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 pre-

mature 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.