PART VI: INTERNATIONAL CLIMATE CHANGE LAW AND CROSSCUTTING ISSUES

https://doi.org/10.5771/9783845242781_867, am 17.05.2024, 22:32:07 Open Access – ((()))) + https://www.nomos-elibrary.de/agb

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26 Limitations of Risk Law

Ivo Appel

Abstract

The rationalisation of the handling of inconclusiveness and knowledge deficits is one of the core problems and crucial challenges of modern law (and especially in the context of climate change) which have not nearly been solved. With this general shortcoming, risk law penetrates major parts of the legal system and thus obtains a rather exemplary significance. The discussion of a risk-based approach brought to the European legal practice from the Anglo-American context seeks to base the justification of state risk regulation on more effective reasons supported by scientific evidence, and to link the adequacy of the cause for risk regulation measures to economic aspects and cost-benefit considerations. This increasingly strong influence of the Anglo-American perspective on the legal handling of risks also in Europe gives reason to review the principles of risk law as a basis on which to take a closer look at the basic problems and limitations of legal risk regulation.

A. Risk as a Central Concept of Law

Society's view of itself as a risk society results from a change of awareness and of a new dimension of perception which has far-reaching consequences also in the realm of law. Consequently, dealing with risk from a legal perspective is among the central challenges facing public law which have emerged in the context of movements in society and the state's response to such movements.¹ The need to overcome the uncertainty and inconclusiveness arising as a consequence of the ever-increasing complexity of technical processes and the inconclusiveness particularly with respect to the mid- and long-term consequences of actions has led to the concept of risk – hitherto

¹ Wahl (2006:70ff.); see also Wahl (1991:409ff.); Wahl & Appel (1995:1ff.).

mainly used in science – also developing into a central concept of law within a comparatively short period of time.² Technology-based (long-term) risks which are inherent to – and these are but a few examples – the use of nuclear energy, genetic engineering and nanotechnology, the condition of the ozone layer, the extinction of species, and global warming have become a central legal issue. Not only has the concept of risk been doctrinally interpreted and refined in this way, but dealing with the risks of the risk society has also comprehensively been declared a task of the state and translated into law with its comprehensive particularities by creating a risk (administration) law which documents the corresponding change in the doctrines of public law.

While the first phase of risk law was concerned with phrasing and specifying the foundations of state risk control and the legal particularities of risk administration law, in a second phase certain risk-law-specific difficulties become apparent. These result partly from the various ways of dealing with inconclusiveness, which are strongly culture-dependent, but also partly from structural limitations. It is largely the discussion of a risk and/or sciencebased approach brought to the European legal practice from the Anglo-American context³ which has led to the identification and scrutiny of the actual or supposed weaknesses of German and European risk law. This particular Anglo-American approach seeks to base the justification of state risk regulation on valid reasoning supported by scientific evidence and to link the adequacy of the cause for risk regulation measures to economic aspects and cost-benefit considerations. It is precisely this increasingly strong influence of the Anglo-American perspective on the legal handling of risks also in Europe which gives reason to review the principles of risk law as a basis on which to take a closer look at the basic problems and limitations of legal risk regulation.

B. Risk and Risk Law

The career and the comparatively rapid establishment of the concept of risk in law have not only led to a new key problem area in law and a new type of administration, but also to the emergence of risk (administration) law as an independent area of law.⁴ While they were initially of very limited sig-

² Wahl (2006:70ff.).

³ See Section C below.

⁴ See inter alia Di Fabio (1994); Wahl (1991:275ff.).

nificance in environmental law only, the concept of risk and risk law have now conquered almost the entire area of environmental and technology law, food and pharmaceutical law, genetic engineering law and consequently the law relating to almost all modern technologies, ranging from mobile communications to nanotechnology. The creation of risk law and of an accompanying risk doctrine have given these areas of law – which appear very different and distant from each other at first glance – a new central concept and systematic commonalities and have at the same time led to a largely coherent area of problems as well as of law. Not only has this led to an increase in systematic, cognitive value across the individual fields, it has also facilitated the exchange of lines of argument, methodical approaches and solutions.⁵

I. Legal Risk Management

One of the widely agreed upon conclusions from the discussion surrounding risk law so far is that reliable predictions on certain consequences, on the exclusion or even only the control of risks of technological influences on health and the environment are practically impossible owing to the sheer number of possible causal chains.⁶ This straightforward conclusion leads to the realisation that the aim of risk law can only be to handle risks and inconclusiveness rationally rather than to avoid them completely.⁷ Furthermore, in view of the lack of conclusive evidence available for damage predictions, it has been clearly established that concepts of risk law cannot be limited to a strategy of avoiding unintended consequences in the sense of a defence or precaution against risks, but must also use the inconclusiveness itself as a starting point for risk control.⁸ Bearing in mind that a graduated response based upon the degree of damage and the probability of its occurrence does not make sense if the risk estimate is highly uncertain, the formula used by the German Federal Constitutional Court (Bundesverfassungsgericht) stating that risks which seem practically impossible to materialise based on current scientific and technological knowledge may be imposed on

⁵ Wahl (2006:72).

⁶ Scherzberg (2011:41ff.).

⁷ Appel (2004:337); Scherzberg (2011).

⁸ For this and the following see Ladeur (1993:209ff.); Scherzberg (2004:241); summarising Scherzberg (2012:41ff.).

the party concerned as a socially adequate burden is not particularly convincing in these cases either.⁹ A lack of sufficient knowledge of risks can clearly neither lead to the conclusion that no risks exist nor to the opposite.¹⁰ Risk law must thus always adopt a two-tier approach. Where there is a well-founded suspicion that a risk exists, it must focus on precautionary measures appropriate to this suspicion. At the same time, however, it must take into account that the risk potential might not be sufficiently known. This is why risk control must also always bear in mind the remaining aspect of inconclusiveness. Against this background, risk management which the state implements or imposes on companies has two principal tasks to fulfil: firstly, the task of producing knowledge about risks in order continuously to stretch the boundaries of knowledge and to ensure that risk decisions are progressively adjusted to the new knowledge base, and secondly the task of determining the respective risk preferences in order to define the extent to which a community is prepared to bear risks.¹¹

II. Core Elements of Risk Law

Systematic commonalities and core elements of risk law have gradually formed across the individual fields and subsequently condensed to form an independent area of problems and of law with specific lines of argument, methodical strategies, system approaches and its own regulatory instruments. These principles and typical characteristics of state risk management include extended precaution by way of risk prediction and limitation, structural and organisational measures to involve scientific and technological expert knowledge, as well as those subject to risk control in the task of risk identification, the granting of considerable discretion for risk assessment, the comprehensive creation and application of sub-statutory standards, the strong procedural focus and a specific methodology for handling inconclusiveness.

