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Liability and Redress in the Context of the Cartagena Protocol on Biosafety

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This article outlines and discusses the key elements of the draft Supplementary Protocol on Liability and Redress in the context of the Cartagena Protocol on Biosafety, tabled for adoption at the fifth Session of the Meeting of the Parties to the Biosafety Protocol to be held in October 2010 in Nagoya, Japan. The first section describes the role of liability and redress under the Biosafety Protocol, followed by an overview of the draft Supplementary Protocol's key elements. The subsequent section looks at outstanding issues and the final section gives an outlook on the Supplementary Protocol's adoption and ratification requirements and its potential impact and effectiveness.

INTRODUCTION

One of the main issues to be addressed by the fifth meeting of the parties (COP/MOP-5) to the Cartagena Protocol on Biosafety (the Biosafety Protocol)[1] – to be held in conjunction with the tenth Conference of the Parties of the Convention on Biological Diversity in October 2010 in Nagoya, Japan – is the adoption of an international instrument on liability and redress for damage arising out of the transboundary movements of living modified organisms (LMOs).[2] This instrument will close the final remaining gap in the legal make-up of the Protocol and will be an important element for the Protocol's effective implementation.

The Biosafety Protocol is the main international instrument addressing the risks and possible damages to the environment arising out of modern biotechnology. Specifically, the Protocol addresses the safe transfer, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, with a specific focus on transboundary movements. It establishes an advance informed agreement procedure for imports of LMOs for intentional introduction into the environment. The Protocol builds on the precautionary approach referenced in Principle 15 of the Rio Declaration[3] and includes mechanisms for risk assessment and risk management, provisions on information exchange, capacity building, and financial resources. The Protocol came into force on 11 September 2003 and, as of July 2010, there are 159 parties to the Protocol.

When the Protocol was originally adopted in 2000, the issue of liability and redress was left outstanding due to opposing positions regarding the need for such rules and whether they should be legally binding. Instead, the Protocol included a mandate to elaborate 'international rules and procedures' in the field of liability (Article 27), which was to be concluded within four years of the Protocol's coming into force, the deadline therefore being COP/MOP-4 in 2008. Despite five meetings of an intersessional working group on liability and redress and numerous regional consultations, no regime on liability and redress could be adopted in 2008, and the negotiations had to be extended beyond the original deadline. Since then, three additional meetings in the format of a Friends of the Co-Chairs Group led to the elaboration of a 'draft Supplementary Protocol on liability and redress for damage arising out of the transboundary movement of living modified organisms to the Cartagena Protocol on Biosafety'. While some issues remain outstanding, the draft Supplementary Protocol has the support of most parties, and delegates are optimistic that the Supplementary Protocol will be adopted at COP/MOP-5.

Liability and redress in the context of the Biosafety Protocol refers to damage occurring in the context of the activities addressed by the Protocol. An international regime on liability and redress would thus regulate how to address damage arising during transboundary movements of LMOs – such as the import of genetically modified seeds – and establish rules and procedures for determining liability, analysing risks and extent of damage and response measures to remedy and compensate damage or prevent damage from occurring. There are currently no international rules and procedures that specifically address issues of

[1] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Montreal, 29 September 2000).

[2] The Biosafety Protocol defines LMOs as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'; see ibid., Article 3.

[3] Rio Declaration on Environment and Development (A/CONF.151/26, 14 June 1992), Vol. I, Chapter I, Annex I, Principle 15.

transboundary damage or liability and redress for such damage. Whether or not countries that suffer damage have recourse against operators from other countries depends on the domestic legislation of these countries. The Supplementary Protocol on liability and redress would provide for a two-tiered approach towards establishing international rules and procedures for holding operators or importers liable for damage arising from the transboundary movement of LMOs: first, an administrative approach, requiring parties to the Supplementary Protocol to establish a competent national authority to monitor transboundary movements of LMOs, evaluate damage and threats of damage, and take adequate and timely response measures or require operators to take such measures; second, the draft text also contains an enabling provision that allows parties to address damage from LMOs through their civil liability systems or to establish specific civil liability systems for that purpose. The Supplementary Protocol deals with holding operators or private entities liable; cases in which damage cannot be recovered through those channels would be covered by subsidiary State liability.

This article gives an overview of the Supplementary Protocol's main elements, including its scope and the core provisions of the two-tired legal approach, as well as outstanding issues. On each of these elements we explain the positions of the main negotiating groups. We also analyse what the potential impact of these provisions will be and how they can be operationalized in order to support the effective implementation of the Biosafety Protocol.

LIABILITY AND REDRESS IN THE CONTEXT OF THE BIOSAFETY PROTOCOL

The main function of liability and redress in the context of international environmental law is to provide for response measures and restitution in the case of certain activities causing damage to the environment. In addition, regimes for liability and redress contribute to preventing damage by exposing operators to financial liability, thus inducing them to adopt measures that minimize risks of damage. Liability and redress therefore not only serves to enforce environmental rules that envisage implementation of the polluter pays principle, it can also be used as a mechanism to prevent damage from occurring.[4] The latter function is particularly relevant since the Biosafety Protocol also embodies the precautionary approach. In accordance with the approach, effective rules and procedures for liability and redress would both strengthen the Protocol's objective to prevent damage to the environment and provide for compensation and environmental restoration in cases where damage has occurred.

