The Legal Significance of the Nagoya-Kuala Lumpur Supplementary Protocol: The Results of a Paradigm Evolution

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THE LEGAL SIGNIFICANCE OF THE NAGOYA-KUALA LUMPUR SUPPLEMENTARY PROTOCOL: 
THE RESULT OF A PARADIGM EVOLUTION

René Lefeber
1. Introduction

Since its identification in the Hong Kong Special Administrative Region in 1997, the Avian Influenza Virus A/H5N1 has spread to other parts of the world infecting domesticated and wild birds. The airborne virus migrates between birds and occasionally from birds to people, but it has not yet been found to migrate between people. Among infected humans, the respiratory illness caused by the virus proved to have a high fatality rate (approximately 60%). The American National Institute of Health procured pathogenic research to monitor natural mutations and prepare emergency measures in case of an outbreak. In early 2012, it was revealed that genetic modifications of the virus had produced a variety that migrates between mammals without the loss of its pathogenic characteristics. The virus may, or may not, evolve naturally into this genetically modified variety. The news caused widespread concern. The publication of the research details was considered a security risk as such details might be used to develop a biological weapon. At the same time, the presence of the genetically modified virus was a safety risk as its release into the environment would be a public health threat. The procurement of the research was criticized and its potential benefits challenged, casting doubts on the proper balancing of the benefits and risks involved. Irrespective of the propriety of the procurement decision, this example demonstrates that the development of living modified organisms may be hazardous.

The technology to modify the genetic properties of living organisms was developed in the early 1970s and commercialized in the early 1980s. Ever since, the benefits and risks of this new technology have been the subject of debate. Notwithstanding the on-going debate, the technology has spread and genetically modified organisms have been developed and released into the environment of many countries, notably genetically modified crops such as soybeans, canola and corn. Such releases only took place following the identification and assessments of any risks for the environment and human health. Risk-assessments enable authorities to balance socio-economic benefits and the risks of adverse effects of an intentional release for the environment and human health. Only when risks are considered to be manageable and acceptable are releases likely to be permitted. This example demonstrates that genetically modified crops do not belong to the same risk-category as genetically modified viruses.

Since adverse effects may occur in spite of risk-management measures or as a result of the failure to identify the risk of adverse effects, the allocation of the costs of such effects should be anticipated and regulated. This became a contentious issue during the negotiations in the late 1990s on an international agreement that would regulate and facilitate transboundary movements of living modified organisms in a safe manner. It was argued by many developing countries that transboundary movements should only

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be permitted if the allocation of the costs of any adverse effects was regulated. Proposals were introduced that would address such adverse effects through the introduction of civil liability provisions.\(^2\) According to other negotiating states, in particular developed countries, the issue was too complex and controversial to be resolved in the time available for the negotiations. The controversy became a major obstacle in the negotiation process as was effectively communicated through the slogan “No Liability No Protocol”. Eventually, the Cartagena Protocol on Biosafety (CPB) was adopted on 29 January 2000 without substantive liability provisions, but with a procedural solution to address the controversy. It provides for a further process to address liability and redress for damage resulting from transboundary movements of living modified organisms (Art. 27 CPB). These negotiations commenced on 25 May 2005 after several technical expert meetings and an agreement on the organization of the process.\(^3\) A long, winding and complex negotiation process followed; a process that has, for now, ended with the adoption of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Supplementary Protocol or SP) on 15 October 2010.

The adoption of the Supplementary Protocol merits assessing whether this liability instrument reflects multilateral treaty practice in addressing liability for damage to the environment or contains elements that contribute to the progressive development of international law in this field. To that end, this paper will first revisit the responsibilities that flow from the principle that the polluter must pay for the damage caused (Section 2). It will subsequently address the responsibility of states for internationally wrongful acts (Section 3), the responsibility of states for the injurious consequences of activities under their jurisdiction or control (Section 4), and the responsibility of the private sector for the injurious consequences of their activities (Section 5).

### 2. The Polluter-Pays Principle

The development of living modified organisms through biotechnology – as well as their use – will normally be a commercial activity. Such use may be contained in laboratories or controlled in field trials, or involve the release of the organisms into the environment for application in agricultural or industrial production-processes or products. Governments may, however, be involved in the development and use of living modified organisms. Such involvement may not only originate in commercial interests (state enterprises), but also in their sovereign interests, including military,\(^4\) food security, and public health interests.

The risks associated with living modified organisms have prompted governments to regulate their development and use for governmental and non-governmental purposes. In view of the expected socioeconomic benefits of the technology, there are governments which allow and encourage the application


\(^3\) On the negotiations, see further Chapter […].

