großer Mengen landwirtschaftlicher Erzeugnisse kommt. Außerdem kann ein Staat, nach dessen nationalen Gesetzen die Freisetzung eines bestimmten LMO – oder von LMO generell – unzulässig ist, sich nicht darauf berufen, dass eine unbeabsichtigte Verbreitung dieses LMO in der Umwelt eines anderen Staates *unerheblich* sei.

Die völkerrechtliche Pflicht zur Verhinderung grenzüberschreitender Schäden gilt nicht absolut, sondern verlangt von einem Staat lediglich, mit der gebührenden Sorgfalt („due diligence") zu handeln. Ist die Gefahr eines grenzüberschreitenden Schadens objektiv erkennbar bzw. vorhersehbar, ist der Staat hiernach verpflichtet, die erforderlichen Informationen über die schadensgeneigte Tätigkeit zu sammeln und auf dieser Grundlage geeignete und angemessene Vorbeugungsmaßnahmen zu ergreifen, insbesondere durch legislative und administrative Maßnahmen gegenüber dem Betreiber der Tätigkeit. Um eine völkerrechtliche Verantwortlichkeit des Herkunftsstaates für einen grenzüberschreitenden Schaden zu begründen, müsste der geschädigte Staat den Nachweis führen, dass der Staat diese Sorgfaltspflicht verletzt hat und dass dieses Versäumnis für die Verursachung des Schadens ursächlich war. Dies erfordert letztlich eine *ex post*-Bestimmung der Maßnahmen, die im Einzelfall aus einer *ex ante*-Perspektive erforderlich und angemessen gewesen wären.

In Situationen wissenschaftlicher Ungewissheit über die Gefahren, die von einer bestimmten Tätigkeit ausgehen, senkt das Vorsorgeprinzip die Beweisschwelle für den Anspruch auf präventive Maßnahmen. Infolgedessen können Staaten verpflichtet sein, bereits dann vorbeugende Maßnahmen zu ergreifen, wenn es zwar Hinweise, aber keine Beweise (oder wissenschaftliche Gewissheit) dafür gibt, dass eine Aktivität zu erheblichen grenzüberschreitenden Schäden führen könnte. Das Vorsorgeprinzip führt jedoch nicht zu einer Beweislastumkehr. Folglich muss ein Staat, der sich auf das Vorsorgeprinzip beruft, zumindest einen Anscheinsbeweis für eine tatsächliche Gefahr erheblicher grenzüberschreitender Schäden erbringen.

Während der materielle Gehalt der völkerrechtlichen Präventionspflicht wesentlich von den Umständen des Einzelfalls abhängt und daher schwer abstrakt zu bestimmten ist, sind die korrespondierenden prozeduralen Pflichten der Staaten deutlich konkreter. Insbesondere ist allgemein anerkannt, dass Staaten bei Tätigkeiten, die ein Risiko erheblicher grenzüberschreitender Schäden mit sich bringen, eine Umweltverträglichkeits- bzw. Risikoprüfung durchführen bzw. für eine Zulassung solcher Tätigkeit voraussetzen müssen. Ob im Einzelfall eine vollständige und angemessene Prüfung durchgeführt wurde, wird von der völkerrechtlichen Rechtsprechung zunehmend detailliert überprüft. Mit der im Rahmen einer Umweltverträglichkeitsprüfung durchgeführten Dokumentation kann ein Staat zugleich auch die Ausübung der gebotenen Sorgfalt dokumentieren, da diese Dokumentation in der Regel eine Beschreibung der potenziellen Auswirkungen der geplanten Tätigkeit sowie der erforderlichen Präventions- bzw. Ausgleichsmaßnahmen enthält. Zugleich führt die höhere Spezifizität der verfahrensrechtlichen Manifestationen der Präventionspflicht bisweilen dazu, dass sich die völkerrechtliche Rechtsprechung mehr auf die prozeduralen Aspekte konzentriert als auf die Frage, ob der Präventionspflicht auch in materieller Hinsicht Genüge getan wurde.

Die Pflicht zur Prävention grenzüberschreitender Umweltschäden verlangt von den Staaten, mit der gebotenen Sorgfalt zu handeln („obligation of conduct"). Es handelt es sich jedoch nicht um eine Garantiepflicht dergestalt, dass jedes Eintreten eines grenzüberschreitenden Schadens prinzipiell eine Verletzung bedeutet („obligation of result"). Umgekehrt wird aber eine Verletzung der Präventionspflicht von der völkerrechtlichen Rechtsprechung erst dann angenommen, wenn tatsächlich ein Schaden eingetreten ist. Auch die Missachtung verfahrensrechtlicher Pflichten soll nicht generell einer Verletzung der materiellen Präventionspflicht gleich kommen. Die Verfahrenspflichten stellen jedoch nicht nur eigenständige Pflichten dar, sondern präziseren zugleich auch die materielle Präventionspflicht. Daher kann die Verletzung von Verfahrenspflichten nach hier vertretener Auffassung jedenfalls ein Indiz dafür sein, dass ein Staat auch seine materielle Sorgfaltspflicht missachtet hat. Zudem sollte die Rechtsprechung anerkennen, dass eine Sorgfaltspflichtverletzung nicht voraussetzt, dass bereits ein Schaden eingetreten ist.

