Genetically modified organisms and transboundary damage: A two-pronged compromise for redress under the Liability and Redress Protocol to the Cartagena Protocol

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Abstract

This paper comments on the two-pronged approach for redress of the eagerly anticipated Nagoya-Kuala Lumpur Supplementary Protocol on liability and redress (the NSP) to the Cartagena Protocol in the event of damage resulting from transboundary movements of living modified organisms (LMOs). State parties to the NSP will be required to set up a domestic administrative mechanism with a national authority to investigate such damage and enable immediate response measures as well as to ensure that civil liability rules and procedures are provided for domestically. This will enable redress for such damage to biological diversity. This paper discusses the limited scope of the LMO-related damage addressed by the NSP and highlights the limitations of these two approaches when compared to a strong international civil liability regime.

1 Introduction

Over the past two decades the international trade in genetically modified organisms (GMOs) has flourished into a multi-billion dollar industry covering agricultural products and pharmaceuticals.¹ The number of biotechnological crop hectares in the world has increased from 1,7 million hectares in 1996 to over 175,2 million hectares in 2013.² However, the benefits and risks of

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¹Tracy 'Does a genetically modified rose still smell as sweet-labeling of genetically modified organisms under the Biosafety Protocol' (2010) 6 *Buffalo Environmental Law Journal* 130; Seto 'Selling the pharm: The risks, benefits, and regulation of biopharmaceuticals' (2004) 27 *Environs: Environmental Law and Policy Journal* 449 450.

²See the International Service for the Acquisition of Agri-Biotech Applications http://www.isaaa.org/default.asp.

products of modern biotechnology are controversial.³ Even if an exporting operator has taken all necessary precautions during a transboundary movement of GMOs, an accident may occur, especially when living organisms are concerned.

While the Convention on Biological Diversity (CBD)⁴ provides for the conservation and sustainable use of biodiversity, it merely states that the issues of liability and redress, including restoration and compensation for damage to biological diversity, are to be examined by the Conference of Parties (COP) at a later stage. In turn, the Cartagena Protocol on the Safety of Transboundary Movement of Living Modified Organisms (LMOs) (the CP)⁵ to the CBD only included an enabling article for liability and redress rules to be discussed at the first meeting of the CP serving as the meeting of the parties (COP-MOP).⁶ Rules with regard to damage resulting from intentional and unintentional transboundary movements of all categories of GMOs, are not yet provided for in a specific international liability and redress regime. In 2010, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (the NSP)⁷ to the CP was finalised, covering the same categories of LMOs⁸ as its enabling

³Buechle 'Great, global promise of genetically modified organisms: Overcoming fear, misconceptions, and the Cartagena Protocol on Biosafety' (2001) 9 *Indiana Journal of Global Legal Studies* 291; Schnier 'Genetically modified organisms and the Cartagena Protocol' (2001) 12 *Fordham Environmental Law Journal* 398; Ludlow 'Gene technology regulation and the Environment Protection and Biodiversity Conservation Act 1999 (CTH)' (2004) 30 *Monash University Law Review* 168; Lefeber 'The legal significance of the Nagoya-Kuala Lumpur Protocol: The result of a paradigm evolution' Centre for Environmental Law and Sustainability, Research Paper 2012/02, 1 http://ssrn.com/abstract=2151282.

⁴United Nations Convention on Environment and Development (UNCED): Convention on Biological Diversity, adopted 5 June 1992 and entered into force 29 December 1993 UN Doc UNEP/Bio.Div/N7-INC.S/4 reprinted in (1992) 31 *ILM* 818. See art 14(2) CBD.

⁵Cartagena Protocol on Biosafety to the Convention on Biological Diversity (adopted 29 January 2000, entered into force 11 September 2003) (2000) 39 *ILM* 1027.

⁶See art 27 CP

⁷See the Nagoya-Kuala Lumpur Supplementary Protocol on liability and redress to the Cartagena Protocol on Biosafety (adopted 15 October 2010, not yet in force) (2010) 50 *ILM* 105.

⁸Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology, art 3(g) CP, and is capable of transferring or replicating genetic material; LMOs can be considered as a sub-group of GMOs according to the Food and Agriculture Organisation. See www.fao.org/newsroom/fr/news/2004/43684/index.html. See Jacob 'Cartagena Protocol-a first step to a global biosafety structure' (2001) 14 *Transnational Lawyer* 83. See art 3(1) NSP. Both 'GMOs' and 'LMOs' will be used in this analysis to the extent that a liability regime needs to cater for damage caused by all categories of GMOs and not only damage caused by LMOs. Several domestic regimes on liability refer to GMOs instead of LMOs. General environmental protection legislation is also a basis for legal actions for compensation. See Secretariat of the CBD 'Liability and redress for damage resulting from transboundary movements of living modified organisms' Intergovernmental Committee for the Cartagena Protocol on Biosafety The Hague 22-26 April 2002 Item 4.1.1 of the provisional agenda, UNEP/CBD/ICCP/3/3, 6 March 2002.

instrument rather than all categories of GMOs. Instead of an international liability and redress regime, the NSP adopts a two-pronged approach for redress with a set of binding administrative measures on the one hand, while on the other hand, liability and redress rules to be implemented at the discretion of state parties. The NSP addresses damage to biological diversity rather than all damage resulting from transboundary movements of LMOs. In the event of damage or sufficient likelihood of damage, a designated local authority in the affected State will carry out an investigation, identify the author of such damage, and ensure that immediate response measures are taken. Even though the NSP is a compromise to a specific international liability and redress regime with regard to damage resulting from intentional and unintentional transboundary movements of LMOs, this Protocol fills an important void. Its timely entry into force is of the utmost importance so that it becomes binding on state parties to adapt their domestic liability regimes in accordance with the rules of this Protocol, or enact a specific liability regime enabling recourse to domestic courts for affected parties in the case of such damage. The existence of liability and redress rules will compel operators to take all necessary measures to avoid damage since they can be held liable for damage resulting from transboundary movements of LMOs.

In parallel with the negotiations on the NSP, a voluntary private sector compensation mechanism known as the 'Compact' was drafted by six major plant biotechnology companies to address damage caused to biological diversity by one of their LMOs. 9 The fact that these key players agreed on such a mechanism is significant in that it acknowledges that LMOs may cause damage to biological diversity. While the main biotechnological companies agree that LMOs may be a threat to biological diversity, there is no consensus on the risks that they may pose to human and animal health. Seeking redress for LMO-related damage under the Compact will unfortunately often occur in terms of the rules of these biotechnology companies. Affected individuals cannot file claims under the Compact, and if an LMO-related damage does not come from LMOs developed by one of the six members of the Compact, recourse to this private compensation mechanism is not possible. This paper discusses the limited scope of LMOs and damage covered by the NSP. It highlights the shortcomings and implications of its administrative approach and civil liability and redress rules in the context of the specificities of modern biotechnology.

⁹The redress mechanism initiated by the six main biotechnological companies, namely BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto and Syngenta, became operational in 2010. See http://www.biodiversitycompact.org/ (accessed 3 April 2013); The COP to the CP acknowledges the existence of the Compact. See Decision BS-V/11 on International rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs of COP-MOP 5 www.cbd.int/mop5/documents/.

2 The limited scope of living modified organisms and damage covered by the Protocol

The NSP covers damage resulting from LMOs which originate in a legal or illegal ¹⁰ transboundary movement ¹¹ within national jurisdiction, ¹² as well as an accidental or unintentional ¹³ transboundary movement after its entry into force.

2.1 The limited scope of LMOs covered by the Protocol

As in its enabling instrument, the NSP covers three categories of LMOs:¹⁴ those intended to be introduced into the environment;¹⁵ those destined for contained use;¹⁶ and those meant for direct use as food, feed, or processing (LMO-FFPs).¹⁷ Whether processed materials coming from LMOs were to be included or not in the LMO-FFPs' category, sparked a hot debate¹⁸ over

¹⁰See art 25 CP.

release may occur, *inter alia*, during research and development (including field trials or production) during export, transit, import, handling, processing, sale, planting, distribution. See 'The Compact. A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a Living Modified Organism' (Compact) (2012) Second Amended Text 22 available at http://www.biodiversitycompact.org/wp-content/uploads/Compact-Second-Amended-Text.pdf (accessed 24 August 2013), or transport by air, by sea or rivers or by land. Damage can be expected to occur 'during' a transboundary movement but can also occur 'as a result' of such a movement several years later. Cullet 'Liability and redress in modern biotechnology' (2006) 15 *Yearbook of Environmental Law* 169.