Throughout the negotiation of the Biosafety Protocol, the issue of liability and redress, at that time referred to as liability and compensation, had been one of the key issues of disagreement marked by a broad North–South divide over the need for, and nature of, international rules in this field. Southern countries generally supported legally binding international rules, and while their individual positions with regard to the exact procedures to be established differed, they agreed that addressing the issue purely under national law would be inadequate. Developed countries generally opposed any provision for liability within the Biosafety Protocol. As the negotiations drew to a close, liability and redress turned out to be the only remaining obstacle to the Protocol's adoption, thus jeopardizing the consensus that had been achieved on numerous other issues. At this point, the global South made the major concession to agree to defer the issue to a later date.[5] To fulfil the mandate laid out in Article 27 (Liability and Redress), COP/MOP-1 (February 2004) established a Working Group on Liability and Redress with a mandate to analyse general issues, potential and actual damage scenarios and situations in which international rules and procedures on liability and redress may be needed, as well as elaborate options for elements of such rules and procedures (Decision BS-I/8).[6]

The group met five times between 2005 and 2008. The first meeting focused on the review of relevant information including scientific analysis, risk assessments and State responsibility for international liability, as well as options for international rules and procedures on liability and redress. Throughout the remaining four meetings of the Working Group, delegates considered various versions of proposed operational texts compiled on the basis of parties' submissions and views. While these meetings achieved considerable progress in elaborating the elements of an international regime, delegates did not reach common ground on key questions, including whether such a regime should be legally binding and what legal approach the instrument should take. The latter point was a source of particular controversy as most developing countries called for a legally

[4] For a discussion of liability and redress for biotechnology, see P. Cullet, 'Liability and Redress for Modern Biotechnology', in O.K. Fauchald and J. Werksman (eds), *Yearbook of International Environmental Law*, Vol. 15 (Oxford University Press, 2006), 4.

[5] See C. Bai *et al*., 'Report of the Fifth Session of the Open-Ended *Ad Hoc* Working Group on Biosafety: 17–28 August 1998', 9:108 *Earth Negotiations Bulletin* (1998); and C. Bai *et al*., 'Report of the Sixth Session of the Open-Ended *Ad Hoc* Working Group on Biosafety and the First Extraordinary Session of the CBD Conference of the Parties: 14–23 February 1999', 9:117 *Earth Negotiations Bulletin* (1999).

[6] Establishment of an Open-Ended *Ad Hoc* Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Protocol (CBD COP/MOP Decision BS-I/8, 27 February 2004).

binding regime based on a civil liability approach, which was strongly opposed by the great majority of developed countries, which instead introduced the concept of international rules to implement a domestic administrative approach. As described below, this conflict mirrored the fundamental disagreements that had already haunted the negotiations of the Biosafety Protocol and it continued to be the major stumbling block until the very end of the process.

Because of these fundamental disagreements, COP/MOP-4 (May 2008), which was originally mandated to complete the negotiations, was unable to adopt an international regime. The meeting did, however, produce a basic compromise to negotiate 'a legally-binding instrument focusing on an administrative approach, but including a provision on civil liability that will be complemented by non-legally-binding guidelines on civil liability'.[7] This formula allowed overcoming the main deadlock regarding the approach to adopt; nevertheless it took three additional meetings in the informal setting of a Friends of the Co-Chairs Group – a setting that had proven to be efficient during the COP/MOP – to negotiate a draft Supplementary Protocol for adoption at COP/MOP-5. In this setting, each UN region only has a certain number of representatives who can negotiate, while others are allowed in the room unless the meeting is closed to observers. Closed meetings were held during COP/MOP-4, as well as during the last two of the Friends of the Co-Chairs meetings in order to hammer out compromises on the most controversial issues. Again the deliberations on the provision on civil liability, although the least substantive, proved to be the most contentious and time-consuming. The third meeting of the Friends of the Co-Chairs Group eventually developed compromise language on this provision and thus removed the major obstacle towards the Supplementary Protocol's adoption at COP/MOP-5. The Friends of the Co-Chairs Group will meet again for three days preceding the COP/MOP in Nagoya to iron out the last remaining issues.

NATURE OF THE INSTRUMENT

It was clear from the outset that much of the impact of an international regime on liability and redress would be determined by its legal nature, i.e. whether its provisions will be legally binding or whether parts will be voluntary guidelines. Over the course of the negotiations, the Working Group had discussed a number of options, including a set of voluntary guidelines and model contractual clauses, an amendment to the Biosafety Protocol that would be immediately binding for all Protocol parties, and a Supplementary Protocol to the Biosafety Protocol, which would have to be adopted and ratified separately. Delegates eventually opted for a Supplementary Protocol, which will become binding only for those parties that decide to ratify it. The advantage of this approach is that every party can decide for itself whether it will be in its interest to ratify the Supplementary Protocol or not. This increases the chance for the Supplementary Protocol's adoption during COP/MOP-5. The separation into a self-standing instrument also avoids deterring countries that are in the process of ratifying the Biosafety Protocol and may have concerns about legally binding provisions on liability and redress.

