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Summary

International Liability for Damage caused by Genetically Modified Organisms

1. The use of genetic manipulation is not a new phenomenon. However, over the last 30 years, our ability to alter organisms has been revolutionised by modern biotechnology. Using sophisticated techniques, scientists have learned how to precisely manipulate the intricate structure of individual living cells. The results are known as genetically modified organisms (GMOs) or living modified organisms (LMOs). The introduction of the first LMOs has initiated a vigorous and often emotionally-charged debate on the possible risks of its use. As modern biotechnology is a global industry and LMOs are cultivated world-wide and traded across borders, the discussion on the risk of LMOs is not limited to a national level but also takes place on an international level. Risks associated with modern biotechnology were first addressed internationally with the Convention on Biodiversity (CBD) of 1992 which focused on establishing universal protection of global biodiversity. On 29 January 2000 the parties to the CBD adopted the Cartagena Protocol on Biosafety (BSP), setting out for the first time a comprehensive regulatory regime to ensure the safe transfer, use and handling of LMOs subject to transboundary movement. Its aim is to protect biodiversity and human health against being impaired by genetically modified food, feed, seeds, animals and microorganisms.

Both conventions lack final regulations on liability and redress. Article 27 of the BSP provides that the Conference of the Parties (COP) 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.”

This provision overlaps in part with Article 14 (2) of the CBD which asks the Signatory states to examine the issues of liability and redress including compensation and restoration for damage to biological diver-

sity, except where such liability is a purely internal matter. Negotiations on both the liability regime under Article 27 of the BSP and the liability regime under Article 14 (2) are still ongoing.

The present publication presents the background of international liability rules to be developed under Article 27 of the BSP, systematises the present discussion on international liability rules in the field of modern biotechnology and highlights key features of a possible liability and redress scheme under Article 27 of the BSP, regulating for damage that may occur in the course of transboundary movement of LMOs.

In this summary an overview of the main findings and ideas of the detailed analysis is given.

2. The first part of the present examination prepares in Chapters 1 – 4 the background on international liability rules for damage caused by LMOs. This section illustrates the discussion on the risk posed by LMOs, reviews the respective rules in the BSP and the CBD and examines the applicability of the concept of State Responsibility in customary public international law. It further outlines existing multilateral treaties and drafts dealing with liability and redress for transboundary harm and provides an inventory of ongoing, related developments in the European Union and Germany.

a. There exist three different scenarios involving transboundary movement of LMOs that could result in adverse effects: Damage could either be caused by unintended transboundary movement of LMOs, by intended transboundary movement of LMOs, or finally, during transport. (1) Unintended transboundary movement of LMOs includes the scenario in which laboratory testing of LMOs under controlled conditions leads to an accidental transboundary release but would also cover cases in which genetically modified crops are introduced into the environment and unintentionally cross the border to another state. (2) Damage caused by intended transboundary movement of LMOs refers to damage that was caused after the export of LMOs, while (3) damage occurring during transport refers to negative effects caused in a third country during transport of LMOs in the course of international trade.

b. LMOs may not only have negative effects for individual goods such as life, human health or property, but may also impair common goods, such as the environment or socio-economic conditions. The perception of the risk associated with the use of LMOs varies between industrialised countries, which have enacted national rules on modern biotechnology and risk-assessment over the last years, and developing countries, which often lack such regulations. At the centre of the discussion

on the risks of the new technology stands the fear of unrecognised, possibly irreversible risks. This concerns mainly long-term risks to the environment and human health caused by genetically modified agricultural products. Accidents involving LMOs can lead to unintentional release of transgene material, which gives also reason for great anxiety. A further concern, mainly raised by industrialised countries, is economic loss caused by the co-existence of genetically modified and conventional crops.

c. The CBD addresses these risks of modern biotechnology insofar as they pose a threat to the conservation of biological diversity and the sustainable use of its components. The BSP regulates the risks of LMOs in connection with transboundary movements of LMO. It goes beyond the scope of the CBD in that it not only addresses potential risks of LMOs to biodiversity, but also specifically aims at controlling the risks associated with LMOs for human health. The BSP further includes risks posed by LMOs that may result in the deterioration of socio-economic conditions, but only refers indirectly to risks posed by LMOs that may lead to property damage or economic loss.