Soweit ersichtlich, hat bislang kein Staat völkerrechtliche Ansprüche wegen nachteiliger Auswirkungen geltend gemacht, die durch die unkontrollierte Ausbreitung von LMO in sein Hoheitsgebiet verursacht wurden. In Anbetracht der im ersten Kapitel geschilderten Fortschritte, insbesondere des Aufkommens selbstausbreitender Biotechnologie wie Gene Drives, erscheint es aber nicht unwahrscheinlich, dass es in Zukunft zu solchen Fällen kommt. Gleichwohl ist zweifelhaft, ob das derzeit geltende Völkerrecht in der Lage ist, unilaterale Freisetzungen selbstausbreitender veränderter Organismen durch einzelne Staaten zu verhindern. Dies gilt insbesondere dann, wenn das Potenzial einer grenzüberschreitenden Ausbreitung im konkreten Fall umstritten ist.

Kapitel 5: Die internationale Regulierung synthetischer Gene Drives

Da die ersten Freisetzungen von Gene Drives in die Umwelt bereits im Jahr 2023 erwartet werden, hat die Debatte über die internationale Regulierung dieser Technologie in den vergangenen Jahren zügig an Fahrt aufgenommen. Während Befürworter der Technik fordern, dem Einsatz von Gene Drives keine zusätzlichen Hürden zu setzen, fordern Kritiker ein Moratorium auf die Entwicklung oder zumindest die Freisetzung von Gene Drives in die Umwelt. Im Jahr 2018 gipfelte diese Debatte in einem Beschluss der Vertragsparteien der CBD, der erstmals substanzielle Leitlinien für die Verwendung von Gene Drives formulierte. Der Umstand, dass die Entscheidung von praktisch allen Staaten – mit Ausnahme der Vereinigten Staaten von Amerika, die keine Vertragspartei der CBD sind – im Konsens verabschiedet wurde, verleiht dem Beschluss ein hohes Maß an Autorität. Wenngleich er nicht im formellen Sinne rechtlich bindend ist, entfaltet der Beschluss gleichwohl normative Bindung als sog. *weiches Völkerrecht* („soft law"). Dies liegt auch daran, dass mit dem Beschluss nicht versucht wird, neue Prinzipien aufzustellen, sondern vielmehr die Anwendbarkeit bestimmter bereits etablierter Regeln auf Gene Drives bestätigt und präzisiert wird.

Durch den Beschluss werden die Staaten aufgefordert, im Umgang mit Gene Drives das Vorsorgeprinzip zu beachten. Entgegen einer vereinzelt vertretenen Auffassung kann das Vorsorgeprinzip jedoch nicht herangezogen werden, um voreilige Freisetzungen von Gene Drives zu rechtfertigen, die mit dem Ziel erfolgen, drängenden Umweltproblemen zu begegnen, die ein schnelles Tätigwerden erfordern. Vielmehr verlangt das Vorsorgeprinzip von den Staaten Zurückhaltung beim Einsatz von Gene Drives, solange Nutzen und Risiken dieser Technologie nicht vollständig beurteilt werden können.

Der Beschluss fordert die Staaten zudem dazu auf, die Freisetzung von Gene Drives nur dann *in Betracht zu ziehen* („to only consider"), wenn eine wissenschaftlich fundierte Risikobewertung durchgeführt wurde, geeignete Risikomanagementmaßnahmen implementiert wurden und, soweit anwendbar, die *freie, vorherige und informierte Zustimmung* („free, prior and informed consent") der betroffenen indigenen Völker und lokalen Gemeinschaften eingeholt wurde. Wie bereits erwähnt, sind diese Kriterien in der CBD selbst niedergelegt oder von ihren Vertragsparteien bereits in anderen Zusammenhängen ausdrücklich anerkannt worden. Gleichwohl lässt der Beschluss unklar, welche Auswirkungen diese Kriterien auf beabsichtigte Freisetzungen von Gene Drives haben. Überdies enthält der Beschluss keinen Maßstab dafür, wie im Kontext von Gene Drives die jeweils „besten verfügbaren Technologien" zu ermitteln sind, die im Rahmen des allgemeinen Sorgfaltsmaßstabs zu berücksichtigen sind. Die Festlegung von technologischen Mindeststandards erfolgt daher derzeit nicht durch die internationale Staatengemeinschaft, sondern vielmehr durch die an der Entwicklung von Gene Drives beteiligten Wissenschaftler selbst. Gleiches gilt, soweit der Beschluss dazu aufruft, die Sicherheit von Gene Drives in Laboren und anderen geschlossenen Systemen zu gewährleisten. In dieser Hinsicht suggeriert der Beschluss gar ein Maß an internationaler Harmonisierung, das tatsächlich nicht existiert.