On the other hand, the approach bears several risks. It could take a prolonged period of time to satisfy the minimum participation clause required for the entry into force of the Supplementary Protocol, which is currently suggested to be 40 parties. Although parties are generally negotiating in good faith and indicating their will to ratify the protocol, administrative procedures and changing political priorities could lead to a substantial delay. Another risk is that only a certain group of countries might ratify and implement the Supplementary Protocol, such as developing countries or LMO-importing countries only. This could considerably weaken the regime's effectiveness, since it is unclear how countries would enforce claims against countries that are parties to the Biosafety Protocol, but not to the Supplementary Protocol on liability and redress. While there is no doubt that the decision for a Supplementary Protocol has contributed to resolving the deadlock in the negotiations, there is still large uncertainty as to when the Supplementary Protocol will come into force and how effective it will be.

SCOPE

The coverage of the regime is determined by two components: the delimitation of the scope and the definition of the types of damage to which it applies. The delimitation of scope is composed of functional scope (activities and actions to which the regime applies), geographical scope (territorial area in which damage has to occur to be subject to liability and redress), subject matter (the definition of LMOs and related materials that could give rise to damage), and several limitations, such as limitations in time and limitation to the liability of operators from countries that are not parties of the Supplementary Protocol or the Biosafety Protocol. In general, the definitions of scope and damage should follow the respective provisions of the Biosafety Protocol. However, many of these are sufficiently vague to allow for different interpretations. In

[7] A. Appleton *et al.*, 'Fourth Meeting of the Parties to the Cartagena Protocol on Biosafety', 9:436 *Earth Negotiations Bulletin* (2008), at 8–9.

other cases, the coverage implied was unacceptable for certain parties, resulting in protracted debates on scope and related definitions.

The functional scope is determined in the draft Supplementary Protocol, Article 3,[8] which specifies that the Supplementary Protocol applies to damage to the conservation and sustainable use of biological diversity, taking also into account risks to human health resulting from transport, transit, handling and use of LMOs which find their origin in transboundary movement. The scope of liability and redress is limited to damage to conservation and use of biodiversity, thus excluding traditional damage. This language is a compromise arrived at between advocates of a broad scope, which would have also included activities in contravention of the Biosafety Protocol, and those suggesting a narrow scope limited to damage caused directly during the transport of LMOs across boundaries.[9] The compromise text includes indirect damage and damage occurring with a certain time delay – a key characteristic of damage from LMOs which may occur years or even decades after their release into the environment.[10] The Supplementary Protocol also covers unintentional and illegal transboundary movements, as referred to in the Biosafety Protocol, Articles 17 (unintentional transboundary movements and emergencies) and 25 (illegal transboundary movements).

The scope is also limited through the definition of damage (Article 2.2(c)), which refers to 'an adverse effect on the conservation and sustainable use of biological diversity', taking also into account risks to human health, which is 'measurable by a scientifically recognized method', and 'significant'. Significance is to be determined on the basis of factors such as the long-term or permanent change that will not be redressed through natural recovery; extent of qualitative and quantitative impacts on components of biodiversity and their ability to provide goods and services; and the extent of adverse affects on human health (Article 2.3). This definition underlines the exclusion of traditional damage and establishes hard criteria for determining damage to the environment. While the criteria as such are necessary and not overly restrictive, they place a substantial burden on the claimant. This burden has been subject to extended debate, since many developing countries currently lack the capacity to provide adequate and timely proof of damage.

With regard to non-parties of the Supplementary Protocol, Article 3.5 states that domestic legislation implementing the Supplementary Protocol shall also apply to damage resulting from transboundary movements of LMOs from non-parties. With regard to limitations in time, Article 3.6 states that the Supplementary Protocol will apply to movements that started after its entry into force in the importing country.

Related to the issue of scope was also the discussion on the concept of 'imminent threat of damage', which would allow the competent authority of an importing country to require the operator to take response measures in cases when there is reason to believe that such damage will occur if response measures are not taken. The inclusion of this notion was supported by the EU, the African Group[11] and a number of other developing countries to take into account the precautionary approach embodied in the Biosafety Protocol (Preamble and Article 1). Known from several other multilateral instruments in which the notion forms an integral part of provisions on liability for damage to the environment, its aim is to impose an obligation to take measures that may be necessary to prevent, mitigate or eliminate grave and imminent danger.[12] A number of countries, mostly from Latin America, but also including Canada, New Zealand and Australia, feared that the inclusion of the notion could be used to erect trade barriers against the import of LMOs. Others raised concerns about the broad application of the concept which left it unclear what kinds of preventive measures could

[8] For the draft text of the Supplementary Protocol on liability and redress, see *Report of the Third Meeting of the Friends of the Co-Chairs on Liability and Redress* (UNEP/CBD/BS/GF-L&R/3/4, 19 June 2010), Annex, available at <http://www.cbd.int/doc/meetings/bs/bsgflr-03/official/bsgflr-03-04-en.doc>.

[9] G.S. Nijar *et al*., *Liability and Redress under the Cartagena Protocol on Biosafety: A Record of the Negotiations for Developing International Rules* (CEBLAW, 2008), at 43.

[10] See P. Cullet, n. 4 above, at 3; and CBD Secretariat, *Determination of Damage to the Conservation and Sustainable Use of Biological Diversity, Including Case Studies* (UNEP/CBD/BS/WG-L&R/2/INF/3, 1 February 2006), at 3, available at <http://www.cbd.int/doc/meetings/bs/bswglr-02/information/bswglr-02-inf-03-en.doc>.