\(^4\) E.g. 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction.
of the technology, e.g. through public research institutes. Other governments, however, have assessed that the risks for the environment and human health, in particular by releasing living modified organisms into the environment, outweigh any socio-economic benefits. The balancing of risks and benefits results in domestic policy choices to allow or prohibit the development and/or use of living modified organisms. When making such choices, a government will have to take into account its international obligations, including those under international trade law.

The conduct of any activity may cause damage or create a risk of causing damage to the interests of others. The level of damage and risk depends on the nature of the activity. The introduction of a new technology to conduct an activity tends to carry a higher risk, because the long-term effects cannot be assessed before gaining experience with the technology. The development and use of living modified organisms is considered to carry a potentially significant risk and has, therefore, been subjected to national and international procedures to assess the risks associated with the genetic modification of a living organism. When such a risk materializes, damage may be caused to the interests of others. Such damage may manifest itself as traditional damage to private goods, i.e. personal injury, property damage and economic loss. An example is damage incurred by an organic farmer as a result of the contamination of his organic crops by the crops of a neighboring farmer growing genetically modified crops. Claims for such traditional damages resulting from living modified organisms have been brought in several jurisdictions, in particular the United States and Canada. It may also take the form of damage to public goods, notably the environment and human health. An example is the loss of wild relatives by the spread of genetically modified crops and, notably, the costs of actions to prevent further loss or restore the loss; another example is the infection of people with an unintentionally released genetically modified virus and, notably, the costs of medical screening and/or inoculation following such release.

A potential legal basis to hold states liable for such damage is the principle that the polluter must pay for the pollution caused by him. This principle has an economic origin. Accordingly, operators must internalize the costs of pollution caused by their activities. The economic objective of the principle is an optimal allocation of the means of production and a maximum value of the production. It is, however, not clear whether the principle only applies to the person in control of the polluting activity or also to the state within whose control the activity is carried on. It could be argued that the application of the principle should be extended to the state within whose control the activity is carried on, because it can permit or prohibit the activity and, if it permits the activity, benefits from the activity through the contribution by that activity to its gross national product. According to such an extended application of the principle, a state must require operators within its jurisdiction or control to internalize the transboundary costs of their activities. In this form, the principle could be applied as a principle of international law that could be invoked by states if the external costs of activities within its jurisdiction

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or control, such as damage to third parties, are not internalized. However, the application of the principle at the international level is not supported by existing international instruments and case law.\(^7\)

3. The Responsibility of States for Internationally Wrongful Acts

International law imposes general and, as the case may be, specific rules on states regarding activities within their jurisdiction or control, including commercial activities. With respect to living modified organisms, specific rules are contained in the Cartagena Protocol on Biosafety for intentional and unintentional transboundary movements of living modified organisms. The rules of this Protocol are predominantly procedural in nature. The Protocol does not impose substantive obligations on exporting states with respect to intentional transboundary movements nor does international law contain any general rules on the export of technology and products to third states with the aim of preventing the occurrence of damage in such states.

With respect to unintentional transboundary movements, the Protocol requires states to take appropriate measures to prevent such movements (Art. 16.3 CPB). This provision reflects a general rule of international law that requires states to take appropriate measures to prevent activities within their jurisdiction or control from causing transboundary damage. This obligation binds all states by virtue of customary international law.\(^8\) Although the corresponding provision in the Protocol does not explicitly refer to a threshold of damage, it appears from its context that it subject to such a threshold. Response measures are only required if the release of a living modified organism leads or may lead to an unintentional transboundary movement that is likely to have “significant adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health” (Art. 17 CPB). This is also consistent with the interpretation of the general rule of international law which is reflected in several international instruments without an explicit reference to such threshold of damage.\(^9\)

The obligation to prevent unintentional transboundary movements of living modified organisms is a due diligence obligation. The objective of the obligation is the prevention of transboundary damage. States are required to exercise due diligence with the aim of achieving the objective, but a failure to achieve the objective will not automatically result in non-compliance with the obligation. Compliance with a due diligence obligation requires states to adopt, implement, supervise, and enforce policies and measures to achieve the objective,\(^10\) in this case policies and measures to prevent the release of a living


\(^9\) On the interpretation of the 1992 Rio Declaration on Environment and Sustainable Development (Principle 2) and the 1972 Stockholm Declaration on the Human Environment (Principle 21), see e.g. Lefeber 1996, at 86-89.