¹²See art 3(5) NSP; Domestic law implementing this Protocol will also apply to damage resulting from transboundary movements from states that are not a party to the NSP. See art 3(7) NSP. Redress for damage that occurs beyond the limits of national jurisdiction is not covered although the CBD applies to areas both within the national jurisdiction of itsstate parties and beyond the limits of their national jurisdiction in some cases, for processes and activities carried out under the jurisdiction and control of CBDstate parties.

¹³See arts 3(3) NSP and 17(1) CP, eg, the spreading of GM seeds by the wind (see Strauss 'We reap what we sow: The legal liability risks of genetically modified food' (2010) 16 *Journal of Legal Studies in Business* 163) by birds or by way of pollen drift (see Preston 'Drift of patented genetically engineered crops: Rethinking liability theories' (2002-2003) 81 *Texas Law Review* 1154); Glenn 'Footloose: Civil responsibility for GMO gene wandering in Canada' Ahrens Torts Symposium (2003-2004) 43 *Washburn Law Journal* 549. See the case filed by organic colza farmers in Saskatchewan against Monsanto and Aventis for the contamination of their fields by GM colza (*Hoffman and Beaudoin v Monsanto and Aventis*, Statement of Claim, Saskatoon, 10 January 2002) and the claim for loss of organic certification (*Hoffman and Beaudoin v Monsanto (Canada*) Saskatoon (2007) QB 67 (*Hoffman* case). See *Monsanto (Canada) Inc v Schmeiser* (2004) SCC 34. ¹⁴ Article 3(1) NSP.

¹⁵For example, transgenic seeds, live transgenic salmon or animal.

¹⁶For example, bacteria which have been genetically modified. These LMOs are subject to specific measures that limit their contact with and their impact on the external environment.

¹⁷For example, transgenic corn, wheat, soya, etc intended as food or feed, transgenic fruits or vegetables to be processed (canned transgenic tomatoes).

¹⁸LMOs which have been processed, eg canned GM salmon, are considered as having no adverse impact on biological diversity. However, the protein products of the genetic material can still

whether processed materials have lost their ability to transfer genetic material or replicate themselves but are still GMOs. For example, GM tomatoes which have been processed to produce tomato sauce no longer have the ability to replicate themselves. It was decided during the final negotiations in Nagoya that state parties may apply this Protocol to damage caused by such materials if there is a causal link between the damage and the respective LMO.¹⁹ However, damage resulting from transboundary movements of categories of LMOs not currently regulated by the CP, will not be covered by the NSP. For instance, LMOs intended to be used as raw materials for the production of pharmaceuticals²⁰ and nutraceuticals²¹ may not be governed by the NSP to the extent that they can be considered pharmaceuticals, although they may look like food products. The contamination of non-GM crops by neighbouring experimental GM crops may also not be covered by the Protocol.²² Damage caused accidentally by transgenic mosquitoes for disease control purposes²³ may not fall within the scope of the Protocol as it is unclear whether they will be regarded as pharmaceuticals or not. As for live genetically-engineered animals intended for laboratory use,²⁴ provisions applicable to LMOs in

be detected and there may be potential adverse effects on human health. Buechle (n 3 above) 286; Processed materials that are of LMO origin, contain detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology; More than 90% of GMO goods are commodities. Schnier n 3 above 414.

¹⁹See Secretariat of the CBD 'Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety Conference of the Parties' (Reposted to incorporate the corrections in UNEP/CBD/BS/COP-MOP/5/Corr.1 and 2) Nagoya Japan 11-15 October 2010, UNEP/CBD/BS/COP-MOP/5/17 para 133; Nijar 'The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An analysis and implementation challenges' (2013) 13 *International Environmental Agreements* 274.

²⁰For example, transgenic plants to be used as raw materials for the production of pharmaceuticals. The CP does not apply to pharmaceutical products addressed by other relevant agreements and organisations (art 5 CP).

²¹Nutraceuticals are considered as foodstuffs with additional health value such as GM rice with added vitamin A or GM crops modified as 'edible vaccines'. See Buechle (n 3 above) 319; Kohm 'Shortcomings of the Cartagena Protocol: Resolving the liability loophole at an international level' (2009) 27 *UCLA Journal of Environmental Law and Policy* 153; Birdsall 'Biopharming, bananas and bureaucracy: The banana vaccine as a case study for products that straddle the definitional food/drug divide' (2011) 66 *Food and Drug Law Journal* 265.

²²For example, LMOs meant for the production of pharmaceuticals designated for human and animal consumption which are used field trials close to neighbouring borders. Glenn n 13 above 553.

²³For example, the use of a transgene for resistance to rodent malaria in mosquitoes.

²⁴For example, pigs used for organ transplant purposes may escape accidentally from their laboratories. See DD Jones 'Food safety aspects of gene transfer in plants and animals: Pigs, potatoes, and pharmaceuticals' (1988) 43 *Food, Drug, Cosmetic Law Journal* 352; Lawrence 'What would you do with a fluorescent green pig? How novel transgenic products reveal flaws in the foundational assumptions for the regulation of biotechnology?' (2007) 34 *Ecology Law Quarterly* 263.

contained use under the CP may potentially apply, but they are not subject to the compulsory risk assessment requirements.²⁵

2.2 The limited scope of damage covered by the Protocol

While a liability regime should ideally cover all forms of damage that may result from transboundary movements of LMOs and GMOs, the NSP addresses only damage to biological diversity²⁶ caused by LMOs. However, it is the first international agreement²⁷ to define damage as 'an adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health'. ²⁸ Only significant and measurable adverse impacts on the conservation and use of biological diversity will be taken into consideration in assessing damage in terms of the NSP. ²⁹ In practice, although scientifically recognised methods will be used, it may be difficult for technical experts to agree on the 'significance' of adverse effects, especially if there is scientific uncertainty on the negative impacts. The CP also refers to the 'adverse effects of LMOs on the conservation and sustainable use of biological diversity', 30 while article 27 clearly covers rules on liability and redress for damage resulting from transboundary movements of LMOs, and not only damage to biological diversity. 31 The NSP's definition of damage seems closer to that of the CBD which refers to liability and redress for damage to

²⁵Risk assessments would be of considerable help to respond to damage resulting from their transboundary movements as well as to evaluate the quantum of damages in the event a claim is filed.

²⁶The forms of damage covered traditionally by domestic regimes are personal injury, loss or damage to property or economic interests caused to persons or property and damage caused to the environment. See Duall 'A liability and redress regime for genetically modified organisms under the Cartagena Protocol' (2004) 36 *George Washington International Law Review* 193. 'Biological diversity' is defined as the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. See art 2 CBD.

²⁷See Lefeber n 3 above 15; Existing international regimes refer to 'environmental damage' for damage caused to the environment. See Munchmeyer, Fogleman *et al* 'Implementation Effectiveness of the Environmental Liability Directive (ELD) and related financial security issues' (2009) Bio Intelligence Service, Report for the European Commission (DG Environment) 21. http://ec.europa.eu/environment/legal/liability/pdf/ELD% 20 Study%20November%202009 .pdf. See the 1997 Protocol to amend the 1963 Vienna Convention on Civil Liability for Nuclear Damage (Vienna Amending Protocol) and the 1996 International Convention on Liability and Compensation for Damage in connection with the Carriage of Hazardous and Noxious Substances by Sea, the HNS Convention, adopted 3 May 1996, not in force, (1996) 35 *ILM* 1415.

²⁸See art 2(2)(b) NSP.

²⁹The Compact's definition of a 'significant adverse impact' is a measurable, significant and adverse change to biological diversity to a species or ecosystem arts 6.2, 8 and 9.4.

³⁰See art 4 CP.

³¹Note 30 above, art 27.

biological diversity.³² Nevertheless, the NSP takes the same stance as the CP with regard to human health risks. Health impacts are not regarded as a main head of damage, but may be taken into account in association with damage to biological diversity³³ as one of the factors to determine the significance of adverse effects.³⁴ Although human health risks³⁵ in relation to GM products may arguably not be specific to transboundary movements of LMOs, the contamination of conventional crops by pharmaceutical GM crops may impact on human health as a consequence of an unintentional movement.³⁶ GM mosquitoes³⁷ in contained use or pathogenic GM micro-organisms released unintentionally during a transboundary movement, may also adversely impact human health.