[11] Negotiating coalitions changed over the process, with the EU and the African Group, respectively, being the most stable. The EU includes all EU members and some of the acceding States. The EU was represented by the European Commission, which has the mandate to speak on biosafety issues. Other industrialized countries did not negotiate as a group. The African Group includes all of the African region, although South Africa took a separate position on a number of issues. Throughout the process, Ethiopia, Uganda, Egypt and Liberia were the main speakers of the African Group. Asian developing countries were represented by Malaysia, India and occasionally others, but did not form a firm group. The Group of Latin America and Caribbean (GRULAC) was split on a number of key issues. This is in part due to the fact that a number of countries in the region are increasingly involved in the biotechnology industry. Countries such as Mexico, Brazil, Colombia, Argentina, Panama, Peru and Chile often took a more moderate position in general and opposed some of the key demands of other developing countries with regard to scope and civil liability. This also impacted on the ability of Group of 77 and China (G-77/China) to be organized in the liability and redress negotiations, although the group had previously proven effective in the biosafety negotiations. Since the group was split on the issue of civil liability, a smaller like-minded group in support of a civil liability regime formed at COP/MOP-4.

[12] CBD Secretariat, *The Concept of Imminent Threat of Damage and its Legal and Technical Implications* (UNEP/CBD/BS/GF-L&R/3/INF/2, 29 April 2010), at 2–5, available at <http://www.cbd.int/doc/meetings/bs/bsgflr-03/information/bsgflr-03-inf-02-en.doc>.

be required by the competent authority.[13] A compromise was found by including a provision addressing situations of 'sufficient likelihood of damage' in the article on response measures (Article 5). The article states that 'parties shall require operators to perform response measures, such as informing the competent authority, valuating damage and taking appropriate measures to prevent, minimize, contain, mitigate, or otherwise avoid damage'. Response measures also include measures to restore biological diversity or to replace loss of biodiversity with other components of biodiversity for the same or another type of use.[14] In addition, Article 5 states that, 'where relevant information indicates that there is a sufficient likelihood that damage will result if timely response measures are not taken, the operator shall be required to take appropriate response measures so as to avoid such damage'. While this solution does incorporate the precautionary approach to a certain extent, in the end result it is weaker than if imminent threat of damage were addressed as a self-standing concept.

CIVIL LIABILITY VERSUS ADMINISTRATIVE APPROACH

The discussion on which legal approach the international regime should take turned out to be the most contentious issue of the negotiations. Since the adoption of the Biosafety Protocol, developing countries had taken a very strong position in favour of an international regime based on civil liability. Such an approach would build on domestic judicial systems by establishing international requirements for addressing cases of damage from LMOs through domestic rules and procedures for civil liability. This approach was strongly opposed by most developed countries, who instead proposed an administrative approach building on executive institutions, such as a national competent authority, to monitor and address cases of damage or threats of damage. The tension around this question reflects not only the diverging interests of developed or LMO-exporting countries against those of developing or LMO-importing countries, but also larger issues of capacity and the perception of the role of the legal system in avoiding and addressing environmental damage from LMOs. To understand these issues and evaluate the outcome, it is useful to take a more detailed look at differences in these two approaches.

[13] Ibid., at 1. See also J. Gnann *et al*., 'Summary of the Second Meeting of the Group of Friends of the Co-Chairs on Liability and Redress in the Context of the Cartagena Protocol on Biosafety: 8–12 February 2010', 9:495 *Earth Negotiations Bulletin* (15 February 2010), at 5–6.

[14] See the definition of response measures in the Biosafety Protocol, n. 1 above, Article 2.2(f).

CIVIL LIABILITY

Civil liability has become a frequently used element of international regimes on liability and redress for damage to the environment including in the areas of oil pollution and nuclear activities.[15] However, so far, some of these regimes have not yet entered into force, in particular if they address cases of transboundary damage. Countries are reluctant to commit to these regimes because often their implementation would require substantive changes to domestic rules and procedures or subordinate their sovereign decisions, with regard to what kinds of damage are covered by civil liability, to an international body.[16] Similarly in the case of biosafety, some countries or groups, such as the EU, New Zealand and Australia, have already adopted comprehensive biosafety legislation. These countries made it clear that they wanted to avoid an international regime that would require them to make substantial reforms. They also did not want to enter into obligations that reached further than their current systems, and requested that the regime leave sufficient leeway to accommodate existing domestic biosafety laws and to develop new ones according to national priorities.[17] Most developed countries also expressed concerns that a broad application of civil liability regimes to biosafety issues would open the gates for claims for traditional damage, which, in their view, was not covered under the Biosafety Protocol.[18]

Another problematic issue was that, in order to address transboundary or international damage effectively, countries would have to provide for the mutual recognition and enforcement of foreign judgements. While a number of instruments and mechanisms exist to do so, the recognition of foreign judgements remains a complex procedural issue as countries use a number of different systems to take the specific characteristics of their own legal systems and those of other countries into account. Harmonization of these systems, in particular in the field of civil liability and between countries with common and civil law systems, has proven very challenging. International private law, which deals with situations of conflicts of laws and enforcement of

[15] For an overview, see CBD Secretariat, *Recent Developments in International Law Relating to Liability and Redress, Including the Status of International Environment-Related Third Party Liability Instruments* (UNEP/CBD/BS/GF-L&R/3/INF/1, 12 May 2010), available at <http://www.cbd.int/doc/meetings/bs/bsgflr-03/information/bsgflr-03-inf-01-en.doc>.