\(^10\) *Case Concerning Pulp Mills on the River Uruguay (Argentina v. Uruguay) (Judgment)* [2010] ICJ Reports, para. 197; Seabed Disputes Chamber of the International Tribunal for the Law of the Sea, *Responsibilities and*
modified organism that leads or may lead to an unintentional transboundary movement. Such policies and measures can only be designed on the basis of an assessment of the risk of the release of a living modified organism. This presupposes the introduction of mandatory risk-assessment procedures. The objective of such risk assessment is to identify and evaluate the potential adverse effects of the living modified organism in the likely potential receiving environment (cf. para. 1 of Annex III CPB). Since the level of risk is related to the nature of the organism, the nature of the genetic modification, the intended use of the genetically modified organism, and the likely potential receiving environment, risk assessments are to be carried out on a case-by-case basis (cf. para. 6 of Annex III CPB). Depending on the risks identified and the level of such risks, policies and measures must be established and maintained to regulate, manage and control the risks (see also Art. 16 CPB). In case the risk materializes, i.e. a release of a living modified organism that leads or may lead to an unintentional transboundary movement, such policies and measures must also provide for actions to address such an event, including the notification of affected states or potentially affected states and the provision of information to these states (see also Art. 17 CPB). If a state exercises the required degree of due diligence and significant transboundary damage nevertheless occurs, the obligation has not been breached.

Only the breach of a general or specific rule of international law through an act attributable to a state entails the responsibility of that state for an internationally wrongful act, including for damage that is caused by that act. Such breach is governed by the rules of general international law with respect to the responsibility of states for internationally wrongful acts.\(^\text{11}\) These rules permit the development of special rules on the responsibility for a specific internationally wrongful act, but this would require an agreement among negotiating states to deviate from the rules of general international law. Such agreement could not be reached in the negotiations on the Supplementary Protocol.\(^\text{12}\) It was agreed that this Protocol shall not affect the rights and obligations of states under the rules of general international law on state responsibility (Art. 11 SP).

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4. The Responsibility of States for the Injurious Consequences of Activities under Their Jurisdiction or Control

4.1 Introduction

In the absence of an internationally wrongful act or any other special rules of international law, damage can only be redressed by recourse to domestic law. In cases involving multiple jurisdictions, such recourse may be frustrated by procedural difficulties, such as the absence of a competent or appropriate forum or the denial of access to assets to satisfy claims on the basis of a foreign judgment, or substantive difficulties, such as the burden of proof. Such difficulties can only be overcome by international cooperation and such cooperation is warranted on the basis of the application of the polluter-pays principle at the international level (see Section 2). States should not walk away, or should not be able to walk away, from the responsibility that comes with the permission of activities within their jurisdiction or control that create a significant risk of causing domestic and transboundary damage. Hence, in order to fill the gap that would otherwise be left, additional obligations should be imposed on states for permitting such activities to be carried on within their jurisdiction or control. In the case of unintentional transboundary movements, the source state should be the subject of such additional obligations; in the case of intentional transboundary movements, both the exporting state and/or the importing state could be an appropriate subject of such additional obligations. Since the advent of new technologies, in particular after the Second World War, the international community has developed three approaches to impose such additional obligations on states and implement the polluter-pays principle at the international level: (a) the obligation of states to pay compensation; (b) the obligation of states to ensure prompt, adequate and effective compensation (civil liability approach); and (c) the obligation of states to ensure prompt, adequate and effective response measures (regulatory liability approach).

4.2 The Obligation of States to Pay Compensation

The most straightforward approach to address the injurious consequences of activities that create a significant risk of causing significant transboundary damage would be to require states to prevent the causation of such injurious consequences in absolute terms. This approach would render the causation of significant damage unlawful when the risk materializes and might give rise to claims to terminate the activity. In the aftermath of the occurrence of significant transboundary damage, it should always be assessed whether adjustments of the activity can be made to minimize the risk of future occurrences. However, states are not required under international law to terminate an activity within its jurisdiction or control if the activity only creates a risk of causing significant damage irrespective whether the risk has materialized or not. International law requires states to exercise due diligence with the aim of preventing significant transboundary damage, but does not require them to prevent significant transboundary damage in absolute terms. This does not necessarily exclude imposing an obligation on that state to pay compensation for the damage caused without labeling the activity or its injurious consequences as unlawful. Pursuant to this approach, the injurious consequences are allocated to the state within whose jurisdiction or control an activity is carried on. This state may recover the costs from private actors within its jurisdiction or control that carry on the activity.
Such an obligation to pay compensation has been imposed on states for damage caused on the surface of the Earth by activities in outer space.\textsuperscript{13} When this obligation was introduced in outer space treaties, in the late 1960s and early 1970s, outer space activities were predominantly carried on or procured by governments. However, these treaties are also applicable to damage caused by commercial outer space activities which have spread in recent years. There is no other treaty in force that imposes an obligation on states to pay compensation for the full amount of damage caused. The only other field where an obligation has been introduced for states to pay compensation relates to the peaceful use of nuclear energy. Nuclear liability conventions impose a primary obligation to pay compensation on the operator of the nuclear installation for damage caused by nuclear material in the installation or in transport.\textsuperscript{14} Only if payments by the operator up to the amount set by the conventions are insufficient to compensate the damage, the installation state is required to provide supplementary compensation.\textsuperscript{15}