The NSP does not address traditional damage³⁸ and adverse impacts on socioeconomic interests, but leaves it to state parties to provide adequate rules for material or personal damage associated with damage to biodiversity.³⁹ Economic loss is a relevant form of LMO-related damage which would need to be provided in domestic liability regimes.⁴⁰ The liability of patent-holders

³²See art 14(2) CBD.

³³See art 1 NSP. Damage to human health was not included as a main head of damage in both the CP and the NSP to the extent that they are considered as multilateral environmental agreements.

 $^{^{34}}Id$ art 2(3)(d).

³⁵With regard to the use of genes from products known for their allergenic characteristics (see Fernandez 'Monsanto and the requirement for real risks in GM food regulation' (2006) 28 Loyola of Los Angeles International and Comparative Law Review 336; Cox 'Genetically modified organisms: Who should pay the price for pollen drift contamination' (2008) 13 Drake Journal of Agricultural Law 404); Van Tassel 'Genetically modified plants used for food, risk assessment and uncertainty principles: Does the transition from ignorance to indeterminacy trigger the need for post-market surveillance' (2009) 15 Boston University Journal of Science and Technology Law 222.; With regard to the use of antibiotic-resistant gene markers which may potentially cause resistance to antibiotics, see Kohm n 21 above 153, World Health Organisation 20 Questions on genetically modified foods available at http://www.who.int/ foodsafety/publications/biotech/20questions/en/.

³⁶In 2002, an experimental crop of corn engineered by ProdiGene to produce pharmaceuticals began sprouting in soybean fields designated for human and animal consumption near the Company's Nebraska and Iowa sites, Strauss n 13 above 165.

³⁷For example, the use of a transgene for resistance to rodent malaria in mosquitoes.

³⁸See Duall n 26 above 193.

³⁹See art 12(2) NSP; Nijar n 19 above 274.

⁴⁰The draft guidelines on liability and redress (draft guidelines) prepared by the co-chairs on liability and redress proposed the inclusion of economic loss. See draft guideline 2 option 1 and (2)(c) (Secretariat of the CBD 'Draft Guidelines on Liability and Redress for Damage Resulting from Transboundary Movement of LMOs' Report on the third meeting of the group of friends of the co-chairs on liability and redress in the context of the Cartagena Protocol on Biosafety, 15-19 June 2010, Kuala Lumpur, Malaysia. UNEP/CBD/BS/GF-L&R/3/4 Appendix I, Annex II; These guidelines were meant to be attached to the report of the third meeting of the GFCLR for further consideration in Nagoya in 2010 but were not negotiated through lack of consensus.

could also be incurred for having released GMOs and contaminated non-GM crops in neighbouring fields. ⁴¹ Furthermore, negative socio-economic impacts could also be a ground on which to claim damages to the extent that the CP includes socio-economic considerations when reaching a decision on a transfer of LMOs. ⁴² The fact that the NSP does not take a stand on harmonised standards on material damage or personal damage associated with damage to biodiversity, will result in discretionary implementation by state parties. In turn, different standards will result in different compensation for such damage depending on the area where the damage occurred.

A binding administrative investigation into transboundary damage for immediate response measures to be taken

An administrative approach to investigating LMO-related transboundary damage to enable the necessary response measures is considered as a compromise⁴³ and has been criticised as originating in states opposed to a strong civil liability regime. The NSP does not clarify which type of LMO-related transboundary damage is to be investigated by the administrative authority – should this be only damage caused to biological diversity, or should it include other LMO-related damage to human and animal health? State parties are required to empower a local authority to carry out an

See Decision BS-V/11 International rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms http://www .cbd.int/ decision/mop/default.shtml?id=12324 (accessed 3 June 2013); St Jungcurt and Scabus 'Liability and redress in the context of the Cartagena Protocol on Biosafety' (2010) 19 Review of European Community and International Environmental Law 203. Eg, contamination of commercial rice crops (see In Re: Genetically Modified Rice Litigation 251 FRD 392, 400 (8th Circ. E.D.Mo.2008); Strauss n 13 above 156). Eg, contamination of organic products (see Department for Environment, Food and Rural Affairs Compendium of UK Organic Standards (2003) 3.5 version; the Hoffman case). Due to the consequences of the contamination of their organic crops, organic farmers may lose state subsidies in the EU and Switzerland. See Petitpierre-Sauvain, 'Coexistence and liability: Implications for international trade drawn from the Swiss example' 1792 in Wüger and Cottier (eds) 'ewts' 2008). For contamination at postharvest stage (see Glenn n 13 above 560-561; In Re: StarLink Corn Products Liability Litigation 211 F Supp 2d 1060 (7th Circ. N.D. Ill. 2002); Bratspies 'Myths of voluntary compliance: Lessons from the StarLink corn fiasco' (2003) 27 William and Mary Environmental Law and Policy Review 593; Nelson 'Legal liability in the wake of Starlink: Who pays in the end' (2002) 7 Drake Journal of Agricultural Law 242).

⁴¹Cullet n 11 above 177.

⁴²See art 26(1) CP and draft guideline 2 option 1 (2)(a)(vi).

⁴³See Jungcurt and Scabus (n 40 above) 201. This approach was inspired by the United States (US) Comprehensive Environmental Responsibility, Compensation and Liability Act (CERCLA) (42 USC §9601 ff (1980) http://www.epa.gov/regulations/laws/cercla.html (accessed 4 April 2013), and the European directive on environmental liability (Council Directive 2004/35 of 21 April 2004 on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage [2004] OJ L143/56). See Nijar n 19 above 274.

investigation in the event of LMO-related damage within their national jurisdictions, 44 identify the author/transgressor, and ensure that necessary response measures 45 are taken. This investigation does not focus on compensating individual plaintiffs. Its main objective is to provide a procedure for immediate and preliminary responses to transboundary LMO-related damage. It would consequently seem necessary that immediate response measures be taken for any LMO-related damage rather than only for damage caused to biological diversity within the jurisdiction of the affected State.

Each state party is responsible for providing a legal mechanism so that in the event of damage or sufficient likelihood of damage, it is mandatory for the operator⁴⁶ whose LMOs have caused the damage to inform the competent authority of the affected state. States' responsibility to monitor the investigation of such damage may consequently bring state parties to strengthen the management of approved transboundary movements of LMOs within their national jurisdictions, and require a risk assessment for LMOs even when this is optional.⁴⁷ In the case of damage affecting several territories, the different countries involved must agree as to which authority will be the competent one. If the damage has not been notified by the operator, it is only once the damage has been discovered and reported to the competent local authority of the affected state, that the latter will proceed to identify 'the operator who has caused the damage'. 48 In this case, evidence of a causal link between an LMO (for which the operator is responsible) and the damage is required for the operator to be identified. Legal causation between the conduct of the suspected operator (or his or her agents) and the harm must be sufficiently compelling

⁴⁴See art 5 NSP. It is at the discretion of states that are not parties to the Protocol to provide for a local authority to carry out the above investigation.

⁴⁵Note 44 above, art 2(2)(d). Although an imminent threat of damage was not included as such in this Protocol, response measures must be taken by the operator when there is a sufficient likelihood of damage. Response measures are 'reasonable actions to prevent, minimise, contain, mitigate or avoid damage' with an order of preference for measures to restore biological diversity to the condition that existed before the damage occurred or its nearest equivalent. In the case of catastrophic and irreversible damage caused to the environment and its natural resources, it will be difficult to find appropriate remedies and evaluate the quantum of damages. In the Mexican maize case, transgenes affected some landraces of maize with irreversible consequences. See *Commission for Environmental Cooperation of North America, Maize and Biodiversity-The Effects of Transgenic Maize in Mexico-Key* (8 November 2004) Findings and Recommendations, Secretariat Article Report 13, 12. See Cullet n 11 above 172; Where restoration or reinstatement is not possible, monetary compensation for the loss suffered may be the only way forward.

⁴⁶The NSP refers to the person or entity who/which is responsible to take response measures as the 'operator' and it may be any person in direct or indirect control of the LMO.