Das Problem einer möglichen grenzüberschreitenden Ausbreitung von Gene Drives findet in dem Beschluss keine Erwähnung, obwohl es im Grundsatz allgemein anerkannt ist. In der Praxis wird jedoch die tatsächliche Wahrscheinlichkeit einer solchen Ausbreitung zwischen dem Staat, der eine Freisetzung plant, und den potenziell betroffenen Nachbarstaaten häufig umstritten sein. Ein möglicher Lösungsansatz – zumindest für die Vertragsparteien des Cartagena-Protokolls – könnte in einem klarstellenden Beschluss bestehen, dass Freisetzungen von Gene Drives, die mit einer gewissen Wahrscheinlichkeit zu einer grenzüberschreitenden Ausbreitung führen, „absichtliche grenzüberschreitende Verbringungen" darstellen, die vor der Freisetzung die vorherige Zustimmung der wahrscheinlich betroffenen Staaten nach dem AIA-Verfahren erfordern.

Im Ergebnis bedeutet der Beschluss der Vertragsstaaten der CBD weder ein Moratorium auf Freisetzungen von Gene Drives, noch enthält er eine umfassende „Checkliste" für die völkerrechtliche Zulässigkeit zukünftiger Freisetzungen. Vielmehr ist die Entscheidung als sorgfältig ausbalancierter Kompromiss zwischen den konträren Positionen von Befürwortern und Gegnern der Technologie sehen. Die Frage, ob verantwortungsvolle Freisetzungen von Gene Drives nach den derzeitigen Regeln des Völkerrechts überhaupt möglich sind, wird durch den Beschluss nicht abschließend beantwortet.

Kapitel 6: Das Zusatzprotokoll von Nagoya/Kuala Lumpur über Haftung und Wiedergutmachung

Das 2010 verabschiedete *Zusatzprotokoll von Nagoya/Kuala Lumpur über Haftung und Wiedergutmachung* regelt die Haftung für Schäden an der biologischen Vielfalt, die durch LMO grenzüberschreitenden Ursprungs verursacht werden. Das Zusatzprotokoll ist nicht nur das erste globale Haftungsübereinkommen für Schäden an einem globalen Gemeingut, sondern nach seinem Inkrafttreten im Jahr 2018 zugleich auch das einzige völkerrechtliche Umwelthaftungsabkommen außerhalb der spezifischen

Bereiche der maritimen Ölverschmutzung, der nuklearen Schäden sowie des Weltraumrechts, das jemals in Kraft getreten ist.

Das Zusatzprotokoll sieht die bereits erwähnte *administrative Haftung* für Schäden an der biologischen Vielfalt vor. Anstatt die verantwortlichen Betreiber lediglich zur Zahlung einer Geldentschädigung zu verpflichten, sollen Schäden durch die Durchführung von Gegenmaßnahmen verhindert, gemildert und beseitigt werden. Für Schäden an Gemeingütern wie der biologischen Vielfalt erscheint dieser Ansatz sinnvoll, da sich der Verlust solcher Güter kaum in finanziellen Summen bemessen lässt.

Die Regeln des Zusatzprotokolls sind jedoch in mehrfacher Hinsicht lückenhaft und lassen den Vertragsparteien einen zu großen Spielraum bei der Umsetzung. Zwar legt das Zusatzprotokoll klar fest, dass die Eindämmung des Schadens Vorrang vor der nachträglichen Wiederherstellung genießt, dass die Wiederherstellung der biologischen Vielfalt in ihren Zustand vor Eintritt des Schadensereignisses das primäre Ziel ist und dass der Schaden nur hilfsweise durch Ausgleichsmaßnahmen an anderer Stelle kompensiert werden darf. Darüber hinaus stellt das Zusatzprotokoll jedoch keine spezifischen Kriterien auf, wann schädliche Folgewirkungen eines LMO als Schaden an der biologischen Vielfalt anzusehen sind. Das Zusatzprotokoll lässt auch weitgehend ungeregelt, welcher Akteur im Einzelnen haftbar gemacht werden soll, da hierfür prinzipiell jede Person in Betracht kommt, die direkte oder indirekte Kontrolle über den LMO ausübt.

Auch zu den zu ergreifenden Gegenmaßnahmen enthält das Zusatzprotokoll keine näheren Anforderungen oder Standards. Zu welchen Maßnahmen die verantwortlichen Betreiber konkret verpflichtet werden, müssen die jeweils zuständigen nationalen Behörden im Einzelfall festlegen. Auch im Übrigen bleibt die Ausgestaltung der Haftungsregeln in weiten Teilen den nationalen Gesetzgebern und Behörden überlassen. Zugleich könnte es ein inhärentes Erfordernis des Ansatzes der administrativen Haftung sein, dass den Staaten ein gewisser Umsetzungsspielraum gewährt wird. Denn es ist praktisch nicht möglich, im Voraus zu regeln, welche konkreten Gegenmaßnahmen in einzelnen Schadensfällen erforderlich sein werden. Zudem gibt es, anders als im Nuklear-, Ölschadens- und Weltraumhaftungsrecht, auch nicht einen klar bestimmbaren Betreiber, sondern eine Vielzahl möglicher Haftungsschuldner. Nationale Umsetzungsgesetze sollten insoweit danach differenzieren, ob sich in einem Schaden ein *Entwicklungsrisiko* realisiert hat, das dem LMO inhärent ist, oder ob der Schaden durch eine konkrete, ggfs. unsachgemäße Verwendung des LMO verursacht wurde.