In the absence of consistent state practice and a common \textit{opinio juris}, no customary obligation can be said to have emerged imposing an obligation on states to pay compensation for significant transboundary damage caused by activities carried on within their jurisdiction or control.\textsuperscript{16} States are also not willing to accept such an obligation as may be illustrated by the proposals to that end in the negotiations on damage resulting from transboundary movements of living modified organisms that gathered little support and provoked strong repudiations.\textsuperscript{17}

States have also been reluctant to accept a procedural approach to the payment of compensation for significant transboundary damage caused by activities within their jurisdiction or control. Pursuant to this approach, states would be required to negotiate a compensation arrangement with potentially affected states or affected states.\textsuperscript{18} Such an arrangement is ideally to be negotiated before the activity creating a significant risk of causing significant transboundary damage is permitted, but it could also be negotiated after the materialization of the risk. An obligation to negotiate a compensation arrangement has been introduced for damage caused by the non-navigational uses of international watercourses.\textsuperscript{19} This obligation, which is part of a treaty that is not in force, is to date the only multilateral example of this procedural approach.

4.3 The Obligation of States to Ensure Prompt, Adequate and Effective Compensation

Claims for damages caused by activities may be brought before domestic courts under domestic civil liability regimes and, in the case of transboundary damage, domestic conflict-of-laws rules. The law generally provides for the injurious consequences of damage to lie where it falls, unless the occurrence of damage is imputable, in the sense of wrongful conduct, to the source of the damage. Accordingly, domestic civil liability regimes are based on proof of fault of the defendant by the claimant, unless a special civil liability regime has been created that introduces strict liability or reverses the burden of proof. When a risk materializes in spite of the implementation of measures to regulate, manage and control such risks, it will be difficult for victims to prove wrongful conduct and the introduction of strict liability or the reversal of the burden of proof is therefore warranted for risk-prone activities. Strict liability regimes have, therefore, been introduced in domestic legal systems for a variety of activities that create a real or perceived significant risk of damage. In cases involving multiple jurisdictions, differences between domestic laws may still leave victims without compensation and/or impede economic development. With the dual aim of protecting victims and facilitating activities across borders, international agreements have been developed that harmonize substantive and procedural civil liability rules, in particular by imposing strict liability for specific risk-prone activities and addressing occurrences of damage involving multiple jurisdictions. These international agreements oblige states to introduce uniform and effective civil law remedies to address domestic and/or transboundary damage caused by such activities.

This approach has found recognition in principles, developed by the International Law Commission (ILC), on the allocation of loss in the case of transboundary harm arising out of hazardous activities. Hazardous activities are defined as those that have a high probability of causing significant transboundary damage or a low probability of causing disastrous transboundary damage. These Principles will, by definition, thus not apply to the development and use of living modified organisms. The release of living modified organisms into the environment, such as genetically modified crops for agricultural produce, is not likely to fall within the scope of this definition, as no government may be expected to approve such release if the risk-assessment reveals either a high probability of causing

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22 For an account of work by the International Law Commission on these principles, see UN Doc. A/61/10, 101. The United Nations General Assembly took note of the principles; see Principles on the allocation of loss in the case of transboundary harm arising out of hazardous activities, UN Doc. A/Res/61/36, Annex.

23 Commentary on Principle 1 of the Principles on the allocation of loss in the case of transboundary harm arising out of hazardous activities, para. 2.
significant transboundary damage or a low probability of causing disastrous transboundary damage. The concerns with respect to the release of these living modified organisms relate to risks not identified in a risk assessment and the correctness of the evaluation of the risk. Yet, the development of other living modified organisms will meet the requirements of the definition – the development of the genetically modified avian influenza virus in a maximum-security laboratory creates, without doubt, a low probability of causing disastrous transboundary damage. The Principles would in any event only apply to unintentional transboundary movements of living modified organisms, because the transboundary damage must have been caused by activities through their “physical consequences”.24 This means that the physical link must connect the activity with its transboundary effects. Damage resulting from intentional transboundary movements is thus not covered by these Principles.

One of the objectives of the ILC’s Principles is to ensure prompt and adequate compensation to natural or legal persons that are victims of transboundary damage (Principle 3(a)). In its commentary, the ILC adds that the Principles serve other objectives as well, including preserving and promoting the viability of economic activities that are important to the welfare of states and peoples.25 Pursuant to the Principles, states “should” take necessary measures to ensure that prompt and adequate compensation is available to victims (Principle 4.1). Some substantive and procedural standards have been formulated by the ILC to elaborate what these measures should be. On substance, it is provided that primary liability should rest with private persons and not with states; should not require proof of fault; should be covered by financial security; and, in appropriate cases, should be supplemented by industry wide funds at the national level (Principle 4.2-4.4). If such measures are insufficient to provide adequate compensation, states should ensure the allocation of additional financial resources (Principle 4.5). On procedure, it is provided that prompt, adequate and effective remedies must be made available to domestic judicial and administrative bodies to adjudicate claims arising out of transboundary damage caused by hazardous activities (Principle 6.1). Since the Principles only address transboundary damage, it is added that victims of transboundary damage should have access to remedies that are no less prompt, adequate and effective than those available to victims that suffer damage within the state in which the damage-causing hazardous activity is carried on (Principle 6.2).