⁴⁷For instance, a risk assessment is not compulsory for the transboundary movements of pharmaceuticals (art 5 CP) as well as LMOs in transit and contained use (art 6 above). ⁴⁸See art 5 NSP.

for the latter to take the necessary response measures. Providing evidence of this causal link will require expertise of the competent local authority in the affected State. If the damage has been caused by a stolen LMO, or through misuse by a third party, it is unclear who will be regarded as the operator of the respective LMO and who will be responsible for taking response measures. State parties are called to determine the operator more precisely in domestic laws since the term 'operator' in the NSP includes a wide range of persons or entities.⁴⁹ This broad definition may result in a number of persons being potentially responsible for response measures in the case or likelihood of actual damage or potential damage.⁵⁰ Further, a lack of clarity in the definition of the operator in a domestic regime may cause potential operators to refuse to take response measures for fear of being held liable if a claim for damages were to be filed against them. In such a case, the final identification process may delay the investigation considerably, and the identity of the author of the damage may still be unknown when the investigation ends.

Following the notification of the operator whose LMOs has caused damage, the national authority competent for the investigation of such damage in the affected State will proceed to an evaluation of the damage together with the operator. If the latter has not notified the damage, the competent national authority in the affected State will evaluate and determine the necessary response measures only once the damage has been discovered and reported. This administrative assessment will also potentially contribute to the evaluation of damage for compensation purposes if a claim for damages is filed at a later stage.

This administrative approach respects the 'polluter pays' principle by shifting the responsibility of taking response measures to the operator, but also ensures that transboundary damage is not left unregulated within the national jurisdiction of state parties. ⁵¹ The affected State party must take the necessary response measures if the operator is not able to do so, or has not been identified. This approach is in accordance with state parties' obligations under the CP to take emergency action, as well as to notify affected states with regard to an unintentional transboundary movement of LMOs. ⁵² The national authority of the affected state can claim the costs of response measures from the operator if the latter has failed to take these measures. As a safeguard

⁴⁹Such as the permit holder, the person who placed the LMO on the market, the developer, the producer, the notifier, the exporter, the importer, the carrier or the supplier. Note 48 above art 2(2)(c).

⁵⁰Note 48 above art 5(3).

⁵¹See Nijar (n 19 above) 274-275; However states which are not parties to the NSP may not have such domestic administrative procedures.

⁵²Article 17(c) CP.

against unfair decisions, the local authority must provide reasons for its decisions and notify the operator. The operator has also to be informed regarding available remedies. He the operator is unknown, the local authority in the affected state will need to take response and restoration measures at state expense. Whether or not the competent local authority in the affected state will be effective in investigating damage will depend to a large extent on the efficacy of a local rapid response team, as well as the financial and technical capacity of the affected state. Further, the NSP is silent on the interplay between the binding administrative approach and civil liability rules in a domestic regime. The outcome of an administrative investigation will nevertheless have an impact on a claim for damages for the same LMO-related damage. For instance, in the case of several possible operators having caused the damage, if the identified operator agrees to take response measures, this may also imply that this operator is liable when the claim for damages is adjudicated.

4 Discretionary civil liability rules in preference to an international civil liability regime

Contrary to the wishes of the proponents of a strong international civil liability regime, the NSP sets up civil liability rules which allow state parties considerable flexibility in developing domestic liability schemes for LMO-related damage. Although the biotechnology industry and GM crop-exporting countries have strong confidence in the safety of the GM products they market, it is interesting to note how vociferously they have fought against an international civil liability regime.⁵⁷ In what follows I examine key elements of these civil liability rules, namely the choice of liability regime, the standard and channelling of liability, legal causation, exemption from liability, limitation periods, financial limitation, and financial security issues.

⁵³Article 5(6) NSP.

⁵⁴For instance, possibilities for administrative or judicial review of such decisions must be made available domestically.

⁵⁵Where the costs of response measures have not been covered by the NSP, such situations may be addressed by additional and supplementary compensation measures. See Decision BS-V/11, Fifth Meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 5) http://bch.cbd.int/Protocol/decisions/?decision ID=12324.

⁵⁶For example, with causal link aspects, the limitation period for the claim, the person or entity liable for the damage, the evaluation of the quantum of damages and restoration measures still to be taken after immediate response measures have been taken.

⁵⁷Main biotechnological companies participated as observers in these negotiations. See Compact n 11 above 9-10; Nijar n 19 above 279.

4.1 The choice of civil liability regime

In the event of damage state parties to the NSP may apply existing general tort law and civil liability provisions, or a combination of both, unless specific legislation on GMO-related damage has been enacted.⁵⁸ If a general liability regime applies, there may be different types of liability triggered in different countries affected by or involved in transboundary damage. These include tort-based liability⁵⁹ against biotech companies for crop contamination, or liability for environmental damage. 60 In general, states prefer to rely on general liability regimes rather than enact laws creating specific liability for particular industries or activities.⁶¹ There is, nevertheless, debate as to the appropriateness of traditional civil liability systems to deal with the unique characteristics of GMOs to the extent that they are products of organisms that have been genetically modified, and their impact on the environment and human and animal health are yet to be tested. 62 Further, as living organisms, LMOs have the capacity to reproduce themselves and once they have been released, intentionally or unintentionally, into the environment, their impacts may stretch beyond human control. To avoid the impracticalities of existing general liability provisions with regard to products of modern biotechnology, a specific liability regime may be more appropriate. 63

⁵⁸See arts 12(1)(a), 1(b), 1(c) NSP. See examples of specific legislation on liability on GMOrelated damage: the Australian Gene Technology Act (Australian GTA) 169 of 2000; the Czech Republic Act on the Use of GMOs 153 of 2000 and the Austrian Gene Technology Act (hereafter the Austrian GTA) (BGBl Nr. 510/1994, idgF); the Norwegian Gene Technology Act 38 of 1993; the Nigerian Biosafety Guidelines http://bch.cbd.int/database/record.shtml? documentid=194 (accessed 7 June 2013); the Swiss Federal Law relating to Non-Human Gene Technology (Swiss FLNHGT) 2003 *Recueil Systématique* 814.91; the New Zealand Hazardous Substances and New Organisms (HSNO) Act 30 of 1996; the South African GMO Act 15 of 1997; the Mauritian GMO Act 3 of 2004; the Chinese regulations on Safety of Agricultural Genetically Modified Organisms Decree 304 of 2001 (Chinese Regulations on Biosafety); the Brazil Biosafety Act 11.105 of 2005; and the Malaysian Biosafety Act 678 of 2007.

⁵⁹See McEowen 'Legal issues related to the use and ownership of genetically modified organisms' Ahrens Torts Symposium (2003-2004) 43 *Washburn Law Journal* 625-626; Glenn (n 13 above) 561; Connor 'Genetically modified torts: Enlisting the tort system to regulate agricultural contamination by biotech crops' (2006-2007) 75 *University of Cincinnati Law Review* 1201-120; Cannon 'Stones and regulatory mortar: Using negligence per se to mend the wall between farmers growing genetically engineered crops and their neighbors' (2010) 67 *Washington and Lee Law Review* 674-7. See the product liability applicable in the EU for any product marketed in the European Economic area, Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products [1985] OJ L 210/29.

⁶⁰General environmental protection legislation is also a basis for legal actions for compensation. See Secretariat of the CBD n 8 above par 14.

⁶¹Lefeber n 3 above 10.

⁶²Canada, Australia and the US have taken the stance that their legal system is sufficient to deal with the potential adverse impacts of GMOs. See Canadian Institute for Environmental Law and Policy 'GMO Statutory Liability Regime: An international review' (2004) 7-9 www.cielap.org/pdf/GMOLiability.pdf (accessed 4 June 2013).

⁶³ A specific regime on GMO-related activities may be better to deal with damage caused to the environment, human health, and animal health due to the enhanced characteristics of a GM plant

4.2 The standard of liability

Protocols specifying civil liability for damage caused by technologically advanced activities⁶⁴ or dangerous activities require strict liability as the standard of liability. ⁶⁵ The NSP does not take a clear stance on the applicable standard of civil liability with regard to LMO-related damage. It only specifies that two main standards of liability are to be applied: fault-based or strict liability. If fault-based liability⁶⁶ applies, legal responsibility may be incurred for damage or injury provided there is evidence of fault or negligence by the operator or third party. Construing fault or negligence⁶⁷ in this type of liability will depend on the applicable regulatory rules and permit requirements. Claims for damages against state parties or states that are not a party to the Protocol, may potentially be brought where damage has resulted from approved transboundary movements of LMOs.⁶⁸ If fault-based liability applies in the affected state, an apportionment of liability or joint and several liability⁶⁹ may be necessary since a number of persons could be held responsible.

