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LIABILITY AND REDRESS FOR MODERN BIOTECHNOLOGY

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I. INTRODUCTION

The entry into force of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD)¹ (Biosafety Protocol) has signalled the start of a process that will probably lead to the development of international rules on liability and redress. The mandate for this is found in Article 27 of the Protocol which provides that

[t]he Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.²

While the process is now formally under way, there remain a number of uncertainties concerning the actual development of a liability and redress regime as well as its specific features. This is due in part to the controversial nature of modern biotechnology and the uncertainties surrounding its long-term impacts on the environment, health and economic development.

The development of a liability and redress regime under Article 27 of the Biosafety Protocol follows a series of other sectoral environmental liability regimes that have been adopted over the past two decades. This implies that the development of a legal regime concerning genetically modified organisms (GMOs) is not conceived in a vacuum but benefits from the experience accumulated with existing legal frameworks. In fact, a number of basic legal concepts have been previously discussed in other fora and the liability and redress regime under the Biosafety Protocol should be able to largely draw from existing legal regimes.

Similarities notwithstanding, the development of a liability and redress regime for GMOs raises a number of questions that need to be addressed separately. This is linked to the fact that the introduction of GMOs into the environment raises novel issues which have not necessarily been examined in the context of previous negotiations over environmental liability regimes.³ Thus, one of the main operative principles of the Biosafety Protocol is the precautionary principle and this principle influences the whole legal regime put in place, something which needs to be reflected in the liability and redress regime. Further, what constitutes damage arising as a result of the introduction of GMOs into the environment cannot be limited to definitions usually adopted to-date. Some of the novel elements that need to be incorporated include the question of socio-economic damage and patent liability.

This article is divided into four main sections. The first section introduces the process currently under way under the Biosafety Protocol towards the adoption of a liability and redress regime as well as some of the issues that member states need to address in this context. The second section moves on to highlight some of the substantive issues that need to be addressed in the development of a liability and redress regime in the field of modern biotechnology. These include the question of environmental damage, a central concern in an environmental treaty, as well as other equally important issues such as risks to human health, socio-economic aspects and the question of patent liability. The third section analyses existing legal frameworks to highlight some rules and principles that current negotiations on liability in the context of the Biosafety Protocol can use as models. It examines international environmental civil liability regimes whose general structure provides an appropriate starting point for liability and redress in biotechnology. It then analyses some existing liability regimes in the field of biotechnology which provide more specific pointers for the development of a biotechnology-related liability regime. The last section examines some of the points that need to be addressed in the context of the ongoing development of a liability and redress regime under the Biosafety Protocol. These include a number of elements within the environmental liability regime which need to be adapted to the field of biotechnology as well as issues concerning the link between environmental liability and patent liability, an issue of increasing importance at the national and international levels.

1 Convention on Biological Diversity, 5 June 1992, 31 I.L.M. 818 (1992) [CBD].

2 Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 January 2000, 39 I.L.M. 1027 (2000) at Article 27 [Cartagena Protocol].

3 In this article, GMO is used as a generic term which also covers living modified organisms (LMO).

II. LIABILITY AND REDRESS UNDER THE BIOSAFETY PROTOCOL

Article 27 of the Biosafety Protocol provides that member states should endeavour to complete their work on liability and redress by 2007.⁴ In this context, the first Conference of the Parties serving as the Meeting of the Parties (COP/MOP) that took place in 2004 adopted a specific decision on liability, formally acknowledging that the elaboration of a liability and redress regime is ‘crucial for the effective implementation of the Protocol’.⁵ As a result, the first COP/MOP formally started the process leading to the adoption of a liability and redress regime by setting up an Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress (Liability Working Group).⁶ The first meeting of the Liability Working Group will take place in mid-2005, followed by another four meetings by the end of 2007. The first COP/MOP also requested the convening of a Technical Group of Experts on Liability and Redress composed of experts nominated by state parties that met in October 2004 to help prepare the first session of the Liability Working Group.

The first COP/MOP adopted the terms of reference of the Liability Working Group. These provide first of all that the Working Group is open to the participation of non-member states as well as all international organisations and all non-governmental actors as observers. The substantive mandate of the Liability Working Group is quite broad. Its first task is to review information relating to liability and redress for damage resulting from transboundary movements of living modified organisms. This is then supplemented by a duty to analyse this information ‘with a view to building understanding and consensus on the nature and contents of international rules and procedures referred to in Article 27 of the Protocol’.⁷ This process which will last until the end of 2007 will be monitored by the COP/MOP which will have a chance to provide further guidance to the Liability Working Group in 2006 should member states find that work is not going in the expected direction.

The mandate of the Liability Working Group has been influenced in part by the fact that some member and some non-member states are opposed to the development of a liability regime and wanted the process to only focus on reviewing existing work done in this area with a view to then determine whether a separate liability regime was necessary.⁸ In the event, even though the terms of reference maintain an information-gathering function which is largely unnecessary since the Liability Working Group already has substantial information at its disposal, the Working Group has been given a clear mandate to come up with a proposal for a liability regime.

A number of issues need to be addressed by the Liability Working Group in coming years. Some of the forthcoming debates were already initiated in the context of the meeting of the Technical Group of Experts in October 2004 and the documents that were prepared for this meeting. Firstly, there remain debates concerning the specific liability and redress regime to be adopted. The first COP/MOP confirmed that the development of a liability and redress regime under the Biosafety Protocol is distinct from the process concerning liability and redress under Article 14(2) of the Biodiversity Convention.⁹ Even though some links between the two regimes should be made when they are adopted, it is important to separate them because Article 27 of the Protocol deals with much more immediate and specific issues whose solution is necessary for the proper functioning of the overall biosafety regulatory framework at the international level. This is less immediately important in the case of a framework convention like the Biodiversity Convention given the lack of specificity of most commitments taken by member states.

Secondly, there are on-going controversies concerning the appropriateness of a fully-fledged civil liability regime and several other proposals have been made. The weakest option would be to provide only international guidelines for national liability regimes. Another option would be to leave states to address the negative consequences of the introduction of GMOs into the environment by private parties. This might appear appropriate under general rules

4 The work of the Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress is to be completed by 2007. See *Terms of Reference for the Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety* [Terms of Reference], in Decision BS-I/8 (Annex), UN Doc. UNEP/CBD/BS/COP-MOP/1/15 (2004) [Decision BS-I/8].

5 Decision BS-I/8, *supra* note 5 at preamble.

6 *Ibid.*

7 *Terms of Reference*, *supra* note 4 at para 4.

8 See, for example, R. MacKenzie, *The Cartagena Protocol after the First Meeting of the Parties*, 13/3 Rev. Eur. Community & Int'l Env'tl. L. 270 (2004).

9 Decision BS-I/8, *supra* note 5 at preamble.

of international law but states have traditionally rejected such models and have instead used civil liability treaties as an alternative. A last option would be to simply harmonise rules of engagement to facilitate transboundary litigation between private parties without providing substantive rules.