Although the ILC’s approach to provide for prompt, adequate and effective compensation through effective civil law remedies finds support in international agreements that harmonize substantive and procedural liability rules, only a few of these agreements have entered into force, notably for the use of nuclear energy and the transportation of oil.26 Numerous other international special civil liability regimes are no longer expected to ever enter into force, such as those related to water-related industrial activities and the transboundary movement of hazardous wastes and their disposal.27 Although differences were overcome during long and intense negotiation processes preceding their adoption, negotiating states either accepted the agreement without the intention of becoming a party

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25 Commentary on Principle 3 of the Principles on the allocation of loss in the case of transboundary harm arising out of hazardous activities, para. 10.
26 See footnote […].
27 See footnote […].
or encountered legal and/or policy difficulties when considering implementation of these agreements in domestic law.

This poor record of international special civil liability regimes was an important reason that no consensus could be achieved on the development of such a regime for damage resulting from transboundary movements of living modified organisms. Although elaborate text proposals on civil liability were submitted and discussed, the negotiations on civil liability resulted in a process solution (Art. 12.2 SP). Although this solution falls short of imposing an obligation on parties to ensure prompt, adequate and effective compensation for damage caused by transboundary movements of living modified organisms, it requires a state to pay serious attention to the regulatory framework for such compensation when it considers becoming a party to the Supplementary Protocol. At that time, a state will have to determine whether (a) existing civil law remedies provide “adequate rules and procedures” for personal and material damage or (b) additional civil law remedies are required to redress such damage. Although the scope of this provision is limited to personal and material damage that is associated with “adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health” (Art. 2.2(b) SP), it may be expected that the parliamentary approval processes in many states will involve a comprehensive assessment and discussion of domestic law related to personal injury, property damage and economic loss (traditional damage) caused by living modified organisms.29

4.4 The Obligation of States to Ensure Prompt, Adequate and Effective Response Measures

Obliging states to ensure prompt, adequate and effective compensation may be suited for addressing damage to private goods (traditional damage), but is less so for addressing damage to public goods, notably the environment. Although scientifically sound models could be designed to determine the monetary equivalent for irreversible environmental loss, e.g. by determining the discounted value of future ecosystem services, the award of compensation is not likely to produce an optimal solution to redress such loss. First, the valuation of irreversible environmental loss in monetary terms is surrounded by uncertainties that will be inherent in any model that seeks to incorporate future uses of a specific environmental component – there is currently no such internationally agreed model available. Second, the rigorous application of such models is likely to result in awards that are beyond the financial capability of the liable person. Third, the value of an environmental component cannot always be reflected in a price, because it is indispensable for people to survive, e.g. the availability of water resources. Fourth, the award of compensation necessitates the identification of a beneficiary and raises the question of guidance for the allocation of financial resources to environmental or other purposes.

29 On civil liability in the Supplementary Protocol, see further Chapter [...].
Yet, it can be done and has been done, as may be illustrated by the awards of the United Nations Compensation Commission addressing environmental claims.\(^\text{30}\)

The award of compensation only emerges as a remedy when prevention of a loss-causing event has failed and, under such circumstances, it should only be resorted to when restoration of the *status quo ante* is not possible. In the event of environmental loss, or threat of loss, the environment benefits most from the avoidance of loss or further loss, or the restoration of the loss. If the loss is irreversible, the *status quo ante* can be approached through restoration by equivalent. This can be achieved through the replacement of the lost components by other components for the same use or a similar type of use at the same location or an alternative location. In international law, the primacy of restoration over compensation to address the injurious consequences of an internationally wrongful act is well-established.\(^\text{31}\) The internationally agreed objective to protect and preserve the environment also favors alternatives for the award of compensation for environmental loss. Such an alternative has emerged and was referred to in the negotiations on the Supplementary Protocol as an administrative approach to liability – it is also known as regulatory liability. This approach requires the implementation of response measures in the event of environmental loss or threat of loss in order to avoid loss or further loss, or to restore the loss. The primary responsibility for the implementation of such response measures should rest with the polluter. If the polluter fails to implement response measures or if the urgency of the situation requires the immediate implementation of such measures, a third person should be entitled, or even obliged, to implement response measures. Such a third person could be the state under whose jurisdiction or control the loss occurs; any state if the loss occurs in an area beyond the limits of national jurisdiction; a private actor that is geographically in the best position to implement response measures; or a private actor that has an interest in the protection and preservation of the environment. Finally, the recovery of the costs of response measures from the polluter by such third person should be facilitated.