In Bezug auf sog. *herkömmliche Schäden* an Personen und Sachen unternimmt das Zusatzprotokoll keinen Versuch, die innerstaatlichen Regelungen der Vertragsparteien zur zivilrechtlichen Haftung zu harmonisieren. Dies trägt dem Umstand Rechnung, dass der Ansatz einer völkerrechtlich harmonisierten zivilrechtlichen Betreiberhaftung in der Staatengemeinschaft allgemein auf Ablehnung stößt, was durch die zahlreichen Abkommen in diesem Bereich eindrucksvoll belegt wird, die zwar verabschiedet wurden, aber mangels ausreichender Ratifikationen nie in Kraft getreten sind. Aus diesem Grund legt das Zusatzprotokoll keine konkreten Standards zur zivilrechtlichen Haftung fest, sondern verpflichtet die Vertragsparteien lediglich dazu, *angemessene* Regeln und Verfahren in ihrem innerstaatlichen Recht *anzustreben*.

Eines der gravierendsten Defizite des Zusatzprotokolls ist das Fehlen konkreter Regeln zur grenzüberschreitenden Durchsetzung der Haftung. Zwar erfasst das Zusatzprotokoll nur Schäden durch LMO, die Gegenstand einer (absichtlichen oder unabsichtlichen) grenzüberschreitenden Verbringung waren. Gleichwohl enthält es keine Regeln für den Umgang mit derartigen grenzüberschreitenden Situationen, etwa wenn in einem Staat Schäden auftreten, der verantwortliche Betreiber – d.h. der Entwickler oder Hersteller des schadensverursachenden Organismus – sich jedoch in einem anderen Staat befindet. In diesem Fall wären verbindliche Regeln zur grenzüberschreitenden Behördenkooperation ebenso erforderlich wie zu Fragen der Gerichtsbarkeit, des anwendbaren Rechts sowie zur gegenseitigen Anerkennung und Vollstreckung ausländischer Urteile. Somit sind grenzüberschreitende Konstellationen zwar eine Voraussetzung für die Anwendbarkeit des Zusatzprotokolls; zugleich behandelt das Zusatzprotokoll die Haftung in diesen Situationen aber so, als handele es sich um eine rein innerstaatliche Angelegenheit.

Nach alledem muss bezweifelt werden, dass das Zusatzprotokoll von entscheidendem Nutzen sein wird, wenn Produkte der modernen, insbesondere der sich selbst ausbreitenden, Biotechnologie zu grenzüberschreitenden Schäden führen. Obwohl das Zusatzprotokoll ausdrücklich auch *unbeabsichtigte* grenzüberschreitende Verbringungen erfasst, bietet es keine Mittel, um mit solchen Situationen umzugehen. Sofern der verantwortliche Betreiber nicht über Vermögenswerte im betroffenen Staat verfügt, in die vollstreckt werden kann, bietet das Zusatzprotokoll einem Staat, der mit schädlichen Auswirkungen eines LMO ausländischen Ursprungs konfrontiert ist, keine Rechtsmittel, um die zivilrechtliche oder administrative Haftung ausländischer Betreiber durchzusetzen. In solchen Situationen bleiben nur zivilrechtliche Rechtsbehelfe in Staaten, in denen der verantwortliche Betreiber ansässig ist oder über Vermögen verfügt, oder aber die Berufung auf die völkerrechtliche Verantwortlichkeit des Staates, der die Freisetzung genehmigt hat, sofern diesem Staat eine Verletzung seiner völkerrechtlichen Präventionspflichten zur Last gelegt werden kann.

Wenngleich die fehlende Harmonisierung zivilrechtlicher Regeln ein großes Manko des Zusatzprotokolls ist, ist dies wohl ein entscheidender Faktor, der die Akzeptanz der Vertragsparteien und damit letztlich sein Inkrafttreten sicherte. Zugleich zeigt sich darin aber auch das geringe Maß an Einigkeit der internationalen Staatengemeinschaft über materielle Mindeststandards für Umwelthaftung im grenzüberschreitenden Kontext. Der Abschluss völkerrechtlicher Verträge zur grenzüberschreitenden Umwelthaftung, in welchen die spezifischen Herausforderungen grenzüberschreitender Sachverhalte überhaupt nicht adressiert werden, könnte sich dabei als Pyrrhussieg erweisen.