⁹ See the decision of the German Federal Constitutional Court BVerfGE 49, 89 (133f.); Scherzberg (2004:241) with further references.

¹⁰ Scherzberg (2004:214); (2011).

¹¹ Summarising Scherzberg (2011).

1. Precaution through Risk Prediction and Risk Limitation

The characteristics of German risk law include the recognition and fundamental statutory regulation of the precaution interest, which opens up the prediction and limitation of risks beyond the risk knowledge already available through experience.¹² Under the aegis of precaution, law can be applied and prevention measures can be taken, despite the existence of inconclusiveness and although the factual basis for predictions is less stringent requiring only that there be sufficient cause for concern. In order to further specify, justify and legitimise this cause for concern and the ensuing precautionary measures, general procedures and rules are designed to guide, substantiate and direct the potentially unlimited ways of handling the consequences of inconclusiveness.¹³ As a rule, requirements for risk regulation are not implemented by way of one isolated administrative decision, but are embedded in a network of preventative levels of investigation, evaluation and decision-making, which are to structure and systemise the handling of uncertainty on a medium level of substantiation. The decisions to be made are thus staged pursuant to a specific procedure and specific rules, which are to provide a certain level of clarity and uniformity, also with respect to the administrative handling of uncertainty. These procedures and rules are concerned with reducing the inconclusiveness to a minimum prior to the decision-making process, identifying and evaluating the consequences of inconclusiveness and ultimately with handling the remaining inconclusiveness through strategies of avoidance or minimisation. The aim is legally to rationalise (risk) decisions which must be made without a sufficient basis for predictions, and at the same time to limit the costs connected with the lack of knowledge.14

2. Refocusing Risk Assessment towards Expert Knowledge and Those Subject to Control

Risk law is characterised by the structurally and organisationally ensured involvement of scientific and technological expert knowledge in the decision preparation phase, as well as by the fact that the investigative burden is

¹² Ladeur (1993:209ff.); Di Fabio (1994:450ff.); (1996a:147ff.); Köck (1999:151ff.).

¹³ Appel (2004:334ff.).

¹⁴ Wahl & Appel (1995:334ff.); Karthaus (2001:72ff.); Scherzberg (2002:134).

largely shifted to those subject to control, in connection with an official investigation which is principally limited to monitoring the process.¹⁵ Since the number of risk factors to be considered tends to be unlimited and is subject to change at all times owing to a dynamic knowledge base, risk assessment and risk management are generally carried out in network-like structures between government, administration, science and the companies concerned, which are intended to guarantee the recognition and consideration of all relevant aspects as best as possible. The state regulating the risk and the operators and/or manufacturers subject to the precautionary measures thus generally do not just encounter each other few and far between, but are involved in a continuous relationship aimed at achieving a dynamised process, as well as a continuous adjustment to the progress of the state of knowledge. The implementation of risk law is not left to the administration alone, but is designed to involve those social forces relevant to risk knowledge¹⁶ so that third parties and the general public are also involved in the decision-making processes at all times.

3. Discretionary Assessment and Sub-statutory Standards

One of the particularities of risk law is the fact that the statutory basis regulating administrative actions is undetermined to a high degree and thus strongly depends upon substantiation provided by the administration. This has led to sub-statutory standards and guidelines playing an important role in the area of risk law – comparable to parts of environmental law. In those areas where standardisation is not possible or exceedingly difficult, risk law has generally responded by granting considerable discretion in terms of assessment, evaluation, tenability and balancing of interests. Where it is difficult to assess the risk in terms of nature and substance, comprehensive discretion is granted to both the legislator for its fundamental decisions and the executive for specific risk decisions – this, in turn, limits the scope of the control exercised by the courts.¹⁷ As the courts cannot carry out the risk assessment themselves or change an existing risk assessment, risk law is typically located on the procedural level. It is thus not a coincidence, but a consequence of structural factors in risk law that legal challenges and legal

¹⁵ Summing up Köck (2003:6f.); see also Di Fabio (1996b:242f.); (1994:457).

¹⁶ Appel (2004:341); Köck (1999:166f.).

¹⁷ Wahl (1991:409ff.).

control mainly relate to the procedures used to identify and evaluate the risk. $^{\rm 18}$

4. Procedural Focus of Risk Law

Owing to the intrinsic difficulty in risk law to formulate clear material standards as well as the general vulnerability of potential material standards, risk law largely focuses on procedural concepts, methods for the identification and assessment of risks as well as the determination of the components and experts involved in these assessments carried out in preparation of a risk decision.¹⁹ It is thus a characteristic element of risk law, in many cases, that it neither directly nor indirectly answers the question as to the permitted maximum level of a particular risk. As a rule, the legal statement is limited to defining who is entitled to use which methods and which expert knowledge to determine which risk is permissible in the specific case. Although first impressions might point to the contrary, risk law is not primarily concerned with determining material limits for the admissible handling of risks - which would be difficult to regulate on an abstract level anyway - but with relocating the almost unregulatable material issue to the level of procedural and competency regulations, which specify who is entitled to make a binding decision on the acceptable risk and which procedure should be used.²⁰

5. Methodology of Handling Inconclusiveness

As far as the methodology of dealing with inconclusiveness is concerned, risk law provides methods, criteria and parameters to guide and rationalise the process of risk identification and risk evaluation which have been formulated across various doctrines and are increasingly also defined specifically for individual areas. Essentially, the four-stage approach – often generally referred to as risk management – of risk identification, risk evaluation, handling of the risk (risk management in the narrower sense of the term) and risk control is almost always applied.²¹ The risk identification is part of the

¹⁸ Wahl (2006:75).