Thirdly, the question of damages also remains contentious. This is due in part to the fact that there are divergences of opinion with regard to how extensive the coverage of the regime should be. It is, for instance, likely that debates over the inclusion of socio-economic considerations within the scope of the liability rules will go on for the next four years. However, even more settled aspects of damage are also controversial. On the one hand, some countries are keen to include such diverse elements as damage to the conservation and sustainable use of biodiversity, including the cost of measures of reinstatement of the environment, risks to human health, personal injury, loss of or damage to property and loss of income.¹⁰ On the other hand, the Global Industry Coalition argues, for instance, that, because of the link between the Protocol and the Biodiversity Convention and in accordance with Article 14(2) of the Convention, damage should be defined exclusively as related to damage to biodiversity.¹¹ The latter view seems incompatible with the Protocol which specifically indicates in its preamble that it is not subordinated to any other international agreement. This implies, for instance, that negotiating states validly decided to include risks to human health within the scope of the Protocol even though the mandate given by Article 19(3) of the Convention only mentions damage to biodiversity.

Fourthly, one of the specific issues that need to be addressed in the context of the Biosafety Protocol is the exact scope of activities covered by the liability and redress regime. There has been some debate around this because of the wording chosen in Article 27 which talks about 'damage resulting from transboundary movements' being covered by the liability and redress regime. This has been taken by some actors to mean that the liability and redress regime should only cover damage occurring during the transboundary movement.¹² A broader interpretation takes into account three other factors. Firstly, damages resulting from transboundary movements cannot be expected to occur only during the 'movement' and given the nature of GMOs, damage occurring as a 'result' of a transboundary movement may take place many years later. Secondly, even while focusing exclusively on transboundary movements it is necessary to remember that these include intentional transboundary movements, unintentional transboundary movements such as accidental releases, illegal transboundary movements and GMOs in transit. It may also include movements between parties and non-parties.¹³ In other words, there are a number of situations where the movement itself is not recorded and limiting the scope of the liability regime to damage occurring during the movement would significantly weaken the system being put in place by, for instance, largely keeping illegal movements outside of the purview of the system established. Thirdly, as emphasised by several member states, it seems appropriate to ensure that the liability regime eventually adopted covers all activities that fall within the scope of the Protocol.¹⁴ This implies that the liability regime should cover various activities including transfer, transit, handling, contained use, intentional introduction into the environment, use as food or feed or for processing. If the liability regime eventually adopted covers only some activities that fall within the scope of the Protocol, this will not only weaken the Protocol overall but also imply that different liability rules will apply to different activities covered by the Protocol, thereby raising the possibility of controversies between rules applicable in general international law, rules applicable under the Biodiversity Convention if the mandate under Article 14(2) of the Convention is fulfilled and rules applicable under the Protocol. No consensus exists on this issue at present.¹⁵

10 See, for example, Submissions by the European Union and Switzerland, in *Liability and Redress (Article 27), Compilation of Views Submitted in Response to Questionnaire on Liability and Redress for Damage Resulting from Transboundary Movement of LMOs*, UN Doc. UNEP/CBD/BS/TEG-L&R/1/INF/1 (2004).

11 Submission by the Global Industry Coalition, in *Liability and Redress (Article 27), Compilation of Views Submitted in Response to Questionnaire on Liability and Redress for Damage Resulting from Transboundary Movement of LMOs*, UN Doc. UNEP/CBD/BS/TEG-L&R/1/INF/1 (2004).

12 *Ibid.*

13 *Liability and Redress (Article 27), Compilation of Views Submitted in Response to Questionnaire on Liability and Redress for Damage Resulting from Transboundary Movement of LMOs*, UN Doc. UNEP/CBD/BS/TEG-L&R/1/INF/1 (2004).

14 See *Synthesis of Views Submitted in Response to the Questionnaire on Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms (Article 27 of the Protocol)*, UN Doc. UNEP/CBD/BS/TEG-L&R/1/2 (2004).

15 See *Report of the Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety*, Doc. UNEP/CBD/BS/TEG-L&R/1/3 (2004).

III. LIABILITY AND GENETICALLY MODIFIED ORGANISMS

The introduction of GMOs into the environment triggers a number of difficult legal questions. This is due to the fact that GMOs are substantially different from many other products insofar as they have the potential to actively interact with wild organisms once they are introduced into the environment. This explains in part the relatively strict conditions that a number of countries have put in place to regulate the introduction of GMOs into the environment so as to prevent the occurrence of harm. Nevertheless, given that the technology remains relatively recent and that its full impacts have not been ascertained, it is impossible to exclude that significant harm will not ensue following the release of GMOs into the environment. Given that human control over the technology largely ceases after the release into the environment, there is a need to provide legal mechanisms that assign liability for harm arising as a result of the release of GMOs into the environment. This has, for instance, been demonstrated in the case of the StarLink corn recall in the United States.¹⁶

In this context, liability and redress constitute one legal response to harm arising from legal or illegal activities. The primary function of liability regimes is usually to provide reparation to affected parties. This often takes the form of compensation.¹⁷ In the case of environmental harm, this may also include the restoration of the environment. Liability and redress regimes can also fulfil other functions. They can, for instance, have a preventive function to induce operators to adopt measures to minimise the risks of damage so as to reduce their exposure to financial liabilities.¹⁸ In this sense, liability regimes contribute to the implementation of the polluter-pays principle by imposing the integration of environmental and social costs. Liability rules can also act as an incentive to promote the implementation of existing environmental rules. Liability regimes thus provide a mechanism which can be used not only for compensation of damage having already occurred but can also contribute to damage prevention.

This section highlights some of the issues which should be addressed by states in the context of the development of a liability and redress regime for GMOs. The first element is environmental damage which is central in the Biosafety Protocol given that it is an environmental law treaty. In this context, significant assistance can be derived from existing liability and redress regimes but a number of issues nevertheless need to be considered in the specific context of biotechnology. While environmental damage is of central importance, it is only one of several potentially significant issues which need to be addressed in negotiations.

At least two other main questions must be considered. As recognised in Article 26 of the Protocol, socio-economic aspects also constitute an important concern of member states and in fact some of the main impacts of the introduction of GMOs in developing country agriculture may turn out to be socio-economic aspects related to livelihood concerns. These impacts need to be addressed in the context of a comprehensive liability and redress regime which contributes to strengthening the regulatory framework for biotechnology generally. Similarly, risks to human health which also fall within the scope of the Biosafety Protocol need to be taken into account since a number of GMOs end up directly or indirectly in the food chain.

The last element which needs to be examined by state parties is the question of patent liability, a novel element in the context of environmental negotiations. Patent liability is relevant in the context of the debate for two broad reasons. Firstly, while there is no recognised legal connection between the granting of a patent on a GMO and the biosafety procedures leading to its commercialisation, the link exists in practice and needs to be recognised. Secondly, while the liability of persons illegally using a patented invention has generally been separate from biosafety considerations, this is, for instance, not the case in the context of genetically modified seeds where there is a potential clash of liabilities between the liability of the entity commercialising the seed and the liability of the farmers found in possession of genetically modified seeds without having purchased it from a licensed dealer.

16 See, for example, R.M. Bratspies, *Myths of Voluntary Compliance: Lessons from the Starlink Corn Fiasco*, 27 Wm. & Mary Envtl. L. & Pol'y Rev. 593 (2003).

17 Cf. A. Boyle, *Reparation for Environmental Damage in International Law: Some Preliminary Problems*, in M. Bowman & A. Boyle eds., *Environmental Damage in International and Comparative Law: Problems of Definition and Valuation* (Oxford: Oxford University Press, 2002) 17.

18 This is, for instance, the approach adopted in Article 1 of the Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage, Official Journal L 143/56 (30 April 2004) [Environmental Liability Directive].