This alternative approach has also found recognition in the ILC’s Principles on the allocation of loss in the case of transboundary harm arising out of hazardous activities. The protection and preservation of the environment in the event of transboundary damage is one of the objectives of these Principles (Principle 3(b)). The Principles require the state under whose jurisdiction or control a hazardous activity is carried on to ensure that appropriate response measures are taken upon the occurrence of an incident involving that activity which results or is likely to result in transboundary damage (Principle 5(b)); and the states affected or likely to be affected by the transboundary damage are required to take all feasible measures to mitigate and if possible to eliminate the effects of such damage (Principle 5(d)).\(^\text{32}\)

The ILC’s approach to ensure prompt, adequate and effective response measures is supported by developments in international law, including the conclusion of international agreements. At first, such

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\(^{31}\) Articles Responsibility of States for Internationally Wrongful Acts (Art. 35); see also commentary on Article 35 of the *Draft Articles on State Responsibility, Yearbook of the International Law Commission* 2001, Vol. II, Part Two, at 96 (para. 3).

\(^{32}\) Commentary on Principle 5(b) of the *Principles on the allocation of loss in the case of transboundary harm arising out of hazardous activities*, paras 3-8; and commentary on Principle 5(d), para 10.
regulatory measures were incorporated in special civil liability regimes as incidental provisions.\textsuperscript{33} These provisions are generic and do not provide for detailed arrangements on the implementation of response measures. They typically oblige persons in operational control to adopt measures to mitigate damage or a threat of damage. It was only in 2005 that the first international agreement with a primary focus on response measures was concluded, namely Annex VI to the Protocol on Environmental Protection to the Antarctic Treaty on Liability Arising from Environmental Emergencies. It had appeared in the negotiations on this agreement that, on the one hand, the protection and the preservation of the environment was the primary objective of the negotiations and, on the other, no agreement could be reached on the conclusion of a comprehensive special civil liability regime.\textsuperscript{34} After many years of unsuccessful negotiations, the negotiators moved away, for the time being, from the development of a special civil liability regime that would also address traditional damage and, instead, focused on addressing environmental loss through the introduction of regulatory liability. The scope of this agreement is modest. It only provides for response measures in the event of an environmental emergency to avoid loss or further loss; in particular, it does not provide for restoration measures.

Thus, the regulatory approach to liability is reflected in incidental provisions in a number of international agreements and only in one international agreement in a prominent way; this latter agreement is not in force, is regionally confined, only involves a limited number of states, and only introduces measures to avoid loss or further loss resulting from environmental emergencies. Hence, it cannot be said that a customary obligation of states has emerged to ensure the implementation of prompt, adequate and effective response measures in case of environmental loss or threat of such loss. Of course, this does not prevent the introduction of this obligation in new international instruments. The launch of the negotiations on damage resulting from the transboundary movement of living modified organisms coincided with the adoption of Annex VI and a directive on environmental liability by the European Union that introduces regulatory liability.\textsuperscript{35} Proposals tabled in the negotiations that captured this alternative approach to liability for damage to the environment logically ensued from the adoption of these instruments.\textsuperscript{36} It appeared subsequently that this approach was the only option for the


\textsuperscript{34} This paradigm shift in the focus of the negotiations is rooted in the personal report that the chairman of the negotiations on liability issued during the twenty-third Antarctic Treaty Consultative Meeting (ATCM); see \textit{Personal Report of the Chairman of the Liability Discussion in WG1}, ATCVM XIII, Working Paper 041 (1999).


adoption of a legally binding instrument. Eventually, the negotiating states agreed to “work towards” a legally binding instrument on regulatory liability that would include an article on civil liability.\(^\text{37}\) This work resulted in the adoption of the Supplementary Protocol.

The Supplementary Protocol provides for regulatory liability. It requires states to ensure that response measures are taken in the event of damage or a sufficient likelihood of damage caused by activities falling within its scope (Article 5). The definition of ‘response measures’ is broad and covers (a) measures to prevent further adverse effects or, in the case of a sufficient likelihood of damage, any adverse effects; and (b) measures to return to baseline conditions or an equivalent alternative (Article 2(d)). The definition of ‘damage’ is limited to adverse effects on the conservation and sustainable use of biological diversity that is measurable or otherwise observable and considered significant on the basis of a list of factors, including the long term or permanent change; the extent of the qualitative or quantitative changes; the reduction of the ability to provide goods and services; and the extent of any adverse effects on human health (Article 2(b)). The response measures consist of obligations of the person in control of the living modified organism (operator) and the competent authority. The responsible operator must be required to: (a) immediately inform the competent authority; (b) evaluate the damage; and (c) take appropriate response measures in the event of damage or a sufficient likelihood that damage will result if timely response measures are not taken (Arts. 5.1 and 5.3). The competent authority is required to: (a) identify the operator; (b) evaluate the damage; and (c) determine which response measures should be taken by the operator (Art. 5.2). The competent authority may also implement appropriate response measures and recover the costs from the operator (Arts. 5.4 and 5.5). The decisions of the competent authority are subject to procedural safeguards, including administrative or judicial review (Art. 5.6).\(^\text{38}\) The Supplementary Protocol does, however, not provide for cross-border enforcement of such decisions.