Kapitel 7: Ein privatrechtliches Haftungssystem: Der „Biodiversity Compact“

Im siebenten Kapitel wird der „Biodiversity Compact“ untersucht. Dabei handelt es sich um ein freiwilliges privatrechtliches Entschädigungssystem, durch das fünf große Biotechnologiekonzerne die Haftung für Schäden an der biologischen Vielfalt übernehmen, die durch von ihnen hergestellte LMO verursacht werden. Der Compact ist als *Vertrag zugunsten Dritter* ausgestaltet, durch den die beteiligten Unternehmen geschädigten Staaten einen Entschädigungsanspruch einräumen. Dies gilt unabhängig davon, ob der betroffene Staat das o.g. Zusatzprotokoll von Nagoya/ Kuala Lumpur ratifiziert hat. Zugleich übernimmt der Compact den im Zusatzprotokoll gewählten Ansatz der administrativen Haftung und erkennt damit an, dass Schäden an der biologischen Vielfalt nicht durch finanzielle Zahlungen, sondern nur durch tatsächlich ergriffene Gegenmaßnahmen sinnvoll begegnet werden kann. Zugleich legt der Compact die Modalitäten der Haftung wesentlich detaillierter fest als das Zusatzprotokoll und richtet die Haftung auf einen klar identifizierbaren Akteur. Zudem enthält er einen für die beteiligten Unternehmen verbindlichen Schlichtungsmechanismus, der einem betroffenen Staat auch dann Mittel zur Durchsetzung der Haftung bietet, wenn sich die haftende Partei außerhalb seiner Hoheitsgewalt befindet.

Wie auch das Zusatzprotokoll leidet der Compact unter einer begrenzten Beteiligung und Repräsentativität. Diese werden sich wahrscheinlich in Zukunft noch verstärken. Denn das Aufkommen des *Genome Editing* führt dazu, dass zu den etablierten Akteuren eine Vielzahl neuer Unternehmen hinzutreten, die innovative Produkte und Technologien entwickeln. Überdies werden *Gene Drives* und andere selbstausbreitende Techniken in erster Linie nicht von etablierten Biotechnologie-Unternehmen, sondern von wissenschaftlichen Forschungseinrichtungen und philanthropischen Organisationen entwickelt bzw. gefördert. Bislang erscheint es eher unwahrscheinlich, dass diese Akteure dem Compact beitreten.

Neben der begrenzten Beteiligung ist der größte Mangel des Compact, dass er die Haftung für Risiken ausschließt, die zum Zeitpunkt der behördlichen Zulassung des LMO bereits bekannt waren. Eine solch einseitige Risikozuweisung ist in Haftungsregimes für gefährliche Aktivitäten oder Substanzen, die aufgrund ihrer sozialen Nützlichkeit dennoch erlaubt werden, höchst unüblich. Zudem erscheint es aufgrund der komplexen Bestimmungen zur Schadensfeststellung, Beweisführung und Geltendmachung von Ansprüchen unwahrscheinlich, ob überhaupt je ein Anspruch unter dem Compact erfolgreich durchgesetzt werden kann. Wenngleich er von den beteiligten Unternehmen als *vertrauensbildende Maßnahme* dargestellt wurde, muss der Compact daher eher als (gescheiterter) Versuch gesehen werden, die Verabschiedung eines rechtlich verbindlichen Haftungsinstruments abzuwenden. Zugleich zeigt die erhebliche Komplexität des Vertragstexts des Compact, dass eine sachgerechte Umsetzung des Zusatzprotokolls mit erheblichen Herausforderungen verbunden sein kann.

Kapitel 8: Eine gewohnheitsrechtliche Verpflichtung zur Sicherstellung einer unverzüglichen und angemessenen Entschädigung für grenzüberschreitende Schäden?

Vor dem Hintergrund, dass die völker- und privatrechtlichen Haftungsinstrumente für grenzüberschreitende Schäden sich als eher unzureichend erweisen, stellt sich die im achten Kapitel untersuchte Frage, ob sich im Völkergewohnheitsrecht Mindeststandards für den Umgang mit den ausländischen Geschädigten grenzüberschreitender Umweltschäden herausgebildet haben. Wenn eine gefährliche Aktivität zu grenzüberschreitenden Schäden führt, ist der Staat, unter dessen Hoheitsgewalt die Aktivität durchgeführt wurde, nach hier vertretener Auffassung mindestens verpflichtet sicherzustellen, dass ausländische Geschädigte einen diskriminierungsfreien Zugang zu innerstaatlichen Rechtsschutzsystemen haben und eine zügige und angemessene Entschädigung erlangen können. Der Herkunftsstaat muss ferner sicherstellen, dass wirksame Gegenmaßnahmen ergriffen werden, um eine grenzüberschreitende Ausbreitung des Schadens soweit wie möglich zu verhindern. Außerdem ist er verpflichtet, potenziell betroffene Staaten von dem Schadensereignis zu benachrichtigen und mit ihnen bei der Bewältigung zu kooperieren.