A. Environmental damage

The consideration of environmental damage as a type of compensable damage in liability regimes has significantly progressed over the past few decades. Today, it is generally accepted that environmental damage needs to be taken into account either as a factor causing personal injury or property loss or as a distinct element. Environmental damage can include the costs of measures of reinstatement of an impaired environment; the loss of income from an economic interest in the use or enjoyment of the environment incurred as a result of the impairment of the environment and the costs of measures undertaken or to be undertaken to prevent environmental damage.

Tackling environmental damage raises a number of specific problems. In practice, where damage is not directly linked to property rights or where damage cannot easily be measured in financial terms such as in the case of the loss of biodiversity, compensation cannot be conceived exclusively in monetary form. Where no direct economic loss is registered, such as in the case of damage to biodiversity which is not currently put to any use by human beings, the restoration of the environment is one possible solution for remedying the damage. This is only the case as long as the specific environment can be restored. In cases where damage is irreversible other solutions must be devised. Possibilities include the creation of a similar environment in a different location or a criminal sanction. These latter two solutions are not optimal from an environmental point of view and should be kept for exceptional cases. In the case of GMOs, the restoration of the environment to its original condition is likely to be often difficult because of GMOs' ability to reproduce or transfer genetic material to other organisms.

Environmental liability in the context of GMOs has a number of specific characteristics which start with the scope of possible damages. These include dangers linked to the instability of the genetic material and the possibility of further changes in GMOs, the transfer of genes to other organisms and the potential for transgenic varieties to outperform other varieties leading to the displacement or disappearance of wild species.¹⁹ As identified in the specific case of maize in Mexico, transgenes have already entered some landraces of maize.²⁰ It is acknowledged that once this happens, it is probably impossible to remove the transgenes.²¹

There also remain significant uncertainties concerning the extent of potential harm and its timeline. The UK field trials have, for instance, shed some more light on the potential for environmental harm of herbicide tolerant genetically modified crops. In the case of beet and spring rape, the study found, for instance, a potential for these crops to disadvantage wildlife and indicated that the occurrence of fewer weeds may substantially reduce the availability of seeds important in the diets of some birds. Further, it indicated that these crops may exacerbate long-term declines of flowering weeds, including those that are important food resources for seed-eating birds.²² This was largely confirmed by the last report concerning winter-sown oilseed rape.²³ While it is impossible to estimate the exact timeline of potential damages, long-term damages cannot be ruled out and should be taken into account in liability rules being developed.

The usual conditions triggering liability need to be discussed in the specific context of modern biotechnology. This raises several issues. Firstly, one of the usual conditions for triggering liability regimes is that actors must be directly identifiable. This can be a source of difficulties in the context of the documented spread of GMOs beyond the specific environment into which they have been introduced. In the absence of an identifiable entity being held responsible, liability may not be a suitable mechanism for compensation.

Secondly, the question of which damage is covered is also a contentious issue. A problem of causality may arise where negative environmental consequences cannot easily be traced to one particular cause or where the damage is too diffuse to be traced. In the context of GMOs, like in the context of other activities where damages have the potential to be significant, long-term or widespread, the scope of damages included in the liability rules, as well as associated transaction costs, ultimately determines the viability of the industry. In other words, the definition of damages may end up having some influence on the development of the biotechnology industry. In principle, from

19 See, for example, Science, Education and Culture Commission – Council of States (Switzerland), 00.008 e Projet Gen-Lex (droit de la responsabilité civile), Report of 27 August 2001.

20 Commission for Environmental Cooperation of North America, *Maize and Biodiversity – The Effects of Transgenic Maize in Mexico – Key Findings and Recommendations* (Secretariat Article 13 Report, 8 November 2004).

21 Commission for Environmental Cooperation, *supra* note 20 at 12.

22 M. Burke, *GM Crops – Effects on Farmland Wildlife* (2003).

23 David A. Bohan et al., *Effects on Weed and Invertebrate Abundance and Diversity of Herbicide Management in Genetically Modified Herbicide-Tolerant Winter-Sown Oilseed Rape*, 272/1562 Proc. R. Soc. B 463 (2005).

an environmental point of view, it is logical to take into account all damages as is done in some treaties.²⁴ In practice, a narrower definition of damage may be chosen. This would, for instance, limit damage to what is directly caused by the properties of GMOs, their reproduction or modification, and the transfer of genetic material from these organisms.

Thirdly, the identification of the link between the source of the contamination of the environment and the felt impacts is also an area of debate. The problem is linked to cases where environmental contamination is caused by sources which are either distant in space or time from the impacts. Examples include the case of damages caused in a radiological emergency which can take years or decades to become apparent and the case of long-range air pollution where the source may be hundred of miles away from the impact and may also be in a different country. GMOs present similar problems since damages may only become visible many years after their introduction into the environment.

Fourthly, apart from the substantive conditions mentioned above, it is also necessary to determine the standard of care which is demanded from persons or entities introducing GMOs into the environment. This depends on the perceived level of danger associated with a given activity. In certain cases such as nuclear energy or hazardous wastes, the activity has a clear potential to create significant environmental harm and states have consistently agreed that liability should be based on the principle of strict liability. In the case of GMOs, it is not yet clear how much harm may ensue from their introduction into the environment. Nevertheless, the central role of the precautionary principle in the regulation of GMOs needs to be taken into account when determining the standard of care demanded from actors introducing GMOs into the environment.

B. Health risks and socio-economic aspects

The introduction of GMOs into the environment is linked to the potential for risk to human and animal health as well as more broadly to a number of socio-economic impacts. While the Biosafety Protocol is primarily an environmental treaty, it clearly recognises that environmental aspects cannot be considered in isolation from other factors. Article 1 of the Protocol specifically brings health risks within the purview of the agreement. Member states are therefore under an obligation to consider health risks as well as environmental aspects when implementing the Protocol. With regard to socio-economic aspects, Article 26 of the Protocol recognises that GMOs can have socio-economic impacts that may or may not be directly linked to their impacts on the conservation and sustainable use of biodiversity. Article 26 focuses on the situation of developing countries as it singles out socio-economic impacts on indigenous and local communities for specific attention. While neither health nor socio-economic impacts are mentioned in Article 27, they can both be included in the analysis of damage and should be taken into account to ensure that all potential damages are covered in the liability and redress regime.

Health impacts remain, like environmental impacts, a largely uncharted area. However, there are situations where health risks exist and this should be taken into account in all regulatory regimes. One of the most well-known cases to-date relates to StarLink corn whose introduction into the environment was approved only under strict conditions. The US Environmental Protection Agency determined that StarLink corn was not fit for human consumption and only permitted its use for such other purposes as animal feed, ethanol production and seed increase.²⁵ The segregation from non-StarLink corn was not successfully undertaken and this led to a massive recall whose legal and economic consequences have been significant and widespread.²⁶ Another case relates to the dietary supplement L-tryptophan. This was linked to eosinophilia-myalgia syndrome, a condition which proved fatal for several dozen people in the early 1990s. A link was identified with a Japanese company producing L-tryptophan with the help of a genetically-altered strain of bacillus amyloiquefaciens which led to suspicion that the GMO involved might be at fault.²⁷ However, firm conclusions on the basis of this case cannot be reached since

24 See, for example, Article 3 of the International Convention on Civil Liability for Oil Pollution Damage, London, 27 November 1992, 1956 U.N.T.S. 255.