¹⁹ For this and the following see Wahl (2006:71).

²⁰ Wahl (2006:71).

²¹ See Wahl & Appel (1995:106ff.); Appel (2004:336ff.); Köck (2003:6f.).

scientific cognition process which seeks to identify, determine and analyse risks, using the means of the respective science. It provides scientific/academic and methodical statements upon which political and legal decisions can be based; it does not, however, make decisions or partial decisions itself. It is decisive in identifying the existing risks to the furthest extent possible by taking into consideration all relevant factors and in connecting this analysis to the respective state of knowledge at the time. Actual decisions are not achieved until the risk evaluation stage which does not fall into the area of responsibility of scientific expert knowledge, but is ultimately - in a modern democratic country - the responsibility of the public bodies authorised and bound by law.²² Since risks do not necessarily trigger defensive measures as many risks are actually tolerated to achieve certain common aims and advantages, it is always necessary to evaluate and to determine at which point risks become intolerable and defensive measures must be provided for. In the context of risk evaluation, scientific expert knowledge only fulfils the task of providing advice or recommendations. At the third stage, which follows the risk evaluation, risk management in the narrower sense of the term plans for and determines the instruments and measures to be applied against such risks which are considered intolerable. Finally, risk control regimes monitor further developments over time by assessing the effectiveness of risk-regulating measures, taking into account any potential changes of the available knowledge and also ideally instigating any potential readjustments.

C. Precaution-based Risk Law versus Risk-based Approach

German risk law is characterised by a strong focus on the principle of precaution. One implication is that the precautionary principle, as opposed to the 'polluter pays' principle, is not based upon strict allocation patterns, but is largely neutral in terms of geography and time.²³ The legal challenge is to limit the infinity and openness of precaution in a rationally comprehensible way and thus also to integrate it into the statutory framework. It is the central task of the security doctrine of risk law to carry out and to justify this limitation. Essentially, it is decisive how detailed and demandingly the require-

²² See Breuer (1994:160).

²³ Wolf (1999:82); previously Saladin (1989:35).

ments for the rational comprehensibility and the consequential limitation of risk-controlling (precautionary) measures are phrased. In this respect, the justification dimension of the precautionary principle for public risk control measures has proved to be particularly strong in so far as the requirements for the justification of causes for concern and their scientific basis are not particularly high in German risk law. Despite the tendency - which has been noticeable internationally for a considerable period of time - to take a more scientific approach to the perception of precaution and risk and to make precautionary measures dependent on the existence of the appropriate 'objective' correlations and evidence,²⁴ the strongly precaution-oriented German risk law grants considerable discretion to both the legislator and the administration in assessing the existing risk. Even the German Federal Constitutional Court is not reluctant to grant the legislator the right within his assessment prerogative to assume a far-reaching 'basic risk' for the entire area of genetic engineering²⁵ without referring to the current state of scientific knowledge. This means that fundamental decisions in favour of precaution and cautiousness can be justified in a way which fulfils the requirements of (constitutional) law without having to provide extensive scientific justification. In cases of unclear or uncertain risk evaluations, a reasonable assumption is sufficient to justify risk-control measures, which might even include a complete avoidance of the risk.²⁶

This comparatively wide approach to precaution has however come under increased pressure recently, as the concept of the risk-based approach has introduced new impulses to the discussion regarding risk law on the European continent.²⁷ Both the term and the idea of the risk-based approach, which originate from the Anglo-American context, have been present also in the European legal practice for some time and are explicitly mentioned in papers of the Network of Heads of European Environment Protection Agencies (EPA Network).²⁸ The risk-based approach is sometimes presented as a strategy to be pursued to achieve an improved regulation of the environment Protection.

²⁴ See Arndt (2009:107ff.); Scherzberg (2010:306ff.).

²⁵ See the decision of the German Federal Constitutional Court BVerfGE 128, 1 (Gentechnikgesetz).

²⁶ Scherzberg (2010:306f.).

²⁷ See inter alia Hutter (2005:2ff.); Rothstein et al. (2006:1056ff.); Gouldson et al. (2009:5283ff.); Hill (2003).

²⁸ Network of Heads of European Environment Protection Agencies (2008:5,7,15); see also Environment Agency for England and Wales (2005:2).

mental sector. In a nutshell, the risk-based approach aims at designing and implementing risk-control measures in a way which is both functional and appropriate to the cause. Pursuant to this approach, the justification of state risk control should require valid reasoning based upon reviewable scientific evidence. Economic aspects and cost-benefit considerations should play a decisive role both in assessing the appropriateness of the cause and in implementing the risk-control measures. The aim is a rationalisation of risk decisions combined with a far-reaching minimisation of the effort (bureaucracy costs) and of the burdens associated with the limitations of freedom caused by risk-control measures (socio-economic costs). The central focus on rationality and scientific reviewability shows that the term 'risk-based approach' - which is commonly used in the Anglo-American context and has now also been introduced to European legal practice - fails to describe precisely the basic interests behind the approach. In line with the term used in American English, this is actually much better described as a 'sciencebased approach'29, as far as the increased science-based requirements applied to the justification are concerned. Looking at the approach as a whole, it would best be described as a 'science- and cost-based approach'.

Although there are some differences when it comes to detail, specific individual basic elements and a basic interest deductible from these elements are almost unanimously associated with the risk-based approach. These basic elements of the risk-based approach include:³⁰

- · linking of state regulation and risk-based procedures
- · handling of risks which is based on rationalisation and scientific evidence
- identifying all relevant risk factors, if possible
- · increased requirements regarding the correlations used for justification
- demand for an increased level of evidence to justify a concern and the corresponding burden of justification placed upon the authorities
- increased focus on consequences and impact
- risk decisions based upon cost-benefit considerations
- consideration of political, social and economic aspects in the decisionmaking process with a clear focus on economic aspects

²⁹ Sunstein (2005); summarising the "science-based approach" Scherzberg (2010:306ff.).