[16] See CBD Secretariat, *Status of Third-Party Liability Treaties and Analysis of Difficulties Facing their Entry Into Force* (UNEP/CBD//BS/WG-L&R/1/INF/3, 15 April 2005), available at <http://www.cbd.int/doc/meetings/bs/bswglr-01/information/bswglr-01-inf-03-en.doc>. See also n. 11 above.

[17] See E. García *et al*., 'Summary of the First Meeting of the Group of Friends of the Co-Chairs on Liability and Redress in the Context of the Cartagena Protocol on Biosafety', 9:457 *Earth Negotiations Bulletin* (2 March 2009), at 11.

[18] See J. Gnann *et al*., n. 13 above, at 7.

foreign judgements, is very complex and it is hard to ensure enforcement of foreign judgements across different jurisdictions with different legal systems and standards. Most countries would have to expand or adjust existing agreements in order to cover new areas. Given the complexity of these issues and their linkages with other legal areas across boundaries, many countries are generally reluctant to accept references to enforcement of foreign judgements, especially if they explicitly require them in new areas. In the end, the Supplementary Protocol did not include any reference to enforcement of foreign judgements, not even in the enabling provision on civil liability. One could have envisioned that at least a reference to the use of existing private international law instruments would be included – but it is not.

ADMINISTRATIVE APPROACH

As an alternative to a civil liability regime, developed countries proposed an administrative approach. Such an approach is centred on a competent national authority, responsible for monitoring movements of LMOs in the country's jurisdiction and to take action in the event of damage or threat of damage. The competent authority can also perform its own evaluation and determine which response measures have to be taken by the operator. In case the operator fails to implement timely and adequate response measures, the competent authority can implement these measures and recover from the operator 'the costs and expenses of, and incidental to, the evaluation of the damage and the implementation of any such appropriate response measures' (Article 5). The competent authority has to deliver the proof that damage as defined under the Supplementary Protocol has occurred, or is likely to occur. This implies that the competent authority must be in a position to document an adverse effect on the conservation and sustainable use that can be measured against a scientifically established baseline and prove that this adverse effect is significant as required by the Supplementary Protocol, Article 3. Furthermore, countries must provide for the possibility to take legal remedies against the decisions of the competent authority, including administrative or judicial review (Article 5.6).

The administrative approach has several advantages and disadvantages compared to a system based on civil liability. The main advantage is that it provides flexibility to accommodate different priorities, legal systems and practices of the operators involved. The key to effective liability and redress under such a flexible system lies in the 'competence' and the 'authority' of the countries' competent authorities. The administrative approach places a strong emphasis on science-based proof of damage or threat of damage. If the competent authority is endowed with the resources and expertise to deliver such proof and determine adequate response measures in a timely manner, it can be an effective tool in preventing and redressing damage. Furthermore, the science-based approach is generally accepted by industry as being transparent and fair. It requires, nevertheless, that the competent authority has the capacity to address a potential state-of-the-art defence by the operator. This means it must have access to the latest technologies and methods for detecting damage and establishing the causal chain to the operator's activities. At the same time, the competent authority must have an independent power to intervene without interference from other institutions or political or economic interests in order to be effective and unbiased in its actions.

The disadvantage of the administrative approach is that it requires substantial resources and capacity to be effective. Many developing countries do not have the capacity to implement such an approach. In fact, the approach was alien to the majority of developing countries, resulting in long debates and misunderstandings on the core concept. Since the administrative approach is implemented by the executive branch, countries that do not have a competent authority, or ones that lack the necessary resources, find it difficult to monitor transboundary movements of LMOs adequately and deal with cases of damage. Many developing countries therefore prefer the civil liability approach that would use the existing court system. Furthermore, while the administrative approach may prove to be a viable procedure for large-scale damages, it would be hard to apply in cases of smaller scale damages, for example to individual farmers. This is a major concern of developing countries, which fear that traditional farming communities would suffer disproportionately from damage from LMOs, in particular in countries that harbour centres of origin of crop species.[19] Contamination at the farm level is also a concern for countries that are exporting to countries that have not yet approved many LMOs, such as the EU countries, or that have specialized in organic LMO-free production. In both cases, contamination could lead to economic losses and it is currently not clear whether and how such damage could be addressed by the competent authority.