25 See, *Marvin Kramer v Aventis CropScience*, 11 July 2002, United States District Court, N.D. Illinois - Eastern Division, 212 F.Supp.2d 828.

26 On liability issues related to the StarLink, see, for example, D. Uchtmann, *Liability Issues: Lessons from StarLink*, 10 Rich. J.L. & Tech. 23 (2004).

27 See, for example, C.A. McGowan, *Learning the Hard Way: L-Tryptophan, the FDA, and the Regulation of Amino Acids*, 3 Cornell J.L. & Pub. Pol'y 383 (1994).

researchers do not seem to have managed to clearly establish the actual trigger for the eosinophilia-myalgia syndrome.²⁸

With regard to socio-economic aspects, two main categories of impacts can be identified. The first concerns the potential for GMOs to negatively impact the income of farmers who do not grow GMOs and more specifically organic farmers. This can take place in any situation where GMOs cross over from the fields where they have been planted onto other plots through cross-pollination, dispersion or any other method. In the situation where the contaminated plots belong to farmers who are organic farmers, the simple fact of contamination by GMOs has immediate negative economic repercussions even in the case where there is no significant or immediate environmental harm. Impacts include the loss of earnings due to the fact that organic farmers must then sell their crops at the lower price fetched by conventional crops or the much more significant loss of organic certification which can take place under certain organic certification schemes. This is due to the fact that an organic product is by definition free from genetically modified material.²⁹ The UK Biotechnology Commission has indicated that the loss of earnings due to a loss of certification could reach in the region of £500 per hectare in the case of organic maize in the UK.³⁰ The significance of the loss of organic certification has, for instance, led organic canola farmers in Saskatchewan (Canada) to sue Monsanto and Aventis, accusing them of having caused the contamination of their fields and thereby forcing them to abandon the production of organic canola.³¹ The loss of organic certification is the most visible form of socio-economic damage but is not the only form of damage likely to affect farmers. More generally, genetic contamination may lead farmers in developing countries to lose their identity markets where there is strong demand for GM-free agricultural commodities.

GMO contamination can also lead to other negative socio-economic impacts. The displacement of existing native plants by genetically modified plants not only has negative impacts on biodiversity generally but may also have negative impacts on agricultural biodiversity. In situations where genetically modified plants displace existing varieties used as food crops to meet basic food needs, their loss has a direct negative impact for people relying on these varieties. Another potential problem relates to the possibility for GMOs to compete with existing crops in the market place. Where genetically modified plant varieties are varieties which can grow in temperate climates while the original variety is a cash crop which normally grows only in developing countries, there is a significant potential for a loss of earnings for individual farmers in developing countries who may lose their export markets if their variety is substituted by the genetically modified one.

C. Patent Liability

Liability and redress is usually conceived as a tool to provide compensation for harm caused by a person or entity engaged in an activity which can have negative consequences for individuals, a community or the environment in general. In the context of GMOs, however, patent liability is also relevant. Patent liability implies that any user, conscious or unconscious, of an invention may be held liable for damages to the patent-holder for using a patented invention without approval. Therefore, under patent liability, what is at stake is not the liability of the entity commercialising a product but the liability of the user of the product. The fact that environmental liability and patent liability both potentially apply in the context of the release of GMOs into the environment implies that there is scope for clashes of liability in case the two do not lead to the same results.

Patent liability is not directly covered by Article 27 of the Protocol. Nevertheless, it needs to be addressed in the context of the development of a liability and redress regime for biotechnology. Sidelining patent issues in the context of biosafety is possible but ultimately leads to the development of skewed legal frameworks which do not effectively address the problems that need to be covered. Since most GMOs are protected by intellectual property rights and most GMOs are subjected to biosafety assessments, it is necessary to take into account both dimensions of the problem in discussing liability and redress.

28 See, for example, D.L. Burk & B.A. Boczar, *Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. Pitt. L. Rev. 791 (1994).

29 See, for example, Department for Environment, Food and Rural Affairs, *Compendium of UK Organic Standards (Version 3.5, 2003)*.

30 Agriculture and Environment Biotechnology Commission, *GM Crops? – Coexistence and Liability* (London: Biotechnology Commission, 2003).

31 See L. Hoffman & D. Beaudoin v. Monsanto & Aventis, *Statement of claim*, Saskatoon, 10 January 2002.

The relationship between the patent-holder and users of genetically modified patented seeds is relatively intricate. In the case of an individual deciding to purchase genetically modified seeds, the practice is now, at least in countries like Canada and the United States, for companies to include a contract which specifically determines the use that farmers can make of the patented seeds they purchase. In such cases, the legal situation is comparatively clear since the contract often specifically indicates that farmers cannot save seeds and cannot use them for more than one growing season. Difficulties arise from the fact that patent-holders cannot stop genetically modified seeds intentionally introduced into the environment from contaminating other fields and the environment in general. This type of contamination is the one that may trigger the liability of the patent-holder in case of socio-economic or environmental damages. At the same time, contamination of other farmers' fields can also trigger patent liability. This constitutes a novel situation where a patented invention can be acquired involuntarily by a farmer who may either be indifferent to the genetic contamination or seek to eliminate it in the case of an organic farmer. From the point of view of the patent-holder, the presence of a genetically modified seed on the land of a farmer who has not purchased the seeds is likely to be seen as a use of the protected product and therefore as constituting an infringement of the patent. This situation has been the object of a landmark decision of the Canadian Supreme Court in a case opposing Monsanto to a farmer from Saskatchewan, Mr Percy Schmeiser which is discussed in Section 4.

IV. POSSIBLE MODELS FOR A LIABILITY AND REDRESS REGIME IN MODERN BIOTECHNOLOGY

There is at present no international liability framework directly applicable to biotechnology. Nevertheless, as indicated above, the types of issues surfacing in the context of biotechnology are not completely new and states have previously developed a number of responses at the national and international levels to address the consequences of harm arising as a result of legal or illegal activities.

Over time, different types of legal mechanisms have been developed for redressing harm. In common law jurisdictions, tort law is often one of the tools used to address liability issues. In the context of modern biotechnology and environmental damage in general, torts may constitute an effective mechanism to allow an injured party to obtain monetary compensation by bringing an action against the tortfeasor outside of a contractual relationship. This ensures that the injured party is directly compensated and forces the tortfeasor to take into account the environmental costs of activities undertaken. In the context of GMOs, tort approaches allow, for instance, an injured farmer to take action against neighbouring farmers that plant GM seeds. This may either take the form of an action in trespass along the lines of the similar liability of farmers for the spread of weeds, or take the form of an action in negligence or private nuisance.³²

Torts nevertheless have substantial shortcomings in the context of environment related liability. Firstly, a tort approach does not provide the basis for a coherent regulatory framework and relies too heavily on private parties' interests for providing an appropriate response to public interest concerns related to the environment. Secondly, in the context of environmental damage, the damage may not be significant enough for one individual party to be willing to take action or have legal standing even if the overall damage is significant.³³ Thirdly, since tort law is primarily focused on the protection of persons and their property, it does not provide an appropriate basis for addressing complex issues linked to environmental damage.³⁴

The scope and limits of the use of tort law is well exemplified in *Cambridge Water v Eastern Counties*.³⁵ After an extensive discussion of tort principles, the judges came to two important conclusions. Firstly, they determined that the increasingly complex and extensive network of structured legislation being put in place in the environmental field implies that courts have a lesser burden in terms of developing common law in this area. Secondly, the judges refused to adopt a precautionary approach to environmental harm and limited themselves to finding that the

32 See, for example, R.A. McEowen, *Legal Issues Related to the Use and Ownership of Genetically Modified Organisms*, 43 Washburn L.J. 611 (2004).