³⁰ See inter alia Hutter (2005); Rothstein et al. (2006); Gouldson et al. (2009); summarising Appel & Mielke (forthcoming).

- increased demand for causality between the use of instruments and positive environmental effects
- linking of the resources used and the scope and extent of the identified risks both in the context of the use of instruments and of risk control, and
- increased transparency, comprehensibility and cooperation.

On the basis of the four-stage approach of risk identification, risk evaluation, handling of the risk and risk control, which was developed for risk management purposes, the individual elements of the risk-based approach concern and influence all four stages of risk management. It appears that to a significant extent, the concept can be understood as a response to the specific problems of risk-related regulation in the environmental sector. This applies specifically to the identification of – where possible – all relevant risk factors, the specification of causes for concern, the increased level of evidence required to justify such concerns, as well as to the establishment of the proportionality of state risk control in situations characterised by inconclusiveness. Although the risk-based approach faces significant difficulties itself and can sometimes be exposed to strong objections,³¹ it still provides a strong reason to review the German and European security doctrines critically.

D. Basic Problems and Limitations of Risk Law

If put to constructive use, the interest inherent in the risk-based approach to achieve a thorough rationalisation of the security doctrines, which should be as transparent as possible, bears a significant critical potential. It thus appears worthwhile to look at the basic problems and limitations of the legal handling of risk in order to be able to judge whether and to which extent the lines of argumentation associated with the risk-based approach can contribute to the further development of risk law and of the risk doctrines.

³¹ See Appel & Mielke (forthcoming).

I. Limitations of Risk Identification

1. Scale and Complexity of Legal and Impact Assessment

One of the basic problems of risk law is the general openness of the impact perspective when identifying potential risks. The spectrum of consequences to be identified and evaluated is generally unlimited. If risk law were linked to a correspondingly complex and demanding open impact perspective, it would be in constant struggle with (over)complexity and an ensuing inability to act in many aspects. It has however become a commonplace in risk and impact assessment that, owing to practical as well as cognitive reasons, it can generally not be the aim to identify completely all consequences, but only to limit the relevant consequences.³² Where typical and recurring cases are concerned, a standardisation and formalisation will generally lead to a limitation of the perspective and to a consequential reduction in complexity. If a standardisation is not possible, the impact orientation must be limited by defining an appropriate scope of investigation in the individual case. The examples of the environmental impact assessment with its scoping procedure and the limitation of the scope of investigation in the context of genetic engineering works in genetic engineering facilities show that a limitation of the risk and impact perspective is possible also in individual cases. In order to be suitable for practical use, risk law must define such a scope of investigation and thus limit the impact perspective. Even a risk-based approach could not avoid carrying out such a limitation process, even if state risk regulation measures should generally be based upon scientific evidence which should be as comprehensive, effective and convincing as possible.

2. Difficulties and Uncertainties of Prediction

A major problem in risk and impact assessment is that the prediction of the potential impact is subject to significant uncertainty.³³ The assessment of the impact and the evaluation of the benefits and risks of environmentally relevant activities, and particularly also of innovative technologies which are relevant in terms of the environment and health, are typically associated

³² See inter alia Grunwald (2000:217ff.); Ladeur (1994:111ff.); Hermes (2004:360).

³³ Frederichs & Blume (1990:31ff.); Bechmann & Jörissen (1992:153).

with significant difficulties regarding prediction.³⁴ In addition, the impacts of certain decisions on the environment and its condition often only become apparent after a considerable period of time. There are generally no prediction methods available which would be suitable to comprehensively grasp and handle the complexity and long-term effects of what might be novel developments. Furthermore, the existing theoretical deficits and lack of knowledge regarding cause-and-effect relationships can make a clear assessment and evaluation difficult. It is characteristic of the decision-making³⁵ processes used in, for instance, impact assessments that specific activities, projects and novel technologies may promise economic or social advantages, while at the same time being unable to exclude risks and damage. Moreover, the long-term positive or negative impact of certain activities and projects or of the introduction and use of a novel technology are hard to predict in most cases. Pollutants are not always stable, environmental impacts are often uncertain and the factual situation in question in each individual case is a variable element. Changes in risk assessment and risk evaluation - the scientific and technological basis of which is hard to distinguish in practice from normative value judgments regarding the tolerable residual risk – show how difficult it is to handle risks in the area of the environment. Substances previously regarded as non-hazardous suddenly prove to be harmful. The resulting danger to the environment is often dealt with by replacing an identified risk with a risk which is (as yet) unknown.³⁶ The riskbased approach also forms part of this development when it attempts to remedy a cause-effect relationship identified as harmful by inducing the polluter to shift the consequences of his conduct to a higher level of uncertainty and complexity, which will then no longer be detectable as a legally relevant potential risk with the present means available to risk assessment and evaluation.³⁷ Against this background, it becomes apparent that even the rational comprehensibility and scientific (lack of) provability are only relative factors.

Risk law can of course – as the respective efforts of the risk-based approach show – make an attempt to include the (always) remaining uncertainty of prediction as a factor to be considered (as a probability coeffi-

36 Wahl & Appel (1995:7).

³⁴ Appel (2009:158ff.).

³⁵ See Bohne (1999:4).

³⁷ See Murswiek (1992:38).

cient³⁸) when evaluating the risk. Provided that a fault tolerance is appropriately considered, a quantification of the risk would thus be possible also in situations of uncertainty. It is however doubtful whether and to which extent uncertainty, particularly if it refers to important goods in the realm of public interest, can really be appropriately integrated into the risk evaluation in the public sector. This applies even more as the effort involved in achieving meaningful evaluation standards can be enormous and only justifiable, if at all, for major projects, while in all other cases the evaluation would have to be carried out on the basis of categorisations and standardisations. In addition, recent research and developments show that there are indeed various types of uncertainty, of inconclusiveness and of the specific as well as unspecific lack of knowledge,³⁹ which require different evaluations and are hard to integrate as meaningful factors in the risk assessment process.