NEGOTIATION DYNAMICS ON THE LEGAL APPROACH

Since the adoption of the Biosafety Protocol, most developing countries had made strong calls for an international regime focusing on legally binding rules for civil liability. They recalled that their agreement to

[19] See A. Appleton *et al*., 'Summary of the Fifth Meeting of the Open-Ended *Ad Hoc* Working Group on Liability and Redress in the Context of the Cartagena Protocol on Biosafety: 12–19 March 2009', 9:435 *Earth Negotiations Bulletin* (2008), at 12.

postpone negotiations on liability and redress had been a major concession to enable the Biosafety Protocol's adoption and that there was a moral obligation by developed countries to make concessions with regard to civil liability now. Throughout the negotiations a strong coalition of developing countries continued to push for an international regime focusing on civil liability, meeting strong opposition from the EU and other developed countries.[20] However, over time, the ranks of supporters of civil liability thinned as a number of developing countries started investing in their own biotechnology industries or became big producers and exporters of agricultural LMOs.[21] These countries started having broader or more multi-facetted interests regarding an international liability and redress regime. While at COP/MOP-4 a coalition of more than 85 developing countries from all regions had pushed through the compromise to negotiate an international regime that would include a legally binding provision on civil liability; the subsequent negotiations on that provision were led by a weaker coalition of the African Group and a dwindling group of Asian and other developing countries led by Malaysia.[22]

The final compromise enshrined in the draft Supplementary Protocol text provides for a liability and redress regime that is centred on an administrative approach and supplemented by an enabling clause on civil liability. The provision, currently Article 12 (implementation and relation to civil liability), stipulates that 'parties shall provide in their domestic law, for rules and procedures to address damage as defined in the Supplementary Protocol'. It then sets out three options: apply their existing domestic law, including, where applicable, general rules and procedures on civil liability; apply or develop civil liability rules and procedures especially for this purpose; or apply a combination of both. When reading those options and the operative wording that 'parties may as appropriate' apply these three options, it is clear that there is indeed no international legal obligation to implement a civil liability system. To reach this compromise, the supporters of civil liability had to make several major concessions: first, they had to accept that there would be no obligation to cover traditional damage through specific civil liability systems; second, they agreed to removing reference to foreign judgments; and, third, they grudgingly accepted that even with regard to damage to biodiversity, the article would be formulated in a way that does not impose an obligation to develop specific civil liability systems for damage arising from the transboundary movement of LMOs. The result is that parties that have existing legal systems which deal with damage from LMOs can continue to use those. To develop a civil liability system is just one option; yet many developing country negotiators felt it was important to at least secure this enabling reference to civil liability.

Initially, the provision on civil liability also included a reference to guidelines on civil liability, compiled from proposals for operative provisions on civil liability submitted by parties. The supporters of civil liability for some time insisted on further negotiating these guidelines with a view to including them as an Annex to the Supplementary Protocol. At the third meeting of the Friends of the Co-Chairs, a Co-Chairs' draft of possible civil liability provisions was tabled, but not negotiated;[23] instead a number of countries indicated that they did not want to see them included, and although still annexed to the report of the meeting, there is no reference to the guidelines in the Supplementary Protocol anymore. The guidelines will thus still be on the table at COP/MOP-5; however, several negotiators of the supporters of civil liability indicated that they would not insist on finalizing the guidelines in order to adopt the Supplementary Protocol. If finalized, the guidelines could be of assistance for those countries that do want to develop specific civil liability systems, but in light of the absence of an obligation to develop such systems, their importance as a soft law element of the international regime has been substantially reduced. The United Nations Environment Programme (UNEP) has however adopted Guidelines for the Development of Legislation on Liability, Response Action and Compensation for Damage caused by Activities Dangerous to the Environment.[24] While the UNEP Guidelines are voluntary in nature, they do state that an activity dangerous to the environment 'means an activity or installation specifically defined under domestic law' (Guideline 3). Some commentators have noted that this would allow countries to define in their domestic law biotechnology or movements of LMOs as an activity dangerous to the environment, something that would not have been possible in the negotiations on the Biosafety Protocol or the Supplementary Protocol. On the other hand, one should bear in mind that the UNEP Guidelines put similar restrictions on the definition of damage to the environment and the burden of proof. This means that the classification of biotechnology or movements of LMOs as dangerous activity *per se* does not necessarily strengthen a country's

[20] See A. Appleton *et al*., n. 7 above, at 8.
[21] See A. Appleton *et al*., n. 19 above, at 12.
[22] See A. Appleton *et al*., n. 7 above; J. Gnann *et al*., n. 13 above; and E. García *et al*., n. 17 above.
[23] See Supplementary Protocol, n. 8 above.
[24] See 'Guidelines for the Development of National Legislation on access to Information, Public Participation and Access to Justice in Environmental Matters', in Environmental Law: Guidelines for the Development of National Legislation on Access to Information, Public Participation and Access to Justice in Environmental Matters (Decision SS.XI/5, 3 March 2010), Annex, printed in *Proceedings of the Governing Council/Global Ministerial Environment Forum at its Eleventh Special Session* (UNEP/GCSS.XI/11, 3 March 2010), at 12, available at <http://www.unep.org/gc/gcss-xi/docs/K1060433-Proceedings-reissued-set-of-options.doc>.

position with regard to liability and redress arising from transboundary movements of LMOs, nor can the classification be used as justification to restrict LMO imports or related activities, since voluntary guidelines would not be recognized by international trade law. It is even explicitly stated in the UNEP decision adopting the Guidelines that they are 'are voluntary and do not set a precedent for the development of international law'.[25]