Der Herkunftsstaat ist jedoch weder dazu verpflichtet noch generell berechtigt, Gegenmaßnahmen im Hoheitsgebiet anderer betroffener Staaten zu ergreifen. Betroffene Staaten sind ihrerseits nach allgemeinem Völkergewohnheitsrecht nicht generell verpflichtet, Gegenmaßnahmen zu ergreifen. Eine solche Verpflichtung kann sich im hiesigen Kontext jedoch aus Artikel 8(h) der CBD ergeben. Wenn ein sich selbst ausbreitender LMO sein beabsichtigtes Zielgebiet überschreitet und dadurch zu einer „invasiven gebietsfremden Art“ wird, die die biologische Vielfalt bedroht, sind nach dieser Vorschrift auch betroffene Staaten zur Eindämmung des LMO verpflichtet. Sofern ein betroffener Staat angemessene Gegenmaßnahmen ergreift, sind die dabei anfallenden Kosten Teil jenes Schadens, für den der Herkunftsstaat im Rahmen seiner innerstaatlichen Rechtsordnung schnelle, angemessene und wirksame Rechtsbehelfe sicherstellen muss. Ein unmittelbarer, völkerrechtlich begründeter zwischenstaatlicher Ersatzanspruch wird hierdurch jedoch nicht geschaffen.

Kapitel 9: Staatenverantwortlichkeit für durch Biotechnologie verursachte grenzüberschreitende Schäden

Das im neunten Kapitel untersuchte *Recht der Staatenverantwortlichkeit* regelt die Rechtsfolgen staatlicher Verstöße gegen völkerrechtliche Verhaltenspflichten und ist als Teil des Völkergewohnheitsrechts für alle Staaten verbindlich. Hiernach liegt eine völkerrechtswidrige Handlung eines Staates vor, wenn ein Tun oder Unterlassen dem Staat zurechenbar ist und eine Verletzung einer internationalen Verpflichtung dieses Staates darstellt. Grundsätzlich sieht das Recht der Staatenverantwortlichkeit weitreichende Konsequenzen für solche Verstöße vor, einschließlich einer unbegrenzten Haftung für die dadurch verursachten Schäden. Zugleich unterliegt es jedoch einer Reihe von Einschränkungen und Vorbehalten.

Staaten sind nicht generell für das Verhalten nichtstaatlicher Akteure innerhalb ihres Hoheitsgebiets verantwortlich. Das Verhalten natürlicher oder juristischer Personen wird dem Staat nur unter bestimmten Bedingungen zugerechnet. Im Zusammenhang mit grenzüberschreitenden Umwelteingriffen stehen daher die Pflichten der Staaten im Vordergrund, gefährliche Aktivitäten angemessen zu regulieren und im Schadensfall für die Haftung und Wiedergutmachung zu sorgen. Gefährliches Verhalten kann jedoch direkt zurechenbar werden, wenn der Staat selbst agiert oder wenn ein nichtstaatlicher Akteur unter der *effektiven Kontrolle* („effective control") eines Staates steht, die über das staatliche Subordinationsverhältnis hinausgeht und dem Staat eine tatsächliche Einflussnahme auf das Verhalten des Akteurs ermöglicht.

Um die völkerrechtliche Verantwortlichkeit eines Staates geltend zu machen, muss der Nachweis geführt werden, dass das Verhalten des Staates nicht im Einklang mit seinen völkerrechtlichen Verpflichtungen stand. Wie bereits erwähnt, indiziert der Eintritt eines grenzüberschreitenden Schadens nicht ohne Weiteres eine völkerrechtliche Pflichtverletzung. Vielmehr muss nachgewiesen werden, dass der Staat konkreten völkerrechtlichen Präventionspflichten nicht nachgekommen ist und dass diese Pflichtverletzung ursächlich für den Schadenseintritt war. Dieser Nachweis wirft jedoch häufig schwierige Beweisprobleme auf. Ähnliche Schwierigkeiten können sich beim Nachweis der (hypothetischen) Kausalität ergeben, insbesondere wenn sich ein Schaden erst nach einem längeren Zeitraum manifestiert oder wenn mehrere Staaten gemeinsam für den Schaden verantwortlich sind. Die völkerrechtliche Rechtsprechung hat es bislang abgelehnt, die Anforderungen an den Nachweis eines Kausalzusammenhangs zwischen einer staatlichen Pflichtverletzung und dem daraus resultierenden Schaden abzusenken oder gar eine Beweislastumkehr vorzunehmen.

Wenn die völkerrechtliche Verantwortlichkeit eines Staates feststeht, muss dieser sein völkerrechtswidriges Verhalten einstellen und *vollständige Wiedergutmachung* („full reparation") für alle durch das Verhalten verursachten Schäden leisten. Grundsätzlich erfasst die Pflicht zur vollständigen Wiedergutmachung nicht nur „herkömmliche" Personen-, Sach- und Vermögensschäden, sondern auch Schäden an der Umwelt an sich. Dies wird insbesondere dann relevant, wenn selbstausbreitende Biotechnologie Schäden an einheimischen Arten, Ökosystemen oder der biologischen Vielfalt insgesamt verursacht.