If strict or absolute⁷⁰ liability applies, a person or entity will be liable in the event of damage even if there is no evidence of fault or negligence. Here strict liability

and its products as well as GM products from a GM-animal or GM fish. By May 2012, 121 countries had completed most parts of their national biosafety frameworks and these frameworks can be said to be partially or fully in place in moststate parties to this Protocol. See www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx (accessed 25 September 2013). The CP has a total number of 166state parties.

⁶⁴The introduction of a new technology to conduct an activity tends to carry a higher risk than activities not involving a new technology. Its long-term effects cannot be assessed before gaining experience with the technology. See Lefeber n 3 above 4.

⁶⁵Yifru and Garforth Review of issues, instruments and practices relevant to liability and redress for damage resulting from the Transboundary Movements of Living Modified Organisms (2012) Biosafety Technical Series 03 UNEP 18. Genetic modifications of the Avian Influenza Virus A/H5N1 are said to have produced a variety of the virus that migrates between mammals without losing its pathogenic characteristics.

⁶⁶This liability is incurred when there is evidence of wrongfully inflicted damage caused by negligence or intentional fault.

⁶⁷The lack of respect of any rule causing damage may lead to a fault or negligence. Negligence can be the failure of the consignor or any other person to furnish information concerning the hazardous nature of the LMOs or failure to take necessary security precautions during the respective transboundary movement. See Canadian Institute for Environmental Law and Policy n 62 above 7.

⁶⁸This approval may have been based on an administrative direction, an expert or professional opinion on information made available by industry. See Glenn n 13 above 566.

⁶⁹Each defendant will be liable for the full amount of the damage caused if other defendants cannot be identified or are insolvent; The draft guidelines included joint and several liability or apportioned as appropriate in the event of multiple operators (see draft guideline 7); The Compact includes proportional responsibility for damage but prohibits 'joint and several liability', see art 12.4 Compact.

⁷⁰An absolute liability regime is similar to a strict liability regime but there is no exemption in the case of absolute liability. See McEowen n 59 above 624.

would mean that affected parties sustaining injury or damage may obtain damages by proving a causal link between the damage and the LMO.⁷¹ The main aim is to channel liability for damage to entities which are in a better position to prevent such damage by managing risks, and can better provide compensation for damage. ⁷² However, different entities or persons may qualify as the operator in different countries. In some states, liability for damage caused by legally approved GMOs is channelled to the producer,73 to the person subject to authorisation, 74 and/or to the notifier. 75 In other states, it is the person who works with a GMO⁷⁶ who may be liable for damage or there may be no channelling of liability.⁷⁷ The identification of the person having direct or indirect control over the LMO also calls for greater precision to enable better implementation in domestic regimes. In the case where the LMO has been stolen and released, it is not clear whether the operator or the thief should be regarded as having direct control over the LMO. Here, the operator would still be indirectly in control and could be held liable. If an absolute form of strict liability were to apply, the operator would be liable even if the LMO were stolen. 78 An operator held liable under strict liability may, in turn, have recourse to legal proceedings against the third party who caused the damage. Should a mitigated form of strict liability apply, the operator could prove his or her loss of control over the stolen LMO and be exempted from liability. Negotiations to adopt strict liability for such transboundary damage failed mainly due to a lack of consensus on the appropriateness of this type of liability for all categories of LMO.⁷⁹ Strict liability

⁷¹See chap 4 par 23 Norwegian GTA; art 30 of Swiss FLNHGT; art 8 of the French Law on GMOs Loi n° 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés Journal Officiel du 26 juin 2008); sec 124G New Zealand HSNO Act.

⁷²Secretariat of the CBD 'Liability and Redress (Article 27) Terms of reference for the Open-Ended Ah Hoc Group of Legal and Technical Experts on Liability and Redress in the context of the Cartagena Protocol on Biosafety: Synthesis Report of submissions received from parties, other Governments and organisations' First Meeting Kuala Lumpur 23-27 February 2004 Agenda Item 6.6 of the provisional agenda, UNEP/CB/BS/COP-MOP/1/9 par 17.

⁷³The Norwegian GTA states that the primary liability lies with the 'person who produces or uses LMOs'. See Secretariat of the CBD Report of the Intergovernmental Committee for the Cartagena Protocol on Biosafety Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms The Hague 22-26 April 2002 UNEP/CBD/ICCP/3/3 Item 4.1.1 of the provisional agenda par 20. The Chinese regulations on biosafety refer to the liability of the unit or person who is engaged in the process of production and processing of agricultural GMOs. See www.wipo.int/wipolex/en/text.jsp?file_id=182624. ⁷⁴See art 30(2) Swiss FLNHGT. Section 124G of the New Zealand HSNO Act states that the person subject to authorisation is liable for damages but also the person who does not comply with legal provisions or who has not been authorised to develop, import or release GMOs.

⁷⁵See the Austrian GTA; Secretariat of the CBD n 73 above para 20.

⁷⁶See s 1 South African GMO Act.

⁷⁷See part 6 Canadian Environment Protection Act (Canadian EPA) (EPA SC 1999, chap 33).

⁷⁸See principle 16 of the Rio Declaration; Glenn n 13 above 558; Strauss n 13 above 155.

⁷⁹Secretariat of the CBD 'Liability and redress (art 27) Update on developments in national, international and regional legal instruments on liability and redress' Conference of the parties

should be preferred as the principal liability applicable in domestic regimes, supplemented by fault-based liability where there has been premeditation or contributory negligence.⁸⁰

4.3 Legal causation

Given the present state of knowledge of the adverse impact of GMOs on the environment and human and animal health, providing evidence of the causal link between the damage and an LMO may not always be easy. ⁸¹ As there are few long-term studies on these adverse impacts, the potential of damage is not yet known. ⁸² In some cases, transboundary harm can be caused by more than one activity and could reasonably be traced to each one of them, although not always conclusively. ⁸³ Impartial scientific expert testimony will also play a significant role in litigation and adjudication in this area, and the use of expert evidence will be particularly challenging for judges. ⁸⁴ Further, in accordance with applicable confidentiality clauses, causation may be established only on the basis of information made available by the operator whose LMOs have been subject to a transboundary movement. The applicable standard of liability, too, will play a significant role in the burden of proof in the case of LMO-related damage. ⁸⁵ However, the NSP merely states that a causal link ⁸⁶

to the CBD serving as the meeting of the parties to the Cartagena Protocol on Biosafety, First meeting, Kuala Lumpur 23-27 February 2004 Agenda item 6.6 of the provisional agenda UNEP/CBD/BS/COP-MOP/1/9/Add 1 par 13. For strict liability regimes for nuclear damage see Convention on the Liability of Operators of Nuclear Ships 1962 (Brussels) (1963) 57 *AJIL* 268; and for the transport of dangerous goods and substances see 1989 Convention on Civil Liability for Damage caused during Carriage of Dangerous Goods by Road, Rail and Inland Navigation Vessels (the CRTD Convention, adopted 10 October 1989, not yet in force Doc. ECE/TRANS/79); and the 1996 International Convention on Liability and Compensation for Damage in connection with the Carriage of Hazardous and Noxious Substances by Sea (the HNS Convention adopted 3 May 1996, not in force (1996) 35 *ILM* 1415; The US, Canada, the United Kingdom and Japan do not impose strict liability but rely on the common law or general environment protection legislation for recourse.

⁸⁰Cullet n 11 above 180.

⁸¹With regard to animal health, in 2012 a Roundup-tolerant maize and Roundup were found to have provoked chronic hormone and sex dependent pathologies in rats over a period of two years by French scientist, Gilles-Eric Séralini. See Séralini and Clair *et al* 'Long term toxicity of a Roundup herbicide and a Round-up tolerant GM maize' (2012) *Food and Chemical Toxicology* www.sciencedirect.com/science/article/pii/ S0278691512005637.