3. Dependency on Scientific Advice and Interdisciplinarity

Ever since its emergence as an independent area of law, risk law has been subject to a strong scientification, which manifests itself above all in the regular and increased involvement of expert knowledge.⁴⁰ In order to be able to handle uncertainties and inconclusiveness appropriately, the proportion of expert knowledge which goes beyond general knowledge and can only be analysed scientifically, as well as investigations and predictions based upon such knowledge, must be kept broad. Risk law thus has - as has environmental and technology law - developed into an area where the issue of involving experts is particularly exigent. There are many sub-areas in which the practical problems are so complex and the ways of responding so uncertain that the consultation of scientific and technological experts has become everyday legal practice. This involvement of experts means that risk law is interdisciplinary in its approach.⁴¹ This interdisciplinarity can lead to serious problems in terms of competencies and responsibility in the relationship between the decision-makers and the technical experts who shape the decision if it is unclear under which conditions risk law can and may incorporate knowledge from other disciplines to enable the state to act effi-

³⁸ Fehling (2004:444).

³⁹ See Hoffmann-Riem (2009:113ff.).

⁴⁰ See Wahl (2006:66).

⁴¹ Wahl (2006:66ff.).

ciently, while also ensuring that these decisions shaped by significant expert knowledge remain justifiable and legitimate.⁴²

The combination of scientific advice and political and administrative decisions which manifests itself in the strong link between risk law and scientific expertise depends on the trust in the availability of expert knowledge and on the well-balanced nature of scientific expertise. This applies in particular to concepts such as the risk-based approach which link risk decisions to justifications that are to contain a high level of scientific evidence. However, the trust in expert knowledge as a central resource of risk law is precarious, and where it is precarious it also infects law.⁴³ Even in pluralistic committees, such as the Central Committee on Biological Safety (Zentrale Kommission für die Biologische Sicherheit im Gentechnikrecht), it often depends on the relative and comparatively random level of knowledge of individual members whether the findings and experience of certain disciplines are integrated into the legal decision-making process. This is even truer if experts from a certain discipline rely on the knowledge bases of relevant or supposedly relevant (neighbouring) disciplines. Moreover, an increase in knowledge does not necessarily result in an increase in certainty, but can, on the contrary, lead to an incessant stream of new and unsolved questions. New knowledge can also create an awareness of how uncertain the premises upon which measuring methods, evaluations, value limit definitions, quality targets and regulatory models are based actually are.⁴⁴ Additionally, the state is not in a position simply to produce and accumulate knowledge as a resource. It must be obtained from science, technology and businesses so that the state depends on cooperative action in this respect. Insofar as risk law relates to matters which operate at the boundaries of knowledge and thus makes clear statements of scientific expertise impossible, trust in scientific expertise starts to fade and the (partial) contribution of expert knowledge to the legitimacy of risk decisions is consequently weakened. Against this background, much speaks in favour of the thesis that there are deficiencies in the risk-based approach in terms of its pursuit of rationality and scientifically founded risk decisions. The requirements of the risk-based approach can be met if and to the extent that the required knowledge is available. However, where an ever-improving specification is not possible or not likely to yield success and risky actions cannot simply be made subject to stricter

⁴² Appel (2011:309f.); Joerges et al. (1997).

⁴³ See Wolf (1999:78).

⁴⁴ Wolf (1999:78).

limitations, risk law must particularly also deal with the question of how to handle inconclusiveness. $^{\rm 45}$

II. Knowledge and Evaluation

The more uncertain the knowledge base and the more severe the lack of theoretical and empirical validation of the knowledge regarding the risk, the more important become the component of political evaluation and the scope of discretion of the legislator, the administration and - to the extent of their rights of control – of the courts in the context of risk decisions.⁴⁶ But even if the knowledge regarding the existing risk is relatively well-established and validated, the risk identification stage is always followed by an evaluation of whether and to which extent certain risks and remaining inconclusive aspects should or should not be accepted. Against this background, the risk-based approach can also be interpreted as an attempt to reduce the relevance of the evaluation element by having recourse to scientific findings and evidence, and presenting these as decisive for certain risk decisions. This carries the danger that the scientifically founded, rationally comprehensible findings regarding individual risk potentials demanded on the risk identification level lead to premature conclusions as to whether action is or is not required. However, the mere description and analysis of specific characteristics of a substance or of certain physical processes and interrelations as the present state does not allow the drawing of any conclusions - unless one is willing to risk a naturalistic fallacy – as to the normative target definition regarding the ecological state or situation which is to be preserved through specific risk regulation measures. The scientific description of substances, situations, interrelations or processes does not provide any standards or criteria as to which risks to human health, the environment or nature should or should not be tolerated. Without more specific information regarding the intended and desired level and type of the ecological reference system, risk regulation, even in the shape of risk minimisation, cannot be a practicable objective. We must not let our fascination with a rational method for the specification and operationalizations of risk research tempt us into deducing certain decisions therefrom. The identification of risk, irrespective of how

⁴⁵ Ladeur (1991:255); (1993:209ff.); (1994:111ff.); (1995).

⁴⁶ Wahl (2006:74).

rationally comprehensible it may be, remains part of the scientific cognition process. It merely provides knowledge on facts and scientific rules and thus leads to statements and not to decisions – not even to preliminary decisions, recommendations or suggestions. A subjective weighting and consideration of the identified facts and rules, and also of the inconclusiveness and knowledge gaps as well as the affected interests of the public and the individual, are not carried out until the risk evaluation stage. A decision can thus only be reached at the risk evaluation stage.⁴⁷

In addition to the difficulties related to the general openness of the impact perspective and the uncertainty of predictions, the risk and impact assessment associated with risk law must address the question as to which consequences should be relevant for a decision in the first place, how they should be weighted, and which standards should be decisive for the assessment and evaluation of the impact.⁴⁸ Impact identifications and impact evaluations can only be used in a rationally comprehensible and thus justified way to the extent to which the weight given to individual consequences as well as the evaluation aspects are clearly expressed and disclosed. It is thus not sufficient to realise and recognise the importance of impact aspects. The realisation that the impact assessment must necessarily be based upon a target and/or purpose structure is just as important. The complex task of defining standards can only be tackled with the means of law to the extent to which these structures are (clearly) evident from the bases for decisions of the applicable regulations.⁴⁹ From this point of view, it is mandatory that the impact perspective is purpose-bound for it to be legally manageable. This correlation is not always reflected in the various approaches to handling risks.