OUTSTANDING ISSUES

Two major issues are still unresolved in the draft Supplementary Protocol text: references to products of LMOs; and a provision on financial security. The reference to products of LMOs has been a source of both contention and confusion during the negotiations. It is contentious, because it could have impacts on the regime's scope and create legal uncertainty with regard to what substances are covered. The African Group and a number of other developing countries insisted on the reference in order to ensure that any biologically active component of an LMO is covered under the regime. This was opposed by both developed countries and some members of the Group of Latin American and the Caribbean (GRULAC) and other groups, arguing that any such substance is already included in the definition of an LMO.[26] The discussion illustrated once again the fear of trade impacts if the scope is defined too broadly or imprecisely. This was best demonstrated by a long discussion about whether it would be useful or acceptable to include the reference to 'products of LMOs that are themselves LMOs' during the second meeting of the Friends of the Co-Chairs.[27] The discussion was complicated by confusion about what a product of an LMO is and what kind of damage to conservation and sustainable use it could create. A key question was, for example, whether a component of an LMO product that is not biologically active in the sense of the definition of an LMO can create such damage, and, if so, whether it should be covered by the Protocol. There are currently no known examples of that scenario, but future progress in research and development could lead to the existence of such hazardous substances associated with LMOs. This raises the question of how the Supplementary Protocol should accommodate future advances in science. One way would be to incorporate some flexibility in the definition of LMOs; however, this would come at the price of reduced legal certainty and clarity. Another way could be regular reviews of the Supplementary Protocol's scope. This raises the question whether a review mechanism could be set up that allows for timely adjustments of the scope. As the negotiating history of the Biosafety Protocol and the Supplementary Protocol on liability and redress show, it has to be questioned whether a fast and responsive review mechanism can be set up and how it would avoid being bogged down by the same contentions that have affected biosafety negotiations so far.

The second outstanding issue is financial security. This currently bracketed provision (Article 10) would allow parties to require proof of financial security, such as insurance, bank guarantees, internal reserves or industry pooling schemes, from an operator before granting permission to import LMOs. Financial security is a key element for an effective liability regime, since it provides for compensation in cases in which the liable party is declared bankrupt or insolvent or cannot pay for response measures or compensation for some other reason. Collective schemes and backup funds can also cover disasters, accidents or other situations in which no party is found liable for any reason or in which the liable party can only be identified with a time delay.[28]

The bracketed text contains two provisions. The first is an enabling clause granting parties the right to require the operator to establish and maintain financial security for any applicable time limit. The second provision urges parties to encourage the development of the respective financial instruments to comply with such requirements, including financial security instruments and markets, as well as funds or other mechanisms to address cases of operator insolvency. The article evolved from an originally mandatory provision proposed by developing country importers. As many LMO-producing countries oppose such a requirement, the debate now focuses on whether an enabling clause allowing countries to require financial security should be included. Still the enabling clause is being rejected by most exporting and developed countries, arguing that the risks of biotechnology are currently not insurable, and that requirements for financial security could distort market access and lead to discrimination among operators.

Financial institutions are so far reluctant to cover the risks associated with biotechnology because the extent of possible liabilities is hard to predict. A number of reasons exist that make liabilities for risks associated with biotechnology difficult to evaluate. Since damage to biodiversity is a relatively new concept with regard to liability and redress, there is little experience, data or methodology to assess the likelihood and scope of damage to biodiversity in economic terms. Economic value and likelihood are the main factors for determining the cost of insurance. Furthermore, it is currently

[25] Ibid., para. 1
[26] See J. Gnann *et al.*, n. 13 above, at 4–5.
[27] Ibid.

[28] D. Currie, *Greenpeace International Explanatory Documents on the Biosafety Liability and Redress Negotiations: Backgrounder for the Fourth Meeting of the Ad hoc Open-Ended Working Group on Liability and Redress in the Context of the Biosafety Protocol* (Greenpeace International, 17 October 2007), at 10–11, available at <http://www.greenpeace.org/international/en/publications/reports/2007-backgrounder-biosafety-liability-redress>.

unclear to what extent traditional damage would have to be covered and how the burden of proof and causation would be regulated. Finally, insurers will not generally enter the market unless they are certain that a critical mass of operators will seek insurance and whether it will be possible to differentiate risk adequately according to the activities they are engaging in.[29]

Some of these uncertainties, such as causation and burden of proof, will be removed once the liability and redress regime is in place. A mandatory requirement for financial security would also ensure that a critical mass of operators will seek insurance; however, with an enabling clause, this figure will depend on the number of countries that decide to put such a requirement in place. In this context, it is also interesting to note that the absence of financial security or lack of insurance policies is often cited as a reason why countries do not ratify existing international regimes on liability and redress.[30] The main problem however remains the uncertainty about the likelihood and economic scope of damage. This uncertainty could be addressed through the introduction of a cap on the amount that operators can be liable for, in combination with a fund to compensate damage beyond the cap and/or rules on residual State liability. The cap would make the risk insurable from the perspective of financial institutions. A fund as a supplementary compensation scheme could be a multilateral State-level institution or a voluntary scheme set up by operators and other members of the biotechnology industry.