33 See, for example, M. Anderson, *Transnational Corporations and Environmental Damage: is Tort Law the Answer?*, 41 Washburn L.J. 399 (2002).

34 See, for example, M. Lee, *Civil Liability of the Nuclear Industry*, 12 J. Envtl. L. 317 (2000).

35 *Cambridge Water v Eastern Counties Leather*, House of Lords, 9 December 1993, [1994] 2 A.C. 264.

unforeseeability of the damage at the time of the contested activities only put on the appellant company the liability imposed by negligence.

As indicated above, one of the characteristics of GMOs is that it is still a rather new technology whose full impacts on the environment are not yet known. As a result, the only appropriate approach and the one that has been chosen by the international community and a majority of states is to rely on the precautionary principle as a basis for the regulation of GMOs. This implies that in a situation like *Cambridge Water*, tort approaches would likely not be helpful. Further, the judges indirectly indicate that the approach of adopting structured environmental legislation may be better even in a common law jurisdiction.

The direct and indirect recognition of the limitation of tort approaches for dealing with complex issues such as harm arising from the release of GMOs into the environment has led states to adopt more structured liability rules. At the international law level, there is no regime that can be directly applied to modern biotechnology but there are an increasing number of liability regimes which provide good starting points for the development of a liability and redress regime in the context of the Protocol. Further, some regional organisations such as the African Union and the European Union as well as some individual countries have already gone further in proposing or introducing liability regimes in recent years.

A. International Law Principles and Rules

In the context of environmental problems, states have used different strategies for addressing the negative consequences on the environment of legal or illegal activities. At the level of inter-state relations, there are few binding treaty-based rules concerning state responsibility and liability. Existing principles include, for instance, a set of articles on the responsibility of states for wrongful acts developed by the International Law Commission (ILC).³⁶ In areas more specifically connected with the environment, the ILC has adopted draft articles on the prevention of transboundary harm from hazardous activities.³⁷ Further, the ILC is now working on the development of principles concerning activities not prohibited by international law.³⁸ As outlined in the Draft Principles, the objective is to ensure that compensation is provided in situations where significant transboundary harm is caused by activities not prohibited by international law. In effect, the Draft Principles seem to privilege pragmatic results by focusing on compensation rather than focusing on the development of a framework for liability that would provide the legal basis for compensation.³⁹ As a result, it is unlikely that these principles will make a significant contribution to the development of liability and redress regimes at the international level.⁴⁰

While states have generally been rather cautious in using rules and principles on responsibility and liability with regard to environmental harm, they have in recent times adopted a number of civil liability regimes which seek to harmonise rules concerning liability and redress. It is in fact in this area that the most interesting legal developments have taken place. A number of treaties introducing specific liability regimes have been adopted in the case of activities deemed particularly hazardous such as hazardous waste disposal, nuclear energy and oil pollution damage. Despite the variety of fora in which these treaties have been negotiated, they tend to provide broadly similar schemes. Firstly, they usually adopt the principle of strict liability in recognition of the need to channel liability to the promoter or operator of the dangerous activity.⁴¹ This is accompanied by certain exclusions such as war or acts of god.⁴² In

36 International Law Commission, Draft Articles on the Responsibility of States for Internationally Wrongful Acts, Report on the Work of its Fifty-Third Session, UN Doc. A/56/10, p. 43 (2001). See also T. Scovazzi, *State Responsibility for Environmental Harm*, 12 YbIEL 43 (2003).

37 International Law Commission, Draft articles on Prevention of Transboundary Harm from Hazardous Activities, Report on the Work of its Fifty-Third Session, UN Doc. A/56/10, p. 370 (2001).

38 See, for example, P.S. Rao, *First Report on the Legal Regime for Allocation of Loss in Case of Transboundary Harm Arising out of Hazardous Activities*, International Law Commission, UN Doc. A/CN.4/531 (2003).

39 International Law Commission, Working Group on International Liability for Injurious Consequences Arising out of Acts not Prohibited by International Law, Revised Draft Principles, UN Doc. A/CN.4/L.661 (2004).

40 Cf. J. Brunnée, *Of Sense and Sensibility: Reflections on International Liability Regimes as Tools for Environmental Protection*, 53 Int'l & Comp. L.Q. 351 (2004).

41 See, for example, Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Basel, 10 December 1999, UN doc. UNEP/CHW.5/29, Annex III (1999) [Basel Liability Protocol].

42 See, for example, Basel Liability Protocol, *supra* note 41 at article 4(5).

certain cases, the strict liability framework is supplemented by a fault-based liability for individuals contributing to causing the damage through negligence or premeditation.⁴³ Some treaties provide a possibility for the entity to which the liability is channelled to have recourse against other actors,⁴⁴ while some deny this option to the operator such as in the case of nuclear energy. Liability is also nearly always limited in time even though this limit can extend to several decades.⁴⁵ The amount that can be obtained is also nearly always finite.⁴⁶ In some cases, such as in the case of nuclear energy treaties, the civil liability regime includes compulsory insurance for nuclear operators as well as a subsidiary liability of the state. In other cases like in the case of oil pollution, a scheme of strict liability can be strengthened with the introduction of an additional fund financed by a levy on oil importers.⁴⁷ With regard to the damages taken into account, damage to the environment has usually been taken into account through the consideration of damages to persons and property as well as economic interests. There has, however, been a move towards the inclusion of other elements, such as the costs of preventive measures and the costs of restoration of a degraded environment.⁴⁸ However, even newer treaties do not usually take into account compensation for non-economic components of the environment where measures to restore the environment cannot be taken.⁴⁹

Besides existing international civil liability regimes, the Council of Europe has made a significant contribution by adopting a convention devoted to liability and environmental damage in general (Lugano Convention).⁵⁰ While the Lugano Convention is only a regional instrument, it has some noteworthy features that could be taken into account in the development of a liability regime for modern biotechnology. Its overall objective is to ensure adequate compensation for damage resulting from activities dangerous to the environment. Among its interesting features, the Lugano Convention recognises among dangerous activities the production, culturing, handling, storage, use, destruction, disposal, release or any other operation dealing with GMOs 'which as a result of the properties of the organism, the genetic modification and the conditions under which the operation is exercised, pose a significant risk for man, the environment or property'.⁵¹ The Lugano Convention is also noteworthy with regard to the definition of damage it proposes which includes not only impairment of the environment – limited to the costs of measures of reinstatement actually undertaken or to be undertaken – but also the costs of preventive measures and any loss or damage caused by preventive measures.⁵² The Convention has not yet come into force even though it was adopted more than ten years ago. This can be partly ascribed to the fact that it goes further than what some of the big states can accept today. This is related, for instance, to the fact that the Convention covers not only transboundary damage but also damage caused within the territory of a member state and that the scope of the Convention is found too wide by some states and the industry.⁵³ This is largely confirmed by the fact that the 2004 European Union Directive on environmental liability provides a much narrower framework for environmental liability than the Lugano Convention.⁵⁴

Overall, existing international liability regimes are of interest in the context of the development of a liability regime under the Biosafety Protocol for several reasons. Firstly, at the global level at least, states have privileged the development of specific liability regimes in the context of individual treaties. They have therefore emphasised the development of sectoral liability regimes over general rules for environmental liability which is consistent with the sectoral manner in which international environmental law has developed over the past several decades. Secondly, the reluctance of European states to ratify the Lugano Convention which seeks to promote a broader approach to environmental liability seems to indicate that it would be impractical to expect the international

43 See, for example, Article 2(5) of the Convention on Civil Liability for Nuclear Damage, Vienna, 21 May 1963 as amended by the Protocol of 12 September 1997 [Vienna Convention].