⁸² Dufour and Barsalou et al 'Mondialisation de l'Etat de droit entre dislocation et recomposition: le cas du Codex Alimentarius et du droit transnational' (2006) 47 Cahiers de Droit 508.

⁸³ Secretariat of the CBD (n 79 above) par 26.

⁸⁴See Mandel 'The Future of biotechnology litigation and adjudication' (2005-2006) 23 *Pace Environmental Law Review* 110.

⁸⁵If a fault-based liability regime is applicable, evidence of the causal link between the damage caused and an LMO as well as a fault or negligence must be established before liability can be incurred. If a strict liability regime is applicable, the burden of proof may be shifted onto the

needs to be established between the damage and the respective LMO in accordance with the applicable domestic law.

4.4 Exemption from liability

The NSP provides for a limited number of defences which may exempt a state or a non-state actor from liability for damage resulting from transboundary movements of LMOs. A state or non-state actor is not liable if evidence is provided that the LMO-related damage arises from an 'act of God', 87 'force majeure, 88 or an act of war or civil unrest. 89 An 'act of God' can be raised by a defendant where there are events or situations which cannot be controlled by man such as storms, hurricanes, and other natural catastrophes. 90 Force majeure results from or forms part of acts which do not originate from the author of the omission or damage, or from the victim. If this act is proved to have been external, irresistible, and unforeseeable, the person held liable will be exempt from liability. 91 An example would be a case of damage caused by pathogenic GM microorganisms released during a shipwreck due to a natural catastrophe. As for 'an act of war', it should occur during a conflict characterised by extreme violence and social disruption between two or more states. In this case, pathogenic GM microorganisms, being transported for other purposes, could be used by state actors or non-state actors, institutions, or persons (other than the operator) to cause damage. Acts of civil unrest are also characterised by violence by non-state actors, and social disruption within a state resulting in damage during a transboundary movement of LMOs. For instance, damage can be caused by the release of untested GM seeds or GM viruses stolen for use in a civil unrest context. Other exemptions or mitigations

defendant with a rebuttable presumption of causation that he or she has caused the harm in accordance with the precautionary principle. According to this principle, an action should not be taken if there are likely to be uncertain and dangerous consequences as enunciated in Principle 15 of the Rio Declaration. See Birnie and Boyle *International law and the environment* (2002) 116; Flückiger 'La preuve juridique à l'épreuve du principe de précaution' (2003) XLI-128 Revue européenne des sciences sociales 117. In countries where a prima facie liability is applicable, once the plaintiff has established a prima facie case for liability, the defendant would have to prove on a balance of probabilities that he or she was not responsible. See Law Reform Commission 'Law Commission Report on Genetic Engineering Liability Issues' (2002) New Zealand par 80.

⁸⁶See art 4 NSP.

⁸⁷Above art 6(1)(a); art 8 Basel Protocol on Liability and Compensation (adopted 10 December 1999, not in force) Doc UNEP/CHW.1/WG/1/9/2; An extraordinary interruption by a natural cause (eg a flood or earthquake) of the usual course of events that experience, prescience, or care cannot reasonably foresee or prevent, www.merriam-webster.com/dictionary/act%20of%20god.

⁸⁸See art 6(1)(a) NSP.

⁸⁹Note 88 above art 6(1)(b).

⁹⁰Fox Dictionary of international and comparative law (1992) 154.

⁹¹Courts do not accept easily that facts amount to a 'force majeure'. Nguyen and Daillier et al (2002) 759.

may be provided at the discretion of state parties within their domestic regimes. 92

4.5 The limitation period

The limitation period is raised by a defendant to defeat an action brought against him or her after the appropriate time has elapsed. The period of prescription for claiming compensation with regard to transboundary LMO-related damage is important since it may take some time before the damage is discovered, and the time limits for normal claims for damages vary from country to country. Unfortunately, the NSP does not take any stance on a specific limitation period but provides that state parties may adopt domestic relative and/or absolute time limits, including limitations for actions related to response measures As a result, different limitation periods will apply in different areas and affected parties could run the risk of not being compensated if their action for compensation is time-barred in the state in which the damage occurred.

⁹²For example, where damage was caused exclusively by an act or omission of other states or non-state actors or a third party. Partial or total exemption will be a domestic policy decision. The Compact provides for the same exemptions as the NSP except for an act originating from *force majeure*. It includes the misuse of an LMO, compliance with compulsory measures imposed by the State, and the realisation of a risk accepted by the state which approved the LMO, see art 10.3 Compact.

⁹³For instance, in common-law countries such as the United Kingdom (UK) and the US, the applicable time limitation is six years for actions founded on tort, and three years for personal injury in the UK (Limitation Act 1980 chap 58) and s 107 of the UK Environment Protection Act (1990 chap 43) defines damage to the environment by GMOs but does not set a specific time limitation for civil actions regarding such damage. Time limitation for civil actions against the GMO permit holder for damage caused will probably be according to the applicable time limitation under the Limitation Act 1980. Time limitation runs four years after the cause of action accrues for civil actions arising under Acts of Congress in the US. See 28 US Code § 1658. For environmental damage in the US, the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (42 US Code chap 103). Statute of limitations for removal or remedial action begins to run upon completion of the removal action (three years running from the completion of the removal action) or remedial action; six years running from the commencement of construction of the remedial action). In civil law countries such as France and Belgium, the time limitation for civil actions in France is five years, see the new art 2224 of the French Civil Code, and ten years for physical injuries but 30 years for damage caused to the environment, see art L 152-1 of the French Environmental Code. Time limitation is five years in Belgium for non-contractual claims from the time the injured party became aware of the damage or its aggravation and of the identity of the person to be held liable. Such claims lapse twenty years from when the event which caused the damage took place, see art 2262bis(2) and (3) of the Belgian Civil Code. Limitation for damage caused to the environment in Belgium is five years from the time the injured party became aware of the damage or its aggravation, and of the identity of the person to be held liable. Such claims lapse 30 years from when the event which caused the damage took place, see art 2277ter of the Belgian Civil Code. 94See art 7(1)(a) NSP.

Ideally, a specific limitation period should be available in specific legislation for GMO-related activities in state parties. A number of issues should be addressed domestically regarding the limitation period – such as the commencement, suspension, or interruption of the applicable period with regard to compensation claims. A time-line should be set for claims to be filed, such as a period of three years up to a maximum of 30 years regarding damage caused by GMO-related activities. 95 This period could start three years from the time when the injured party became aware of the damage⁹⁶ and of the person liable. Domestic policy choices on the limitation period will also have to take the administrative investigation of such damage into account. The limitation period could end 30 years from the time the damage-causing event occurred in the company or ended, or from the date on which the GMOs were marketed.⁹⁷ Where the incident consists of a continuous occurrence, the 30 year period could run from the end of that occurrence. Where the incident consists of a series of occurrences originating at the same time, the 30 year period could run from the date of the last of such occurrences.

4.6 Financial limitation on liability

The NSP does not provide for any financial capping of liability with regard to the total amount of compensation that could be paid. Nevertheless, financial limits for the recovery of costs and expenses related to response measures may be set by state parties. If fault-based liability applies, there should be unlimited liability for damage caused, especially where there is evidence of intentional damage. If strict liability applies, a fixed or minimum limitation on amount could be considered. However, financial capping of liability may not be fair to affected parties given the uncertain extent of an LMO-related damage. Furthermore, when compensation is limited, there might not be enough to pay for all claims and capping would also limit the application of

⁹⁵See art 32 Swiss FLRNGT; In the EU, claims with regard to damage resulting from dangerous activities or environmental damage are subject to a limitation period of three years from the date on which the claimant knew or ought reasonably to have known of the damage and of the identity of the operator. See art 17 Lugano Convention on Civil liability for damage resulting from activities dangerous to the environment (hereafter the Lugano Convention) (adopted 16 September 1993, not yet in force) ETS 150 21 VI 1993 http://conventions.coe.int/Treaty/en/Treaties/ Word/150.doc.

⁹⁶See Law Reform Commission n 85 above par 95. The time limitation set by the Compact runs three years from the time the affected State submitted the claim or should have known about the damage (art 11.1(a) Compact) or from the time of effective notice by a citizen of the affected State (above art 11.1(b)).