It appears from the Supplementary Protocol that a large number of other issues were identified and considered relevant in the context of a regulatory liability regime. The Supplementary Protocol does not provide for harmonization in respect of these issues, but leaves discretion to the parties whether and how to address them in domestic law. These issues include the identification of the operator (Art. 2(c)); the right of the operator to invoke exemptions (Art. 6); time limitation of liability (Art. 7); financial limitation of liability (Art. 8); and the establishment and maintenance of financial security by the operator (Art. 10). There was no agreement to harmonize these issues and the only agreement that could be reached was to forego harmonization. The identification of these issues in the Supplementary Protocol and the attribution of discretion to parties to address them in domestic law were nevertheless essential. Leaving these issues out of the Supplementary Protocol could be interpreted as a rejection of a party’s right to address the issue in domestic law. It may also reflect the novelty and complexity of the new approach to address liability for damage to the environment and, as in the case of the Supplementary Protocol, damage to biological diversity.\(^\text{39}\)

\(^{37}\) See Liability and redress under the Cartagena Protocol on Biosafety, Decision BS-IV/12, Annex.

\(^{38}\) On regulatory liability in the Supplementary Protocol, see further Chapter [...].

\(^{39}\) On this issue, see further Chapter [...].
5. The Responsibility of the Private Sector for the Injurious Consequences of their Activities

In an international community dominated by states with exclusive territorial sovereignty, the exercise of jurisdiction with respect to natural and legal persons, or their assets, in another state is impeded by legal and practical difficulties. In the event of civil liability, judgments of domestic courts and tribunals are not automatically recognized and enforced in other states in the absence of an international agreement. In the event of regulatory liability, administrative decisions related to response measures can only be recognized and enforced in other states on the basis of an international agreement. Since states are reluctant to assume liability for damage caused by activities carried on by private actors within their jurisdiction or control (Sections 3 and 4.2), or to harmonize domestic liability regimes in whole or part (Sections 4.3 and 4.4), effective remedies to address damage resulting from transboundary movements may not be available. To demonstrate corporate social responsibility and to facilitate intentional transboundary movements, the private sector should consider resorting to self-regulation to address such claims.

In the negotiations concerning liability and redress in the context of the Cartagena Protocol on Biosafety, the private sector did not only actively participate in the intergovernmental negotiations, but also developed a proposal for self-regulation. This proposal eventually evolved into a contractual mechanism for response in the event of damage to biological diversity caused by the release of a living modified organism (Compact). The membership consists of six companies with large market shares in the agricultural biotechnology market, but is open to other entities that meet the conditions of membership. This private-sector initiative was “noted” in the decision by which the Supplementary Protocol was adopted.

A member is contractually bound to respond under the terms of the Compact if the release of a living modified organism into the environment by that member causes damage to biological diversity irrespective of the place of release and the place of damage. States are third-party beneficiaries of the Compact with the right to bring claims under a claims process that provides for recourse to binding arbitration under the auspices of the Permanent Court of Arbitration. States may seek the implementation of remediation measures and/or monetary compensation in specified situations. A member may avail itself of a number of exemptions, limitation of liability in time, and limitation of liability in amount. Each member is required to demonstrate their financial capacity to meet their financial obligations under the Compact, including by proof of self-insurance.

The Compact is not intended to be an alternative to domestic regulatory liability regimes. Although the Compact precludes the multiple recovery of damage and the simultaneous pursuit of claims under the Compact and domestic law, it provides states with an option that is complementary to the Supplementary Protocol and domestic law implementing the Supplementary Protocol or otherwise providing for regulatory liability. And it may be the only option for states if the damage cannot be recovered on the basis of domestic law, including cases where a Compact member does not have any or

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40 For the text of The Compact, as first amended on 19 November 2010, see [www.biodiversitycompact.org](http://www.biodiversitycompact.org).
41 International rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, Decision BS-V/11, Preamble.
42 On the Compact, see further Chapter [...].
sufficient assets in that state. Furthermore, the Supplementary Protocol and the Compact were both finalized in 2010, but only the Compact is currently and universally operational.