44 Basel Liability Protocol, *supra* note 41 at article 8.

45 See, for example, Vienna Convention, *supra* note 43 at article 6.

46 A noticeable exception is the Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, Lugano, 21 June 1993, 32 *Int'l Leg. Mat.* 1228 (1993).

47 See International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage, London, 27 November 1992, 1953 U.N.T.S. 373.

48 See, for example, Vienna Convention, *supra* note 43 at article 1(k).

49 See, for example, R.R. Churchill, *Facilitating (Transnational) Civil Liability Litigation for Environmental Damage by Means of Treaties: Progress, Problems, and Prospects*, 12 *YbIEL* 3 (2003).

50 Lugano Convention, *supra* note 46.

51 *Ibid* at article 2(1).

52 *Ibid* at Article 2(7).

53 See, for example, *Responsibility and Liability, Conference of the Parties to the Convention on the Transboundary Effects of Industrial Accidents*, First meeting, 22-24 November 2000, UN Doc. CP.TEIA/2000/14/Add.1.

54 Environmental Liability Directive, *supra* note 18.

community to rapidly develop a general binding framework for environmental liability. This implies a necessity to carry on with the sectoral approach and develop one more sectoral regime for biotechnology even if this may not be the best approach from a theoretical point of view. Thirdly, questions concerning state responsibility and civil liability should be addressed separately even though the basic principles are similar.

B. Selected Biotechnology-related Liability Regimes

The liability and redress regime under the Biosafety Protocol will likely borrow from existing international environmental liability regimes. Nevertheless, since there is little in existing international frameworks which is directly relevant in the case of modern biotechnology, further insights on the possible shape of an international liability and redress regime can be gained by examining some of the existing biotechnology-specific liability regimes.

This section analyses two different regimes: At a regional level, the Organisation of African Unity adopted a Model Law on Safety in Biotechnology in 2001 which contains a section on liability. At the national level, several countries have adopted liability regimes in the past decade. While various countries have come up with their own specific solution to liability issues,⁵⁵ this section focuses on the case of Switzerland's Gene Technology Act which constitutes one of the most evolved regimes in this area to-date.

The liability and redress regime to be adopted under the Biosafety Protocol is likely to be different from either the African Model Law or the Swiss Act. Nevertheless, both are relevant because they address issues that must also be considered under the Biosafety Protocol and because international civil liability regimes by their very nature cannot be understood in isolation from national regulation. Further, all states need to adopt liability regimes at the national level alongside the development of an international regime.

1. The African Model Law on Safety in Biotechnology

African countries have been in favour of the development of a stringent liability and redress regime since the time of the negotiations for the adoption of the Biosafety Protocol. As part of the process leading to the operationalisation of the Protocol, African states adopted a Model Law on Safety in Biotechnology (Model Biosafety Law) which includes an Article 14 specifically addressing issues of liability and redress.⁵⁶

The Model Law imposes strict liability for any harm caused by GMOs or GMO products that are imported, made, in contained use, released or placed on the market. Such harm must be fully compensated. Under Article 14, liability is attached to the person responsible for the activity which results in the damage as well as the provider, supplier or developer of the GMO. In situations where there is more than one person responsible for the damage, injury or loss, liability is joint and several.

With regard to environmental damage, Article 14 largely follows the model proposed by the Lugano Convention and provides that compensation must include the costs of reinstatement of the environment, rehabilitation or clean-up measures which are actually being incurred and, where applicable, the costs of preventive measures.

One of the important contributions of the Model Law is with regard to socio-economic aspects. It specifically provides that liability extends to harm or damage caused directly or indirectly to the economy or social or cultural practices or the livelihood or indigenous knowledge systems or technologies of a community. Such harm includes the following: disruption or damage to agricultural systems, reduction in yields and damage to the economy of an area or community.

The liability provisions are linked to a system of criminal sanctions in a range of situations outlined in Article 15. This includes cases where GMOs are imported, released or placed on the market without the written approval of the competent authority, where conditions attached to the grant of approval are violated, where false, misleading or deceptive information is provided in order to secure an approval, where GMOs are not labelled or identified or where identification is misleading or deceptive. The consequences applied under Article 15 include the usual

⁵⁵ See, for example, Norway, Act Relating to the Production and Use of Genetically Modified Organisms, 1993 and Germany: Gesetz zum Neuordnung des Gentechnikrechts, 2004.

⁵⁶ African Model Law on Safety in Biotechnology (2001).

sanction of imprisonment and fine as well as the prohibition of engaging in any activity related to GMOs for any natural or legal person that is convicted of infringement.

The African Model Law clearly reflects African states' negotiating positions during the Biosafety Protocol negotiations and their stated desire to introduce stringent liability and redress regimes as an integral part of the operationalisation of the Protocol.⁵⁷ Since the adoption of the Model Law, significant legislative activity has taken place in the field of biosafety in African countries in the general context of the coming into force of the Protocol for the thirty-odd countries that have ratified it as well as in the context of the UNEP-GEF Biosafety Projects.⁵⁸ However, countries that have been drafting biosafety regulatory frameworks do not seem to be closely following the Model Law. This is, for instance, illustrated in the case of Cameroon's Biosafety Act which limits itself to provide that '[I]iability for any damage resulting from the release of genetically modified organisms shall be borne by the implicated user'.⁵⁹ In Kenya, the Biosafety Bill simply provides that liability for biotechnology is to be addressed according to the existing legal framework, while in Zimbabwe, the Biotechnology Bill does not include a liability provision.⁶⁰ This seems to reflect the wavering position of some African states with regard to the incentives or disincentives they seek to offer to modern biotechnology.

2. The Swiss Gene Technology Law

Switzerland is one of relatively few countries to have gone through a comprehensive legislative debate over genetic engineering and adopted a biosafety legislation with a liability regime. The regime adopted offers a number of interesting lessons for the development of national and international liability regimes. This is due to the fact that while Switzerland has often adopted progressive environmental policies over the past few decades, its policies in the field of biotechnology are also strongly influenced by the important biotechnology industry lobby. Consequently, given the prevailing culture of consensus, the resulting legislation is a compromise which is generally acceptable to all actors, including the biotechnology industry and NGOs opposed to modern biotechnology.

The Gene Technology Law is a general biosafety law that has as its main aim to protect humans, animals and the environment from abuses of gene technology and to serve the welfare of humans, animals and the environment in the application of gene technology.⁶¹ Of particular importance, the law is based on the precautionary and the polluter-pays principles.⁶²

The adoption of a separate biosafety law and a separate liability regime was not planned from the outset. This is instructive because the debates that took place in the Swiss parliament largely mirror existing debates at the international level. In the first place, the proposal was for a series of amendments to the pre-existing Environment Protection Act.⁶³ This was eventually not accepted because the parliamentary commission dealing with this issue decided that there were too many specificities in the field of genetic engineering and that the proposed amendments to the Environment Protection Act would not adequately address all relevant issues. The Commission specifically indicated in its report that its proposal for a separate act stemmed among other things from the necessity to define more specifically the risks for humans and for the environment linked to the introduction of GMOs into the environment and from the necessity to provide specific liability rules, taking into account the interests of the agricultural and forestry sectors as well as the interests of the research community and industry.⁶⁴

The liability regime adopted as part of the law is a central component of the overall biosafety regime adopted. This is related to the fact that the legislation is in part the result of a compromise whereby Switzerland would not

57 See, for example, P. Kameri-Mbote, *Towards a Liability and Redress System under the Cartagena Protocol on Biosafety: A Review of the Kenya National Legal System*, 1 East African L.J. 119 (2004).