Even if the correlation between the impact perspective and a target and purpose structure is recognised in general, there is often a lack of precise and rationally reviewable criteria stipulating upon which of a multitude of possible constitutional rights or purposes of the law the evaluation of identified impacts should be based and which specific weight should be given to the individual purposes. While the fields of technology assessment and environmental impact assessment have always been concerned with avoiding adverse effects on life, health and the environment so that the pursued aims have always been comparatively clear and (more) homogenous, the ap-

⁴⁷ Breuer (1994:160f.).

⁴⁸ Appel (2009:159f.).

⁴⁹ See Lohmeyer (1984:489); Ropohl (1990:198); Bechmann & Jörissen (1992:161f.).

proach adopted by risk law leads to a more open aim structure.⁵⁰ The aim is to recognise and release the potential and the benefits of certain technologies, while avoiding or at least reducing the negative and critical effects and side effects. The approach does not define the scope to which each of these aims should be decisive and how they are to be set in proportion to each other. Where multi-layered targets are the only starting and reference points for the impact assessment,⁵¹ an important aspect of the task to be fulfilled by the administration, the courts and legal academia is to specify the targets (set by the legislator) and to devise the respective methods so that a rationally comprehensible impact orientation becomes possible at all on the basis of such targets. It appears that in the context of the risk-based approach, the costbenefit analysis is intended to fulfil this role, although this analysis faces standard-related problems itself.⁵²

III. The Economisation of Risk Law

In line with the generally increased importance of economic considerations in the legal field, risk law is also subject to a growing trend towards economisation. Cost-benefit analyses, which also form a central element of the riskbased approach, are among the most prominent and at the same time the most problematic instruments in this context. Cost-benefit analyses in risk law are different in nature as their perspective is significantly broadened.⁵³ This is due to the fact that the risk evaluation is intended to weigh the total expected costs against the total expected benefits in order to reach the best and/or most profitable solution. It must be kept in mind that, in the context of risk evaluation, cost-benefit analyses are typically to be applied in the area between unacceptable risks and acceptable, negligible risks. In this area, where risks should be kept as low as reasonably possible, cost-benefit analyses can help with the decision as to how various possible options should be graded taking chances and risks into account – and how a decision should be made in favour of a certain option. It is decisive for the application of cost-benefit analyses that all relevant costs and benefits of those involved and concerned,

⁵⁰ See Appel (2009:159f.).

⁵¹ Wäldle (1979:12).

⁵² See section C.III. above.

⁵³ For this and the following see Appel & Mielke (forthcoming); Fehling (2004) with further references.

including the uncertainties, can be reflected in the costs and benefits and that not only direct but also indirect costs (time required for administration, delays to investments etc.) are included in the analysis.

The strength of cost-benefit analyses lies in particular in the comparability of costs and benefits in the same currency. The transparency of the decisionmaking process can thus be increased significantly. An increased transparency also increases the strength of the information available for further decisions.⁵⁴ The disadvantage of cost-benefit analyses lies in the comparatively one-dimensional approach in which monetary aspects are decisive, while strategic aspects do not (or cannot) find the appropriate consideration because of the approach. In addition, there is the problem - which is crucial particularly in the public sector and for which the qualitative cost-benefit analysis does not provide an adequate solution - that it is impossible to allocate a monetary value to many (abstract) public interest objectives and purposes and that it is generally impossible to evaluate these appropriately.55 The problems of cost-benefit analyses thus lie in particular where the factors to be included are not easily quantifiable and monetisable (in a rationally comprehensible way) and the creation of standards is particularly severe. Where there is no market for a specific good, the method generally applied is to rely on surveys to identify the (hypothetical) willingness of a representative group of persons to pay for the good to be preserved and/or to find out the sum in exchange for which these persons would be willing to give up the respective good (willingness to pay/willingness to accept). This is essentially an attempt to create a hypothetical market. However, where the good to be monetised is human life, this procedure - and the monetisation attempt in general - runs into increased difficulties.

This issue is connected to the general problem of the commensurability of goods or values, which makes it more difficult to prepare exact costbenefit analyses. Another difficulty besides the comparability of the individual factors is the selection of the factors to be included in the analysis. How broad or narrow the scope of the investigation should be is already an evaluative decision which cannot be rationally justified down to the last detail. However, there is a danger that the cost-benefit analysis will be used to create the illusion of an objective decision. The subjective element is only shifted to an earlier stage – from the decision level to the selection level.

⁵⁴ Weis (2009:140f.); Hanusch (1994).

⁵⁵ Hutter (2005:8ff.); Adams (1995:93ff.).

Until these problems are solved, exponents of the cost-benefit approach – despite the plausibility of the basic idea – may face the accusation of creating a mere illusion of an objectiveness of the analyses prepared.

Finally, the definition of the correct tax discount rates for future costs is a frequently recurring problem in the context of cost-benefit analyses. Owing to the manner in which the discount is usually applied, benefits which will materialise in the distant future generally only have a negligible influence on the decisions made today. The suitability of the method is thus limited with respect to the long-term consequences, which are of importance particularly in the environmental sector, and the inclusion of risks for future generations, which is a requirement set not least by European and constitutional law. It is thus true also in the context of the risk-based approach that cost-benefit analyses can provide (potentially major) assistance in terms of information, justification and decision-making. However, since in the area of public environmental and health protection, they generally fail to reflect fully all costs and benefits, they cannot replace the evaluation and decisionmaking stage under any circumstances, but can only assist in the preparation by providing useful arguments. Since almost any activity and situation can lead to damage under certain circumstances, which can never be excluded completely, it is decisive which evaluation is required in order to assume that there is a cause for concern and thus also a reason to take the respective countermeasures. It is necessary to evaluate how to handle the remaining inconclusiveness, whether residual (uncertain) risk should be accepted and who is to bear any potential consequences and burdens. A decision based upon a weighing of interests is thus required, which cannot be replaced (even) by the risk-based approach. This approach with its individual basic requirements can only prepare the decision by making maximum use of the available evidence. Despite all reservations when it comes to detail, costbenefit analyses - in addition to other balancing considerations - can clearly be of use in this context. Their relative cognitive value can be used to prepare the decision, insofar as it does at least create an awareness of the weight of the identifiable advantages and disadvantages.