Die völkerrechtliche Verantwortlichkeit eines Staates kann nur von anderen Staaten geltend gemacht werden. Sofern nicht durch spezielle völkerrechtliche Abkommen anderes geregelt ist (etwa durch Investor-Staats-Schiedsklauseln), können ausländische nichtstaatliche Akteure ihre Ansprüche nicht direkt gegen den Herkunftsstaat geltend machen, sondern müssen sich durch ihren jeweiligen Staat vertreten lassen. Prinzipiell gelten auch in Fällen grenzüberschreitender Umweltschäden die völkerrechtlichen Grundsätze zur Ausübung von *diplomatischem Schutz* („diplomatic protection"). Allerdings findet der Grundsatz, dass der nichtstaatliche Akteur zunächst den lokalen Rechtsweg im verantwortlichen Staat erschöpfen muss („exhaustion of local remedies") im vorliegenden Kontext keine Anwendung, da er sich – im Gegensatz zu den Standardfällen der Ausübung von diplomatischem Schutz – nicht freiwillig der Hoheitsgewalt des Herkunftsstaates unterworfen hat.

Da im Völkerrecht keine allgemeine Pflicht besteht, die Zuständigkeit eines internationalen Gerichts anzuerkennen, scheitert die effektive Implementierung der völkerrechtlichen Verantwortlichkeit eines Staates häufig am Fehlen eines adäquaten Durchsetzungsmechanismus; dies gilt auch für grenzüberschreitende Schäden durch den Einsatz selbstausbreitender Biotechnologie. Der durch das Cartagena-Protokoll geschaffene, für alle Vertragsparteien verpflichtende Compliance-Mechanismus kann zwar einen Beitrag dazu leisten, die zukünftige Einhaltung internationaler Regeln zu fördern; zur Durchsetzung von Wiedergutmachungsansprüchen ist er jedoch nicht imstande.

Aufgrund der beschriebenen Schwierigkeiten ist die praktische Relevanz des Rechts der Staatenverantwortlichkeit eher begrenzt. Die völkerrechtliche Verantwortlichkeit eines Herkunftsstaats für einen grenzüberschreitenden Umweltschaden wurde bislang nur in wenigen Fällen erfolgreich geltend gemacht. Gleichwohl kommt dem Recht der Staatenverantwortlichkeit eine zentrale Rolle bei der Durchsetzung des Völkerrechts insgesamt zu: Die Aussicht eines Staates, für die Nichteinhaltung völkerrechtlicher Regeln verantwortlich gemacht zu werden, legitimiert und sichert die praktische Wirksamkeit aller völkerrechtlichen Primärpflichten, einschließlich jener zur Prävention grenzüberschreitender Schäden und zur Umsetzung der Betreiberhaftung. Dies gilt umso mehr, wenn Staaten die Freisetzung von LMO mit der Fähigkeit zur Selbstausbreitung unilateral und nicht in internationaler Koordination vorantreiben.

Kapitel 10: Staatliche Gefährdungshaftung für grenzüberschreitende Umweltschäden?

Nach dem geltenden Völkerrecht sind Staaten nur selten für grenzüberschreitende Schäden selbst verantwortlich, die von ihrem Hoheitsgebiet ausgehen. Aus diesem Grund ist in der Völkerrechtswissenschaft weithin anerkannt, dass eine subsidiäre, verschuldensunabhängige Staatenhaftung für erhebliche grenzüberschreitende Umweltschäden *de lege ferenda* sehr wünschenswert oder gar erforderlich ist. Das zehnte Kapitel zeigt jedoch, dass die einschlägige Staatenpraxis derzeit keine hinreichende Grundlage für die Annahme einer gewohnheitsrechtlich anerkannten Gefährdungshaftung der Staaten für grenzüberschreitende Schäden durch selbstausbreitende Biotechnologie bietet. Zwar sind nur wenige Fälle grenzüberschreitender Schadensereignisse bekannt, in denen der Herkunftsstaat keinerlei Anstrengungen zum Ausgleich der entstandenen Schäden unternommen hat. Staatliche Zahlungen erfolgten jedoch meist ausdrücklich auf freiwilliger Basis und ausdrücklich ohne Anerkennung einer *rechtlichen* Verantwortlichkeit oder Haftung für die entstandenen Schäden.

Folglich haftet ein Staat nicht generell für grenzüberschreitende Schäden, die durch den Einsatz selbstausbreitender Biotechnologie verursacht werden, sofern dem Staat kein völkerrechtswidriges Verhalten nachgewiesen werden kann. Hat ein Staat demnach alle im Rahmen der gebotenen Sorgfalt als erforderlich erachteten Maßnahmen ergriffen, um nachteilige grenzüberschreitende Auswirkungen zu verhindern, haftet er auch dann nicht, wenn gleichwohl Schäden auftreten. Dies zeigt erneut, dass ein effektiver Schutz vor grenzüberschreitenden Schäden letztlich nur durch eine Stärkung der Präventionspflichten erreicht werden kann. Da ein Moratorium auf die Freisetzung selbstausbreitender Biotechnologie nicht in greifbarer Nähe scheint, sollte zumindest angestrebt werden, klare Bedingungen für ihren Einsatz in Gestalt von völkerrechtlichem *soft law* zu vereinbaren.