58 For further information on the UNEP-GEF projects, visit <http://www.unep.ch/biosafety/>.

59 Section 11(1), Law N° 2003/006 of 21 April 2003 – Law to Lay Down Safety Regulations Governing Modern Biotechnology in Cameroon.

60 See respectively Section 42, Kenya: A Bill for an Act of Parliament to Regulate Biotechnology and Biosafety Matters and for Connected Purposes (2003, not yet passed) and Zimbabwe: National Biotechnology Bill (2004).

61 Article 1, Law relating to Non-human Gene Technology, 21 March 2003, *Recueil systématique* 814.91 [Gene Technology Law].

62 Article 2, of the Gene Technology Law, *supra* note 61.

63 See *Projet de modification de la Loi sur la protection de l'environnement, Feuille fédérale*, p. 2327 (2000) and Federal Law relating to the Protection of the Environment, 7 October 1983, *Recueil systématique* 814.01.

64 Science, Education and Culture Commission – Council of States, 00.008 e Modification de la loi sur la loi protection de l'environnement (LPE) [loi sur le génie génétique, LGG], Report of 30 April 2001.

enforce a moratorium on GMOs but would provide a legal framework providing strict conditions for the release of GMOs and a strong liability regime.

The central characteristic of the liability regime is the adoption of a strict liability framework where the injured party is a consumer or farmer. Thus, the Law provides that

[t]he person subject to authorisation is solely liable for damage that occurs to agricultural or forestry enterprises or to consumers of products of these enterprises through the permitted marketing of genetically modified organisms, that is a result of the modification of the genetic material.⁶⁵

In other cases, there is a product liability regime whereby the person who has been given the authorisation to introduce GMOs into the environment is liable for defects which, according to the state of knowledge and technology at the time when the organism was marketed, could not have been recognised.⁶⁶ One exception is that the person subject to authorisation can take action against persons who have handled organisms inappropriately or have otherwise contributed to the occurrence or exacerbation of the damage.

The legislation also specifically provides a duty to compensate environmental harm. It provides that the person who is liable for the use of the GMOs must also reimburse the costs of necessary and appropriate measures that are taken to repair destroyed or damaged components of the environment, or to replace them with components of equal value.⁶⁷

Another noteworthy feature concerns the time limit for bringing up claims against the person subject to authorisation. It recognises that it is currently impossible to determine with precision the point at which damages will occur. As a result, the law provides that the right to claim damages expires thirty years after the event causing the damage or thirty years after the date on which the GMO was marketed.⁶⁸

The law also addresses the question of damages to areas which are not the object of real property rights, such as common lands. It provides that where the person liable to restore or repair the environment does not take appropriate measures, the relevant community is statutorily given the right to seek reparation.⁶⁹ This constitutes one question which must be addressed at the international level concerning areas that do not fall under national sovereignty. The direct or indirect introduction of GMOs in the high seas is, for instance, an issue which needs to be addressed on the basis of the precautionary principle even if existing GMOs are not deemed to constitute significant threats to the high seas at present.

With regard to procedural aspects, the law specifically addresses the question of burden of proof. While it specifically puts the onus on the party claiming damages to prove causation, it also provides that the judge can be satisfied with an 'overwhelming probability' where the proof cannot be provided with certainty.⁷⁰

Besides the liability regime itself, the law provides that the central government can also provide that parties wishing to commercialise GMOs may have to provide financial guarantees to cover their potential liability.

Overall, the Swiss legislation provides an interesting starting point for the development of liability regimes in part because it is based on a compromise which is acceptable to opponents and proponents of modern biotechnology. Nevertheless, the Swiss regime is not a panacea for all issues related to liability in the field of modern biotechnology. Thus, it appears, for instance, that nothing in Swiss law would stop companies marketing GMOs from shielding themselves at least partly or indirectly from their statutory liability. This may be achieved by introducing technology-use agreements that farmers need to sign when purchasing genetically modified seeds and which may include certain conditions that farmers have to follow when planting genetically modified seeds, such as a specific buffer zone. In other words, there is a possibility that private contracts may partly limit the effectiveness of the rather strict provisions of the legislation.

65 Article 30(2) of the Gene Technology Law, *supra* note 61.

66 Article 30(4) of the Gene Technology Law, *supra* note 61.

67 Article 31 of the Gene Technology Law, *supra* note 61.

68 Article 32 of the Gene Technology Law, *supra* note 61.

69 Article 31(2) of the Gene Technology Law, *supra* note 61.

70 Article 33 of the Gene Technology Law, *supra* note 61.

V. TOWARDS A LIABILITY AND REDRESS REGIME UNDER THE BIOSAFETY PROTOCOL

Modern biotechnology is a technology that has the potential to have undesirable impacts even if it is implemented according to the strict biosafety standards that a number of countries have adopted. The simple fact that some or all of these risks may be realised is sufficient to warrant the development of a liability and redress regime. This is true at the national level for all countries which do not have liability regimes which can cover the specificities of modern biotechnology. This is also true of international law which does not include a liability regime that could cover the kinds of risks arising in the context of the release of GMOs into the environment.

A. Liability and redress: An integral part of the biosafety regulatory framework

The development of liability rules is a necessary complement to the development of biosafety frameworks. This is already implied in Article 27 of the Protocol which acknowledges that the task was left unfinished during the negotiations for the Protocol. The special characteristics of modern biotechnology reinforce the need for a separate statutory liability scheme. Relying on existing mechanisms such as torts in common law countries or existing principles of international law is an inadequate legal strategy because it creates significant uncertainty of outcomes in view of biotechnology's specificities. This will therefore neither allow the orderly development of the biotechnology industry nor provide an adequate level of protection to the environment and human health.

The development of liability rules remains sensitive because the specific regime adopted will have a significant influence over the development of modern biotechnology. A liability regime provides an indirect incentive or disincentive for proponents of a specific activity. Where states regulate hazardous activities, they are often faced with different policy options. They can decide to completely ban an activity or they can decide to authorise it but to impose a strict regulatory framework and the sanction of a liability regime in case damage occurs. The liability regime can be made more or less strict depending on the kind of incentives that states want to give for the development of an industry. This is typically what occurred in the case of the nuclear industry. States decided from the outset to protect the nuclear energy industry from the full consequences of potential claims on the basis that this may have discouraged investment in nuclear energy, an industry whose benefits seemed clear for a long time to most governments.⁷¹ The Biosafety Protocol which provides the main regulatory framework for modern biotechnology seeks to balance the recognition of the potentially dangerous nature of GMOs, by providing the possibility to base decisions on the precautionary principle, and the promotion of transboundary movements of GMOs. This approach requires the adoption of a liability regime to complement a system which does not ban the transboundary movement of GMOs but recognises the potential for harm. This liability regime should be related to the primary instrument and reflect the main objective of the Biosafety Protocol which is to ensure an adequate level of protection concerning the transfer, handling and use of GMOs. This provides a way to ensure that the precautionary principle is implemented throughout the regulatory regime put in place, from the risk assessment to the liability regime and the sanctions imposed.