⁹⁷It ends twenty years after the first authorisation or release of the LMO. See art 11.1(c) Compact.

⁹⁸See art 8 NSP. In Denmark, liability in this case is unlimited whereas there is no ceiling in Canada for damages awards. See Secretariat of the CBD n 8 above par 29.

the 'polluter pays' principle.⁹⁹ The determination of the level of fixed liability and the identification of the entity which may provide for the reparation of damage caused beyond financial capping, will depend to a large extent on domestic policy choices.

4.7 Financial guarantee mechanism

During the negotiations of the NSP, a compulsory financial security system with specific liability provisions was considered by proponents of a stringent liability regime as a prerequisite for the effectiveness of this regime. Financial guarantees are necessary to induce operators to adopt preventive measures to minimise risks of damage, as well as to reduce exposure to financial liabilities.

The setting up of a fund or supplementary collective compensation arrangements would be helpful where the operator no longer exists or does not have adequate funds fully to compensate the victim. Should damage be widespread and diffuse with no clear sources, the impact of LMO-related damage may not be easily remediable through a regime of individual liability. Where there is considerable damage and no evidence that the defendant failed to exercise the care and skill expected of a reasonable person in that field, a fund could ensure compensation for affected parties. However, there should be prior identification of the appropriate entities to provide for financial security as well as the necessary infrastructure. 103

Insurance would reduce the risks to which operators are exposed by transferring part of these risks to the insurers.¹⁰⁴ However, insurers are generally reluctant to accept incalculable risks where it is difficult to predict the loss scenario with regard to GMO-related liability.¹⁰⁵ The applicable

⁹⁹See financial limits for any single incident of damage to biological diversity in the Compact. For the restoration of damage, a maximum sum of 30 million Special Drawing Rights (SDRs) and for compensation alone, a maximum of 15 million SDR (see art 13 Compact). An SDR is an international type of monetary reserve currency, created by the International Monetary Fund in 1969, www.imf.org/external/np/fin/data/rms_sdrv.aspx.

¹⁰⁰Secretariat of the CBD n 79 above par 14.

¹⁰¹Law Reform Commission n 85 above par 97.

¹⁰²Note 101 above pars 67-68.

¹⁰³For example patent-owning companies on GM seeds and livestock setting up contingency funds for compensation. See 'National Farmers' Union Policy on GM foods' art 9, Canada; Glenn n 13 above 553.

¹⁰⁴Yifru *et al* n 65 above 19. Members of the Compact must demonstrate their capacity to meet their potential financial response obligations and are encouraged to develop commercial insurance cover these, Compact n 11 above par 26.

¹⁰⁵See Swiss Re Centre for Global Dialogue, Conference Report, International Biotechnology Forum, 2003 www.phase1.nccr-trade.org/images/stories/International%20Biotechnology% 20Forum%202003.pdf. Reluctance of the NFU Mutual, the largest insurance company for the British farming community and Swiss Re to insure genetic contamination or damage. Law

standard of liability plays an important role in the assessment of risks and in the availability of insurance. Fault-based liability tends to promote insurability. If strict liability is applicable, insurability requires that the claimant bear the causal burden of proof, and that the insured is allowed specific defences beyond those of 'act of God' or *force majeure*. ¹⁰⁶ The insurance industry will have to adapt insurance concepts to the specificities of GMOs. This could include the triggering factor for insurance cover, as well as product exclusions for GMO-related damage. ¹⁰⁷ In practice, there might be a cluster of associated claims and the various risks may not be offsetting. ¹⁰⁸

Even with a potential lack of insurance, other mechanisms such as letters of credit, trust funds, and bonds could be used. ¹⁰⁹ Bonds could be another way of ensuring that the genetic engineering industry has access to funds to cover claims for damages. In this case, operators will be required to deposit a specified amount for the real risk period. ¹¹⁰ If a bond is retained on the GMO-related activity, the amount to be retained, the evaluation of such amount, as well as the time-limit for retaining this bond will be subject to domestic policy choices.

Efforts to seek compulsory financial security for transboundary movements of LMOs have failed mainly because the biotechnological industry has been concerned that financial guarantees would result in increased prices for GM crops. ¹¹¹ The NSP only states that financial security mechanisms ¹¹² may be set up at the discretion of state parties. Discussions on this issue are still to be finalised by the COP to the CP. ¹¹³

Commission 'Liability for Loss Resulting from the Development, Supply or Use of Genetically Modified Organisms' (2002) Study Paper 14 New Zealand para 112 www.lawcom.govt.nz/sites/default/files/publications/2002/08/ Publication 104 263 SP14.pdf.

¹⁰⁶Yifru et al n 65 above 28.

¹⁰⁷See James 'Genetic engineering: A "potential" emerging coverage issue' www.potteranderson .com/ publication/genetic-engineering-a-potential-emerging -coverage-issue (accessed 4 April 2013). A 'rejection insurance product' may be made available for organic growers. See Mayerson 'Insurance recovery for losses from contaminated or genetically modified foods' (2003-2004) 39 *Tort Trial and Insurance Practices Law Journal* 845.

¹⁰⁸Law Reform Commission n 85 above par 108.

¹⁰⁹See Munchmeyer et al n 27 above 58.

¹¹⁰Law Reform Commission n 85 above pars 124-126.

¹¹¹There is neither a pre-payment fund nor a collective compensation measures for damage to biological diversity in the Compact n 11 above 11.

¹¹²See art 10 NSP.

¹¹³After the entry into force of this Protocol, the Secretariat will be empowered to undertake a comprehensive study addressing the modalities of financially mechanisms, their impacts and an identification of the appropriate entities to provide financial security, above art 10(3).

4.8 Settlement of claims on transboundary damage caused by genetically modified organisms

In terms of the NSP, state parties are responsible for establishing the necessary civil law procedures to enable affected parties to bring claims on LMO-related transboundary damage to biological diversity in domestic courts. In practice, domestic liability regimes may set rules for GMO-related damage and damage caused by all categories of GMOs, and not only LMO-related damage. Affected parties may also have recourse to the traditional approach to settlement of disputes by interstate claims based on the principle of State responsibility, ¹¹⁴ or to the contractual mechanism set by the Compact provided they fulfil the required conditions. ¹¹⁵

Under the NSP, a state or non-state actor can seek redress provided that there is evidence of transboundary damage to biological diversity. Affected states may file a case against the potential creators of transboundary damage to the extent that part of their territories or part of their population or traditional agricultural cultivations, have been affected by transgenes. Non-state actors such as individuals and companies can claim compensation in domestic courts for damage caused to property, personal injury, and environmental damage provided they show that a legally protected stake or personal interest has been affected. State parties may decide whether collective interests are also protected and there is no restriction on any right of recourse or indemnity that an operator may have against any other person. Public interest litigation, class actions, or other forms of collective interest may be used to claim damages for injury or environmental damage.

¹¹⁴Birnie and Boyle n 85 above 178. The NSP respects the rights and obligations of states under the rules of general international law regarding the responsibility of states for internationally wrongful acts (art 11 NSP). See the different forms of dispute settlement indicated in art 33 of the United Nations Charter 1 UNTS xvi.

¹¹⁵The Compact deals with claims for LMO-related transboundary damage to biological diversity but not claims for traditional damage. It provides only for contractual liability between importers and exporters although transboundary damage may affect parties who are not in a contractual relationship. If a claim against a Compact member cannot be settled, the matter can be resolved by way of arbitration under the aegis of the Permanent Court of Arbitration, www.biodiversitycompact .org/about/principles. It provides for exemptions, limitation in amount and in time, and rules on the standard of proof, but precludes the multiple recovery of damage and the simultaneous pursuance of claims under the Compact and domestic law. See Lefeber n 3 above 14-15.

¹¹⁶Only those who suffer damage can claim to secure such redress, whether they are states relying on the international law of State responsibility, or individuals relying on their right to bring transboundary actions in national law. See Birnie and Boyle n 85 above 7.

¹¹⁷See art 9 NSP. The draft guidelines proposed that any person, groups of persons, or public authorities can claim compensation for traditional damage and where appropriate the reimbursement of the costs of response measures. See draft guideline 9(1).