d. Many industrialised states have introduced specific liability regulations applicable for damage caused by LMOs which provide for strict liability of the operator and cover risks that were unforeseeable, according to the state of the art, when the damaging action occurred (development risk). This study uses the case of Germany to exemplify national liability rules applicable for damage caused by LMO. It suggests that national liability rules of an industrialised country with a rather high regulatory standard in the field of biotechnology do not necessarily provide a solution to all problems posed by the specific risk of LMOs. This is especially true with regard to biodiversity damage which does not amount to economic loss and damage caused by the coexistence of LMOs and conventional crop.

e. International customary law does also not sufficiently address the problem of liability and redress for damage caused by transboundary movement of LMOs. Since a strict liability rule has so far not been accepted in international law only the customary rule of State Responsibility is applicable. This rule presupposes that a breach of an enforceable obligation directed towards reducing or preventing the specific damage. On this basis, State Responsibility cannot be applied to damage caused by LMOs that was not predictable at the time of the damaging activity of a state. Its applicability is also questionable if economic loss is caused by the co-existence of of genetically modified and conventional crops. Only few indices can be found in state practice for a rule that would

hold the exporting state liable for damage occurring in the territory of the importing country or during transboundary transport. These indices have so far not amounted to a rule in customary international law. No state practice exists with regard to the causation of damage to biodiversity, insofar as the concept of biodiversity damage goes beyond the concept of environmental damage. The customary rules on compensation for environmental damage adopt the structure of the traditional civil law approach. They do therefore not provide a solution if reinstatement of adverse effects to the environment caused by LMOs is either materially infeasible or involves an economically unproportional burden.

f. The acceptance of international liability rules in the field of modern biotechnology including the specific characteristics of such rules must be seen against the backdrop of the developments in international treaty practice.

An analysis of existing treaties and drafts in the field of liability shows that a future liability system for the BSP would, on the one hand, be in accordance with latest developments in international liability law: Thereafter, parallel to the increasing regulatory activity of the international community, regulatory regimes have increasingly incorporated the topic of liability. Moreover, recent international liability regimes have elaborated on the concept of environmental damage. Remarkable progress in the field of environmental liability has been made with the Proposal of the EU-Commission for a Directive on Environmental Liability with Regard to the Prevention and Remedy of Environmental Damage of 23 January 2002 (Proposal for a EU-Liability Directive). The EU-Liability Directive strictly links rules on environmental liability to environmental EU-legislation and thus to administrative risk control. Due to this administrative law approach, the Directive can rely upon existing regulatory standards on nature conservation and can avoid the difficulties of civil liability regimes with regard to compensation of environmental damage.

On the other hand, international liability regulations for damage resulting from modern biotechnology also pose a new challenge for the community of states: States have generally more easily achieved consensus on international liability rules that deal with specific activities bearing a verifiable risk of causing significant damage. Negotiations on liability rules for protected areas or the environment which cover various scenarios and activities have proven to be much more difficult. Liability regimes aimed at levelling out different regulatory standards within developed and developing countries that deal with damage occurring after

transboundary movement of hazardous substances have to date been rarely discussed.

3. Building upon the findings in the first part, the second part of this publication proposes in Chapters 5 - 14 a possible structure for a liability and redress regime under the BSP. It does, however, not seek to propagate a specific structure of a future international liability regime. It rather seeks to analyse the variety of problems to be resolved within such a liability scheme and discusses possible elements of such a regime.

a. This study submits that a liability protocol based on Article 27 BSP partly implements the mandate of Article 14 (2) CBD. On these grounds, the coordination of both processes is necessary in order to avoid the implementation of contradictory international provisions.

For enhanced efficiency of the liability rules under Article 27 BSP the new liability regime should build upon the scope of the underlying regulatory regime. It is suggested that it includes all three scenarios involving transboundary movement of LMO that could result in adverse effects, thereby covering all activities that fall under the scope of the BSP. The regime should extend past LMOs with a verified high potential for harm. An exemption is possible for genetically modified pharmaceuticals, as for these, the BSP contains only subordinated rules. Limitations with regard to liability for adverse effects of LMOs which occur in the course of international trade may also be necessary in order to avoid distorted effects on international trade.

b. A strict liability standard is suggested as a starting point for a Biosafety Liability Protocol, complemented by fault-based liability rules. Fault-based liability could be taken into account when damage was either caused or worsened due to the failure to comply with the provisions of the BSP or in the event that the victim has deliberately exposed himself to the risk. The specific characteristics of risks connected with modern biotechnology only allow for a few exceptions from the strict liability standard. One could argue to exclude the liable party from liability if the competent authorities had previously identified the risk that led to the damage and had considered it to be tolerable. Liability for development risks, on the other hand, seems to be an essential part of a liability scheme that regulates liability in the field of modern biotechnology. In order to ensure economic predictability and insurability in the interest of the liable party, liability for development risk should be combined with limitations in time and amount.