Kapitel 11: Ersatzfähigkeit von Umweltschäden im Völkerrecht

Das abschließende elfte Kapitel ist der Frage gewidmet, inwiefern Schädigungen der Umwelt im Völkerrecht eine ersatzfähige Schadenskategorie darstellen. Grundsätzlich ist allgemein anerkannt, dass Umweltschäden von der Pflicht zur vollständigen Wiedergutmachung ebenso erfasst sind wie herkömmliche Schadensarten. Dies umfasst zumindest jene Kosten, die dem geschädigten Staat bei der Untersuchung des Schadens, der Verhinderung von Folgeschäden und der Wiederherstellung der Umwelt in den *status quo ante* entstehen, sofern die getroffenen Maßnahmen nach den Umständen des Einzelfalls und dem Stand der Wissenschaft geeignet und angemessen sind. Die Entschädigung erfolgt in der Regel durch die Erstattung der Aufwendungen, die dem betroffenen Staat bei der Durchführung solcher Maßnahmen entstehen. Diese Grundsätze gelten für alle Arten von Umweltschäden, die durch selbstausbreitende Biotechnologie verursacht werden können, einschließlich möglicher grenzüberschreitender Schäden.

Auch vorübergehende oder dauerhafte Beeinträchtigungen der Umwelt *an sich* („damage to the environment *per se*“), die nicht in Aufwendungen oder anderen unmittelbar finanziell bemessbaren Nachteilen resultieren, sind prinzipiell ersatzfähig. Während sich im Völkerrecht eine Tendenz abzeichnet, dass solche Schäden primär durch den Ersatz von Aufwendungen für angemessene Ausgleichsmaßnahmen auszugleichen sind, ist auch die Zahlung einer rein finanziellen Entschädigung ein akzeptiertes Mittel; dies gilt insbesondere dann, wenn keine geeigneten Ausgleichsmaßnahmen ersichtlich sind.

Die Beeinträchtigung von Umweltgütern und -dienstleistungen, die einer wirtschaftlichen Nutzung zugänglich sind und für die daher ein Marktwert ermittelt werden kann, wird in der Regel nach diesem Marktwert entschädigt; dies gilt unabhängig davon, ob eine wirtschaftliche Nutzung tatsächlich erfolgt ist. Auch die Ersatzfähigkeit von Umweltbestandteilen, die keinen unmittelbaren wirtschaftlichen Wert haben, ist grundsätzlich anerkannt. Allerdings ist umstritten, wie in diesen Fällen Art und Umfang des Schadensersatzes bestimmt werden sollen.

Ein Ansatz ist die sog. *Ausgleichssanierung* („compensatory restoration“), womit der Ersatz verloren gegangener Umweltgüter durch die Erhaltung oder Verbesserung anderer Umweltbestandteile gemeint ist, die in der Lage sind, ähnliche Umweltgüter und -dienstleistungen zu erbringen wie die geschädigten Bestandteile der Umwelt. Andere Ansätze versuchen, einen monetären Wert der beeinträchtigten Umweltgüter und -dienstleistungen zu bestimmen, indem *nicht-marktbezogene Bewertungsverfahren* herangezogen werden, etwa sog. „stated preference“- und „revealed preference“-Methoden. Außerdem können im Rahmen eines sog. „benefit transfer“ in anderen Zusammenhängen gewonnene finanzielle Bewertungen auf den konkreten Schadensfall übertragen werden. Schließlich kann auch auf die Kosten von „hypothetischen“ Gegen- oder Ausgleichsmaßnahmen abgestellt werden.

In der völkerrechtlichen Praxis hat sich bislang keine der oben genannten Methoden durchgesetzt. Aus diesem Grund werfen Fälle grenzüberschreitender Schäden infolge des Einsatzes selbstausbreitender Biotechnologie nicht nur schwierige rechtliche Fragen und Beweisprobleme über die Verursachung des Schadens, sondern auch über dessen Ersatzfähigkeit auf. Das erste Urteil des Internationalen Gerichtshofs zur Ersatzfähigkeit von Umweltschäden aus dem Jahr 2018 hat in dieser Hinsicht wenig

Klarheit geschaffen, da der dort gewählte Ansatz einer *Gesamtbewertung* („overall assessment“) im Wesentlichen auf der Ausübung von richterlichem Ermessen zu beruhen scheint. So gibt es derzeit keine eindeutige Möglichkeit, den Ersatz für Umweltschäden, die durch die Anwendung selbstausbreitender Biotechnologie verursacht werden, zu quantifizieren.

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