¹¹⁸For example, a class action can be used by a group of persons or even a single individual to defend the interests of a category of persons in the US (Rule 23 of the 1966 Federal Rule of

diversity occurs beyond the limits of national jurisdiction, the main questions are; who will have the standing to claim compensation; and what form the compensation should take. 119

In the event of damage, the NSP provides that recourse can be had to the affected party's domestic court, even if the latter is not a party to the Protocol. Jurisdiction over actions lies with the court of the party in whose territory the damage occurred according to the itinerary of the transboundary movement of the respective LMOs. In practice, there may be several victims in one single incident or an accident involving several nationalities. This then leads to issues with regard to the applicable laws, the competent court, ¹²⁰ and the enforcement of judgments. Damage may also occur in territories where there is no specific liability regime, or where the liability regime is inadequate to address such damage. Consequently, access to justice and compensation for affected parties will depend largely on the area where the damage occurred.

5 Conclusion

Although the biotechnological industry and GM crop-exporting countries claim that genetically engineered products are safe, it is interesting to note the

Civil Procedure (as amended to December 1, 2010)) and in Canada (The Class Actions Act SNL 2001, ch C-18.1). In India, a case can be filed in the public interest by any member of the public in good faith, in the case of environmental damage. See Deva 'Public interest litigation in India: A critical review' (2009) 28 *Civil Justice Quarterly* 27. In the European Union, any association or foundation (which according to its statutes aims at the protection of the environment in compliance with the laws of the State where the request is submitted) may bring an action for compensation. See art 18 Lugano Convention.

¹¹⁹Secretariat of the CBD 'Liability and Redress for Damage Resulting from the Transboundary Movements of Living Modified Organisms'. Review of existing relevant instruments and identification of elements, Intergovernmental Committee for the Cartagena Protocol on Biosafety, Second Meeting, Nairobi, 1-5 October 2001, Item 4.1 of the provisional agenda, UNEP/CBD/ICCP/2/3 para 10. The conservation of biological diversity in areas beyond the limits of national jurisdiction is considered as a 'common concern of humankind' but is of uncertain legal status, scope and implications. Initial proposals for the term 'common heritage of mankind' encountered opposition. Birnie and Boyle (n 85 above) 97-98. Whether the 'international community of States' can claim this 'common concern' for damage to biological diversity of global significance remains a question to be answered (*id* 99); Compensation could mainly be in terms of restoration measures.

¹²⁰If courts of different parties have been seized of actions or claims, any court other than the court first seized is required to stay its proceedings until the jurisdiction of the first court is established. This requirement allows the consolidation of related actions and single determination by one competent court. Yifru n 65 above 20.

¹²¹Where a judgment has been entered by a court of competent jurisdiction that is enforceable in the State of origin and is no longer subject to ordinary forms of review, the judgment is to be recognised and enforced in the territory of any contracting party. The judgment is to be recognised as final and binding in the respective territories of contracting states and states should ensure that a victim should be able to enforce it in any of those territories (*ibid*).

extent to which both have fought against having a strong CP as well as a liability and redress protocol during the respective intergovernmental negotiations. Lack of consensus on the regulation of transboundary movements of GMOs at the international level resulted in a regulatory framework applicable to LMOs only and no liability regime in the 2001 CP. Instead of a strong liability framework, the NSP adopts a two-pronged approach with a binding administrative mechanism and civil liability rules to be implemented with much leeway by state parties in 2010. Interestingly, a few months before the NSP was adopted, major biotechnological companies came up with their own compensation mechanism for LMO-related damage to biological diversity under the Compact. The very existence of such a compensation mechanism among these key players acknowledges that LMOs may cause damage to biological diversity and that existing instruments do not cater adequately for such damage. However, having recourse to the Compact, as has been shown above, has its limitations and will be done mainly in accordance with the rules of the biotechnological companies. Affected individuals cannot file claims under the Compact and only states can have recourse to this private compensation mechanism for LMO-related damage caused by an LMO developed by one of the six members of the Compact. Further, this private compensation mechanism does not allow double recovery regarding claims for damages under the Compact and domestic law.

The coming into existence of the NSP recognises that separate rules on liability and redress for damage resulting from transboundary movements of LMOs were necessary at the international level and fills the gap for such rules. It is the first multilateral environmental agreement to offer an international definition of damage to biological diversity, taking into account risks to health. It provides for a binding administrative mechanism in state parties to the NSP in the case of LMO-related damage, or sufficient likelihood of damage, so that the necessary response measures can be taken. It places the responsibility on the operator whose LMOs have caused the damage to notify the competent local authority in the affected State and take necessary response measures. If the author of the damage is unknown, the competent local authority in the affected State will be responsible for ensuring that timely response measures are taken. This has the benefit of not leaving LMO-related damage unregulated in areas under the jurisdiction of state parties even if the claim adjudication process takes time to be completed in the domestic court of the affected State. In the light of the administrative responsibilities that state parties to the NSP have with regard to LMO-related damage, importing countries are called to become more stringent in assessing risks related to their imports of genetically engineered products. This Protocol will be a trigger for state parties to assess whether their domestic liability regimes have adequate rules and procedures on civil liability and redress. Although a financial guarantee mechanism has

not been finalised, importing states may require financial security in their domestic laws with regard to genetically engineered products.

Moreover, both the administrative and civil liability approaches have their shortcomings. The administrative approach depends on the cooperation of the operator whose LMOs have caused the damage. If the latter has not notified the local authority in the affected State of the damage, then it is only when the damage is discovered and reported to the local authority that the administrative investigation procedure for such damage will be triggered. The administrative investigation may face issues such as a lack of evidence of the causal link between the damage and the LMO, undue delay, lack of cooperation by the operator/s, and the financial costs of response measures if the author of the damage is unknown. If several possible operators caused the damage, accepting the responsibility to take response measures may also imply that the identified operator is liable if there is a claim for damages. Furthermore, states¹²² may not have an administrative mechanism for monitoring LMOrelated damage when such damage occurs. The civil liability approach of the NSP does not establish a specific international liability regime with harmonised standards for transboundary damage caused by LMOs. State parties have a discretion to decide where to channel liability since there is no international strict liability standard. The Protocol does not address all damage resulting from transboundary movements of LMOs but lays down that state parties should aim at providing rules and procedures for material or personal damage associated with damage to biological diversity. Establishing causation with regard to LMO-related damage may be a daunting task in the case of scientific uncertainty. Civil liability and redress depend heavily on applicable rules in the area where the damage occurred and, consequently, the option for the parties involved to seek redress in different jurisdictions may have different outcomes.

Further, the interplay between the administrative and civil liability approaches when a claim for damages is filed, is not clear. The administrative approach came into play as a compromise and it may be considered as a standalone procedure to address LMO-related damage, or may be called upon to supplement the domestic liability regime of the affected State in terms of response measures. The outcome of the administrative investigation in an affected State will definitely impact on the causal-link aspects, the limitation period for the claim, the person or entity liable for the damage, the evaluation of the quantum of damages, and restoration measures still to be taken after immediate response measures have been taken. On the domestic level, the

¹²²For example, states which are a party to the CP but not party to the NSP, or states which are a party to neither Protocol.

administrative legal mechanism will doubtlessly have to be carefully drafted to avoid these unwelcome impacts. I wonder how far states, which are not parties to the NSP, will be willing to cooperate with regard to the implementation of this administrative approach as well as enabling redress pertaining to an LMO-related damage domestically.

It took more than six years to get more than an enabling clause¹²³ under the CP for liability and redress for damage resulting from transboundary movements of LMOs. The NSP undoubtedly contributes to the implementation and enforcement of the provisions of the CP in support of a precautionary approach. However weak this combination of legal and procedural safeguards set up under the NSP may be, it is the outcome of a consensus that did not exist in 2001 when the CP was adopted. In 2010, consensus was at last reached by state parties to the CP as well as six of the biggest biotechnological companies, to acknowledge that LMOs may be a threat to biological diversity and that response measures are needed.

The urgent ratification of the NSP¹²⁴ is of paramount importance so that it becomes binding for state parties to the CP to provide for civil rules and procedures enabling redress domestically in the case of an LMO-related damage.

¹²³Article 27 CP.

¹²⁴As at 20 May 2014, the NSP had been ratified by 22 state parties to the CP and eighteen ratifications are needed for its entry into force, http://bch.cbd.int/Protocol/parties/#tab=1 (accessed 24 April 2014).