The provisions of the Compact addresses issues in much more detail than the Supplementary Protocol which will need to be implemented in domestic law to make it operational. In some respects, the Compact is more restrictive than the Supplementary Protocol (it does not address threats of damage) and in other respects it may be more restrictive than domestic law (it provides for exemptions; limitation in amount; limitation in time; and rules on the standard of proof). However, in other respects, it is more progressive than the Supplementary Protocol (it provides for monetary compensation; compulsory financial security; and action to develop commercial insurance).

It thus appears that the Compact fills a regulatory gap that states have not been able to fill, but it should be borne in mind that the rules were set by the private sector. An opportunity was provided to states and other stakeholders, including civil society, to comment on draft texts in regional dialogues and these comments resulted in significant improvements of the original text. Yet, there were red lines that could not be crossed, notably on the standard of proof, defenses, time limits, and financial limits. Be that as it may, the Compact is a unique demonstration of corporate social responsibility that may become an innovative model for addressing damage to the environment.

6. Conclusion

The parties to the Cartagena Protocol on Biosafety demonstrated their responsibility for the protection and preservation of the environment by adopting the Supplementary Protocol. The Supplementary Protocol is the first global and comprehensive agreement providing for regulatory liability and a definition of damage to biological diversity. It is global as states from all United Nations regions participated in its development. It is comprehensive as response measures include avoidance as well as restoration of damage, and must be implemented to address damage arising from environmental emergencies as well as damage with a slow onset.

Although states have the right to provide for regulatory liability without an international agreement, the Supplementary Protocol requires its parties to implement it in domestic law. By voluntarily assuming a binding obligation to provide for prompt, adequate and effective response measures in the event of damage caused by the transboundary movement of living modified organisms, states expressly accept the responsibility that comes with their consent to the import of living modified organisms. By adhering to and implementing the Supplementary Protocol, states give effect, at the international and national level, to the principle that the polluter must pay for the injurious consequences of activities under their jurisdiction or control that create a significant risk of significant damage. The Supplementary Protocol contributes to filling the gap in international law with respect to addressing damage involving multiple jurisdictions.

The Supplementary Protocol only fills the gap in part though. It only covers damage to biological diversity and not also traditional damage as intended by the states pushing for a liability regime at the time of adoption of the Cartagena Protocol on Biosafety. This limited approach finds justification in the

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43 Dialogues were held in Asia (Singapore in January 2009 and the Philippines in January 2010), America (Costa Rica in June 2009), Europe (Belgium in November 2009), and Africa (Kenya in August 2010).
objectives of the Convention of Biological Diversity and the Cartagena Protocol on Biosafety, but there is no legal impediment to address traditional damage in a liability instrument in the context of these Conventions. But a regulatory liability regime is not suited to address traditional damage: this type of damage needs to be addressed through a civil liability regime.

Furthermore, the Supplementary Protocol places the responsibility for the implementation of response measures on the importing state. This was also not the intention of the states pushing for a liability regime at the time of adoption of the Cartagena Protocol on Biosafety. These states aimed at channeling liability to the developers of living modified organisms and, hence, at requiring exporting states imposing liability on the developers for damage caused by their products. The importing state may be in a better position to assess the impact of a living modified organism on the receiving environment, but its knowledge of the risks of the technology is likely to be limited and depends on its capacity to review risk-assessments. The state of import may require a foreign developer to implement response measures under its domestic law, but the Supplementary Protocol does not provide for the transboundary recognition and enforcement of decisions related to response measures. Since the Compact allows for recourse against foreign developers, it adds value to the Supplementary Protocol.

Whether the regulatory liability approach to address damage to the environment will be successful depends on the entry into force of and the adherence to the Supplementary Protocol as well as the future applications of this approach. The functional scope of the Supplementary Protocol is limited as it only addresses damage to biological diversity resulting from transboundary movements of living modified organisms. Regulatory liability is suited for application to other activities and/or types of damage. It could, for example, be introduced for: (a) damage to biological diversity caused by other activities, such as the transboundary movement of invasive alien species, under the Convention on Biological Diversity; 44 (b) damage to the environment under other multilateral environmental agreements; or (c) other types of damage, such as public health costs resulting from unexpected negative effects of the introduction of medicines.

The adoption of the Supplementary Protocol originates in regional and domestic precedents. It may therefore not have been a paradigm change in addressing liability for damage to the environment, but it is certainly part of a ‘paradigm evolution’ of international liability law. In times when harmonization of domestic civil liability regimes is not, or is no longer, an acceptable option for many states to address liability for damage involving multiple jurisdictions, developing and agreeing on an alternative approach to address the common concern of preventing and restoring damage to the environment is a paradigm change. Yet, it remains to be seen whether the regulatory liability approach will survive and evolve further to become a sustainable approach to address liability and redress for damage to the environment.

44 It may be noted that Article 14.2 CBD calls for the examination, on the basis of studies to be carried out, of the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter; for the latest development, see Decision IX/23 (2008) of the Conference of the Parties.