IV. Minor Impact of Constitutionally Stipulated Requirements

Risk law is generally characterised as having a strong link with constitutional law.⁵⁶ Among the major constitutional problems are – leaving aside the questions of sufficient substantiation and legal reservation - the questions of the scope of the protective duty of constitutional law in the relationship with the legislator,⁵⁷ as well as the proportionality of (precautionary) riskregulation measures. However, a closer look reveals that the importance and the significance of the constitution to risk law are comparatively small. The reasons cannot be described in detail at this point;⁵⁸ they can however briefly be illustrated using the example of the proportionality principle. Although the constitutional proportionality principle is generally presented as a requirement to be fulfilled also by measures under environmental law which restrict freedoms, the principle typically becomes relevant in the context of risk law in multipolar relationships and often even in multipolar relationships in which decisions have to be made under uncertain circumstances. While it is already difficult to examine the proportionality in multipolar relationships,⁵⁹ a meaningful proportionality test under uncertain circumstances is almost impossible on the basis of standard doctrines. For if it is a basic function of the risk law doctrine of precaution to make the implementation of freedom-limiting measures possible even under inconclusive circumstances, then the proportionality test must take this uncertainty into account at all stages. However, it is very difficult to even assess the suitability of a precautionary measure taken under environmental law since the level of inconclusiveness makes a serious examination of the basic predictions upon which such measures are based almost impossible. This is even truer for the assessment of the necessity of the measure if it is impossible, owing to the causal connections being largely unclear, to carry out a clear grading of the intervention intensities of various legal instruments, which takes into account the effectiveness with which the aim is achieved.⁶⁰ In such cases, the proportionality test is effectively limited to a reference to the estimation, evaluation and assessment prerogative of the legislator.

⁵⁶ Wahl (2006:74f.).

^{57 (}ibid.).

⁵⁸ Appel (2011).

⁵⁹ See Calliess (2001:566ff.).

⁶⁰ See decision of the German Federal Constitutional Court BVerfGE 128, 1 (Gentechnikgesetz), 183.

Against this background, the risk-based approach can be understood as an option to substantiate the proportionality principle under the conditions of risk regulation (precaution) and the associated uncertainty.⁶¹ For essentially, the risk-based approach tries to achieve a substantiation of the relationship between purpose and means - which must be established between the purpose of avoiding or reducing risks which might cause damage and the applied means, i.e. (precautionary) risk-regulating measures by the state which limit freedoms. Under the comparatively unambiguous conditions of an application of the law where the basic facts are known, the proportionality of state measures can be reviewed relatively clearly and comprehensibly based upon the test stages of established doctrines by looking at whether the means used are suitable, necessary and appropriate to achieve legitimate aims. Under the conditions of increased uncertainty and inconclusiveness typical of risk regulation, this referential connection cannot be applied without difficulty. This makes it even more important to specify the meaning of proportionate risk regulation (precaution) and in particular to define how the proportionality of the means used to achieve the objectives of risk regulation (aims of precaution) can be ensured. This specification must, above all, refer to the amount of (justification) effort required to show that (precautionary) risk-regulating measures are suitable and necessary in view of the aims pursued, and to a definition of the permitted scope and intensity of these (precautionary) risk-regulating measures so that these measures are (or remain) justifiable in terms of their necessity and appropriateness.

Both the precautionary and the proportionality principle are principles with an open structure which depend on further specifications. Unless substatutory specifications exist, there are usually very few rules (if any) to determine how law should be established pursuant to the precautionary principle so that it complies with the requirements of the proportionality principle. The German interpretation of the precautionary principle, pursuant to which the justification dimension of the precautionary principle is strong and almost entirely releases both the party establishing the law and the party applying it from providing (scientific) evidence, is one option of specification. Another possible specification is the application of the risk-based approach, which imposes stricter requirements regarding the correlations used for justification and the rational comprehensibility of the risk identification process, enables an inclusion of cost-benefit considerations into the risk

⁶¹ Appel & Mielke (forthcoming).

identification process and links the use of instruments and resources for the regulation of the assumed risks to the scope and extent of the identified and assessed risks.

Control over which of the specification options will prevail is limited this depends not least on the influences which prevail in the discussion on a European level. It thus makes sense to speak of competing concepts. Essentially, it cannot be denied that the risk-based approach - despite the associated challenges and problems - can contribute to a rationalisation and increased systematisation of the proportionality test under inconclusive conditions. On the downside, however, the requirements of the risk-based approach may lead to a partial limitation of the scope and reach of precaution. Insofar as a doctrinal grading is carried out with respect to the precautionary principle, this influence affects all levels of the doctrine of precaution. Owing to the more stringent requirements applied to the correlations used for justification and the rational comprehensibility of the decision-making process, the identification of the relevant risk factors and the overall increase in impact orientation, the risk-based approach makes it necessary to limit clearly the causes for precautionary measures. Despite all difficulties and uncertainties of predictions when it comes to detail, the approach aims at consistently designing the risk identification and evaluation process so that it is possible, using the evidence available, to gain maximum understanding of the specific risk potential, the situation causing the concern and the specific risks to be regulated.

However, these requirements regarding the rationally comprehensible justification of the reasons for precautionary measures also entail a tendency to raise the level, for when such a reason can be regarded as sufficient to permit the use of precautionary measures since. Ultimately, state risk regulation measures which limit freedoms and use resources will only be justifiable using rationally comprehensible and scientifically founded reasons. In addition, cost-benefit considerations can already lead to prioritisations and the corresponding grading at the stage of identifying the reasons for precautionary measures. If certain risk potentials are considered comparatively low(er), then the weight of the associated reasons for precautionary measures also tends to be lower, which means that on the subsequent stages of the precaution doctrine, and particularly in the context of the proportionality test, they can only be considered with this relatively low weight.