c. As a basic structure this publication submits to combine primary liability of private persons with residual liability of states. For the chan-

nelling of primary liability it proposes that liability should be channelled to the operator, i.e. the person who had operational control of the activity at the time of the incident causing damage if the damaging LMO had not been previously introduced into the market. Once a damaging LMO has been brought onto the market the producer who first placed it on the market should, in general, be liable for all development risks. The person exercising control over the LMO at the time when the damage was caused should, however, be liable in this stage if he could have prevented the damage by applying adequate precautionary measures. This structure allows for additional channelling of liability to the exporter, importer, the person who notified the LMOs in question, or any other person who contributed to the creation or worsening of the harm by failure to comply with the provisions of the BSP.

Against the background of existing state practice subsidiary state liability regardless of negligence and fault seems only to be conceivable within a liability regime for the BSP for cases in which LMOs cause significant negative impact after unintended transboundary movement. Also, subsidiary state liability could be acceptable if a failure of a state either contributed to the damage or to insufficient financial security of the primary liable person.

d. A liability regime building upon the BSP should primarily cover damage to biodiversity but also include adverse effects to human health. This does not exclude the protection of property as long as the liability rules - at least indirectly - intend the protection of biodiversity and/or human health. On the other hand, the concept of the BSP does not suggest liability rules with regard to negative socio-economic impacts. The same is true for negative effects caused by genetic pollution.

Damage to biodiversity triggering the liability regime can be described abstractly as any significant negative impact on the conservation of biodiversity and its sustainable use. Criteria which could be used to increase the specificity of this abstract definition need to be developed for a liability protocol under the BSP taking into account the new concept of biodiversity as laid down in the CBD. The criteria should make allowance for the fact that the value of single components of biodiversity in many cases is not known, or results from interdependence within an ecosystem. Taking into account the precautionary principle, the minimum threshold that quantifies significant damage and triggers the regime could be the point when evidence is provided that transfer of the genetically modified characteristics of the LMOs has taken place and that the recipient organism gained a selection advantage through this transfer. The liable party can rebut the presumption of damage if he can

provide evidence that apart from these negative effects no further damage will occur.

Based on recent developments in international liability law, this study submits that reparation for biodiversity damage is based on an obligation to restore the damaged natural resource but also comprises both, alternative restitution and monetary compensation if reparation is not feasible at a proportional cost. Further development of these three elements as elaborated within existing liability regimes is needed since even a combination of these options would still leave a large part of damage to biodiversity uncompensated. Monetary compensation for remaining damage to biodiversity does regularly not fill this gap since it requires an economic evaluation of the damaged biodiversity. Due to the complexity of the subject-matter and the lack of knowledge in many cases, with existing evaluation methods such an evaluation is not possible even if different methods are combined.

e. It is suggested that within a liability scheme under the BSP a probability standard should suffice to prove the causal nexus in view of the plaintiff's allegation that the damage was caused by a specific LMO. If it can be established that the adverse effects were caused by several actors, joint and severally liability will lead to appropriate risk allocation provided that the contribution of each actor was sufficient to cause the total loss.

If the damage was caused by the unintended transboundary movement of one specific LMO involving several actors, and the contribution of each actor cannot be established retrospectively, the causality criteria could potentially be replaced with the criteria of statistically verifiable probability for causation of the damage. The gradual causation of damage by different LMOs and the phenomenon of genetic pollution as a result of international trade share the same characteristics as damage caused by pollution of a diffuse character, in that it is impossible to link the negative effects with specific individual actors. These cases usually cannot be solved within a traditional liability regime.

f. This analysis suggests that an international liability scheme for damage resulting from LMOs be supplemented by compulsory insurance. Also, it submits that a supplementary fund scheme be conceived to provide compensation for victims or remedy for damage that might otherwise not be covered by a liability system that is designed in order to guarantee insurability. This fund could be financed through voluntary contributions and monetary compensation for remaining biodiversity loss. Contributions from states could also be considered. Another possible situation in which the idea of a fund could be of assistance is

remedying damages caused by genetic pollution in connection with the international trade of LMOs.