One such voluntary scheme is the Global Industry Compact[31] currently being devised by the world's six largest biotechnology crop companies to handle claims for damage to biodiversity caused by the release of an LMO produced by the member companies. The Compact is a legally binding agreement among biotechnology producers that the companies enter into. The exact terms of the Global Industry Compact are currently being negotiated with the aim of the contract being completed by COP/MOP-5. It allows States to file claims for damage to biodiversity only, excluding individual claims as well as claims for traditional damage. It thus covers a significant part of the damage covered by the Biosafety Protocol, but not all of it. The motivation for the companies to create the Compact was twofold. On the one hand, they hoped that the establishment of a voluntary compensation scheme would weaken the demands for an international legally binding regime on civil liability. On the other hand, they used the Compact to promote the safety of their products, arguing that the fact that they are voluntarily assuming responsibility proves that the risks associated with their products are small and that they are capable of adequately evaluating this risk.

The Compact also introduces a cap on the value of claims that can be compensated. The question is whether this cap is adequate to cover most cases of damage to biodiversity – a question that is still difficult to answer. On the other hand, the Compact and its cap could set a precedent that could encourage other companies or insurers to develop similar instruments, using the cap, or experiences with claims made under the Compact, as guidance. The Compact could thus be a first step towards making the risks associated with biotechnology insurable, in particular if the Supplementary Protocol removes some of the administrative uncertainties with regard to providing insurance.

CONCLUSION

There is a broad consensus among delegates that a final Supplementary Protocol will be adopted at COP-10 in Nagoya and that it will likely also receive the necessary ratifications to enter into force, sparing it the fate of other liability and redress regimes that to date have not entered into force. The question is at what cost? Although delegates set out to devise an 'international regime' on liability and redress, in the end the administrative approach *per se* is the incarnation of a 'national' approach where decisions are left to the discretion of a competent national authority. In addition, although delegates agreed to 'legally binding' provisions, the very wording of many of the provisions refers back to national systems. Numerous provisions (for example on time limits, financial limits and exemptions) start off with the operative wording 'parties may provide in their domestic law . . .', subjecting key substantive issues to national law. The leeway built into most of the provisions was intentional to spare countries with existing legislation from the obligation to

[29] On financial security and availability of insurance, see M.G. Faure and D. Grimeaud, *Financial Assurance Issues of Environmental Liability: Report for the European Commission* (METRO and European Centre for Tort and Insurance Law, 1 December 2000), available at <http://ec.europa.eu/environment/legal/liability/pdf/insurance_gen_finalrep.pdf>; P.K. Freeman and H. Kunreuther, 'Managing Environmental Risk through Insurance', in H. Folmer and T. Tietenberg (eds), *International Yearbook of Environmental and Resource Economics 2003/04* (Edward Elgar, 2004), 159; CBD Secretariat, *Financial Security to Cover Liability Resulting from Transboundary Movements of Living Modified Organisms* (UNEP/CBD/BS/WG-L&R/2/INF/7, 13 February, 2006), available at <http://www.cbd.int/doc/meetings/bs/bswglr-02/information/bswglr-02-inf-07-en.pdf>; and CBD Secretariat, *Financial Security to Cover Liability Resulting from Transboundary Movements of Living Modified Organisms* (UNEP/CBD/BS/WG-L&R/3/INF/5, 10 January 2007), available at <http://www.cbd.int/doc/meetings/bs/bswglr-03/information/bswglr-03-inf-05-en.doc>.

[30] See CBD Secretariat, n. 16 above.

[31] For more information about the Global Industry Compact, see Croplife International, *Frequently Asked Questions about the Compact* (Croplife International, undated), available at <http://www.croplife.org/public/compact_FAQs>.

rebuild their systems completely when implementing the Supplementary Protocol. The question is whether such a flexible and only minimally binding regime can lead to effective and efficient prevention of damage or restoration and compensation through liability and redress.

To create an effective international system of liability and redress, all parties to the Biosafety Protocol must ratify the Protocol and be in position to establish effective competent authorities. Furthermore, the competent authorities must acquire a reputation of intervening in a timely and strict manner in cases of damage or imminent threat of damage, while being transparent and fair. This would create the maximum incentive to prevent damage as well as provide for adequate and timely responses in cases where damage occurs. Given the capacity, expertise and resources required to maintain such a competent authority in the true sense of the name, it can be expected that there will be a strong imbalance in implementation between developed and developing countries. Most developed countries already have established the institutional structure to implement an administrative approach, whereas many developing countries so far do not have the capacity to do so and it will take them a long time to acquire the necessary expertise and experience, notwithstanding the resources necessary for their development. In a way, the Supplementary Protocol confirms the *status quo* in which those of the industrialized countries that have made prevention of damage from biotechnology a priority have put the systems into place to address damage associated with transboundary movements of LMOs, while developing countries with similar priorities struggle to do the same. The only way to address this gap will be a significant increase in capacity building and collaboration for developing countries, in particular least developed countries.

The Supplementary Protocol is a first step towards an effective international regime, but it must be complemented with a strong component for capacity building and international cooperation. In this context, it should be remembered that it was the absence of a level playing field for seeking redress in cases of damage from transboundary movements of LMOs that led developing countries to demand a system based on a legally binding civil liability approach in the first place. Somewhat less urgent, but no less important, is finding an approach towards the provision of financial security. Once these additional components have been put into place, the Supplementary Protocol may become an effective tool for liability and redress under the Biosafety Protocol and thus one of the main pillars of the Protocol's implementation itself.

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