However, the similarity to the discussion of constitutional protective duties in the area of risk, which is also characterised by uncertainties of the predictions, makes it clear that the procedural requirements as well as the burden of providing justifications, both in the area of public protective duties and of precaution, must be more stringent to achieve transparency as to why actions are or are not taken. This speaks in favour of the assumption that at least the increased requirements which the risk-based approach imposes regarding the correlations suitable for justification purposes cannot simply be rejected.

V. Connection between State Risk Decisions and the Communication of Risks to the Public

Both the perception and the evaluation of risks strongly depend upon subjective, social and cultural views and preconceptions.⁶² The selectivity of risk perception, the difficulties in providing rationally justified risk comparisons, the actual or perceived familiarity with certain technologies and their risks, differing assumptions regarding the attributability and controllability of certain risks, as well as the temporal proximity and level of distribution of risks can be more or less decisive factors. The way society perceives and handles risks can be entirely different from how risk researchers handle risks. The assessment of society is generally based upon social and cultural patterns, rather than upon scientific relationships between the probability of the occurrence of damage and its expected severity. The perception, evaluation and handling of risks can thus vary significantly between cultures and only allows the conclusion that overcoming inconclusiveness is a phenomenon which is strongly influenced by cultural factors.⁶³

Against this background, a significant aspect of the task to be fulfilled by risk law and risk administration is to make a contribution to the communication of risks and to enable politically initiated public discussions about risks in order thus to act as an intermediary between the political and the public perception of risks.⁶⁴ In a democracy, the level of abstraction of the solutions and reactions to a problem devised under risk law may deviate from the understanding and acceptance of individuals. However, the discrepancy between society's perception of a problem and the political (and legislative) willingness to perceive risks in a certain way and to overcome them in a certain manner must not be allowed to increase without limitation in a

⁶² Wahl & Appel (1995:107ff.); Scherzberg (2004:231); (2011); (2006:125f.).

⁶³ Scherzberg (2004:231); (2011); (2006:125).

⁶⁴ See Scherzberg (2006:125f.); (2011); Wahl & Appel (1995:211ff.).

democracy, i.e. a form of government led by consensus.⁶⁵ It will only be possible to achieve social acceptance and to avoid causing fundamental anxiety among the public – whether these concern the use of nuclear energy, green genetic engineering or nanotechnology or the industrial production of food - if the political evaluation of the risks of environmentally and healthrelevant (technological) developments and of their potential impact is linked to society's perception of risk and values. While it is difficult enough to achieve this connection on a national level, the required communication of risk in international contexts - referring to the risks of genetic engineering, nanotechnology, nuclear energy, etc. - proves to be one of the major future challenges. (Risk) law can only play a limited role in this context. It would be an illusion and an overestimation of the possibilities of control offered by law to assume that a discourse on risk is possible by legal means alone. Law could, however, play the more modest, but not insignificant, role of creating and maintaining room for such discourse to take place. And to the extent to which law has a certain scope of influence - via the administration, courts and legal academia and not least also via (sub-statutory) processes of setting rules and standards - it can contribute to the discourse. Keeping these correlations in mind, the risk-based approach can also be interpreted as an example of a basic risk discourse on a European and - in relation to the United States – also on an international level.

E. Paths of Development for Risk Law

The discussion regarding the further development of risk law illustrates that the rationalisation of the handling of inconclusiveness and knowledge deficits is one of the core problems and crucial challenges of modern law and has not nearly been solved. With this general problem, risk law penetrates major parts of the legal system and thus obtains a rather exemplary significance. It is impossible at this stage to assess conclusively whether, and if so, to which extent the risk-based approach will be successful on the European and international level. However, the likelihood is high that it will meet a certain amount of approval and that at least some aspects will be used as a way to further substantiate the proportionality principle in the risk regulation environment (prevention). German risk law should therefore famil-

⁶⁵ Wahl & Appel (1995:211ff.).

iarise itself with the risk-based approach and should clearly state the apparent deficiencies of the approach in the discussion on the European level. Furthermore, an attempt should be made constructively to combine the German interpretation of the precautionary principle with the critical potential of the risk-based approach. In this context, the advantages of the German and European doctrine of precaution, which allows for a high level of protection at comparatively low effort (bureaucracy costs), especially in cases of remaining uncertainty, should be promoted rather aggressively. The the general value of precaution and of the associated risk-regulating measures cannot be made dependent on certainty when the discussion regards high potential damage, while it is impossible to predict sufficiently and safely certain consequences and/or impacts. In this respect, the demand to make regulatory intervention dependant on conclusive evidence regarding the existence of risks must be categorically rejected.⁶⁶

At the same time, however, the attempt to achieve a maximum amount of rationality and comprehensible justifications for risk regulation measures should be pursued and the potential for rationalisation - which clearly exists - should be used in favour of the existing doctrine of precaution. Beyond the existing specifications of the precautionary principle, the interests of the risk-based approach can be met by requiring that reasons for precaution must always be sufficiently substantiated and based upon a risk identification and evaluation for which risk assessment as an instrument of risk prevention can provide a basic model. In case of remaining inconclusiveness, it should, however, be pointed out against the tendency of the risk-based approach that, where inconclusiveness and knowledge deficits exist, a lack of (clear) scientific evidence must not lead straight to the assumption of the freedom of (economic) actions. In view of the ambivalence of unpredictability, an evaluative assessment which takes into account all relevant aspects, including the respective public interests, is required particularly in these situations. It should finally be made clear that cost-benefit analyses can clearly play a constructive role in the context of risk regulation, not as a replacement for the required evaluative decision but - comparable to the environmental impact assessment – as an instrument to prepare decisions in the sense of a formalised realisation of the interests which are at stake and their (relative) weight. The scope of cost-benefit analyses could be limited by including only such considerations in the analysis as are covered by the respectively

⁶⁶ Appel & Mielke (forthcoming).

relevant purposes of the law. Although this would not bring the trend towards economisation connected to the risk-based approach to a complete halt, it would limit it to the purposes intended by the legislator, which generally do not include efficiency as an end in itself.

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