At present, there remain substantial uncertainties concerning the specific form of the liability and redress regime that may be adopted by member states in coming years. At this juncture, it is not possible to do more than outline a few elements that would be required to ensure the adoption of a liability regime that contributes to realising the operative principles of the Biosafety Protocol. Firstly, the liability and redress regime adopted needs to have clearly defined aims related to underlying instruments. These include the need to foster environmental conservation together with the need to protect human health. More specifically, liability rules need to contribute to conserving biodiversity, soil fertility and the integrity of living organisms.

Secondly, liability rules need to have socio-economic objectives, including the realisation of the right to food and generally fostering access to food as a basic need. As recognised by the African Model Law, the introduction of GMOs can have disruptive impacts on the local economy of a community which may have direct repercussions on food security where agriculture is mainly a livelihood activity.⁷² Beyond the issue of basic needs, liability rules should also contribute to ensuring consumer choice between organic – and generally non-GM products – and GM

⁷¹ See, for example, M. Lee, *Civil Liability of the Nuclear Industry*, 12 J. Envtl. L. 317 (2000).

⁷² See Article 14(5), African Model Law on Safety in Biotechnology (2001).

products. In environmental protection terms, the development of liability rules has direct connections with the issue of co-existence of GM and non-GM crops.⁷³ Without taking measures to ensure the complete separation of GM and non-GM crops, consumer choice will simply be denied in practice. Consumer choice is in fact an issue which has been given increasing recognition. Thus, in the context of the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Århus Convention), the convention's core issues have been further debated concerning GMOs following its entry into force.⁷⁴ This resulted in the adoption by the first Meeting of the Parties to the Århus Convention of a set of Guidelines on GMOs.⁷⁵ These Guidelines provide relatively general, yet GMO specific, guidance to states concerning public participation in decision-making concerning certain GMO-related activities, access to information, its collection and dissemination as well as access to justice.⁷⁶ These Guidelines constitute an important first step in strengthening the tools available to consumers, farmers and citizens to ensure transparency in GMO-related decisions.

A number of issues also arise with regard to the choice of elements from existing civil liability regimes. Concerning the level of protection necessary in the context of modern biotechnology, the central role of the precautionary principle in the regulation of biotechnology necessitates the adoption of a strict liability approach. This is linked both to current uncertainties concerning the magnitude of possible damages and the extent to which they may occur over a long period of time. This is, for instance, the position adopted by Switzerland, partly for pragmatic reasons.⁷⁷ In parliamentary debates concerning the Gene Technology Act, the adoption of a strict liability framework was seen as a necessary response to proponents of a complete moratorium on the introduction of GMOs into the environment.⁷⁸ The adoption of a strict liability regime constitutes a compromise which may neither fully satisfy proponents nor opponents of modern biotechnology. Strict liability provides a relatively stringent protection regime which is seen as impeding the development of biotechnology. Conversely, opponents would prefer a regime of absolute liability and one which comes without limitation on the scope of damages that are recoverable. This is linked to the question of limitations placed on the amounts that can be recovered. Damage limitations provide one of the most immediate ways in which incentives or disincentives can be provided to the biotechnology industry. Historically, industries facing liability regimes have always tried to ensure that some limit is put on the claims that can be made against them. The justification for introducing limits depends on the nature of the activity and the perception that society has of its usefulness for socio-economic development, health or the environment.⁷⁹ In other words, a regime of strict liability with limited damages constitutes the compromise which allows the industry to develop while taking into account the significant concerns of some actors and uncertainties concerning potential damages. Damage limitation needs to be associated with an insurance regime or fund to ensure that claims are covered to the largest possible extent.⁸⁰

With regard to damages, the liability and redress regime needs to build upon existing principles in the field of civil liability and take into account the specificities of modern biotechnology. This implies providing a definition of damages which includes damages to the environment, to human health, to property and to economic interests. Further, the definition of damages needs to determine whether plaintiffs must wait for actual damage to become visible or whether an evidence of gene introgression is sufficient. Another difficulty which needs to be addressed concerns the different levels of risk involved with damages in different regions. Because of the nature of GMOs, the introduction of a genetically modified variety in an area which is a centre for diversity for the crop in question is of much higher significance in terms of biodiversity conservation than its introduction in another region. The liability and redress regime therefore needs to include special rules concerning the contamination of centres of origin given their importance in meeting today's and tomorrow's food needs for the whole of humankind. This may imply adopting an even stricter regime for zones that are either known to be ecologically sensitive or known to be of great importance for biodiversity conservation.

73 On the issue of co-existence, see generally Agriculture and Environment Biotechnology Commission, *supra* note 30.

74 Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Århus, 25 June 1998, 38 Int'l Leg. Mat. 517 (1999).

75 Decision I/4, Genetically Modified Organisms, Report of the First Meeting of the Parties to the Århus Convention, Lucca, 21-23 October 2002, UN Doc. ECE/MP.PP/2/Add.5.

76 Guidelines on Access to Information, Public Participation and Access to Justice with Respect to Genetically Modified Organisms, UN Doc. MP.PP/2003/3-KIEV.CONF/2003/INF/7 (2003).

77 Other countries have adopted a strict liability approach. See, for example, Brazil: Article 20, Law No. 11.105 of 24 March 2005.

78 See Pierre-Alain Gentil, Conseil des Etats, Séance du 14 juin 2001, BO 2001 E 332.

79 See, for example, Churchill, *supra* note 49 at p. 35 concerning ship owners' liability.

80 This is often a thorny issue in negotiations as witnessed in the case of Basel Liability Protocol, *supra* note 41 which has largely left the question open for future negotiations.

The means of addressing damages is another issue which warrants careful consideration. In the context of genetic contamination, it is not clear whether genetic clean-up would be a feasible option. Since direct compensation may not be possible, alternative mechanisms such as penalties should be available. In fact, this is a solution which has already been proposed in certain cases such as in the Convention on the Protection of the Environment through Criminal Law and is partly reflected in Brazilian law.⁸¹

Another issue which needs to be determined in the liability regime is the identification of the natural/legal person responsible for damages that may occur. Given the ability for GMOs to actively interact with wild organisms once introduced into the environment, the liability regime needs to address this issue in clear terms. The liability regime needs to ensure that a lack of specificity in liability rules does not indirectly lead to final users such as farmers being held responsible, an inappropriate solution given that farmers are generally unable to distinguish GM crops from non-GM crops. As a result, the solution adopted in the Swiss Law which targets the person/entity receiving the authorisation from the state to introduce a specific GMO into the environment provides an appropriate starting point.⁸² This has the advantage of making the identification of the person/entity liable relatively easy since, in an increasing number of cases, commercialised GMOs are protected by patent rights. Further, the absence of a rule focusing the liability on the patent-holder may render GMOs unattractive to farmers who might see themselves sued by their neighbours for contamination of their fields.⁸³ The rule that all liability may be channelled to the entity introducing GMOs on the market must nevertheless be qualified at least in part at the international level. Firstly, in an international context, since the Biodiversity Convention Secretariat is not given the power to approve the commercialisation of GMOs, the decision has to be taken at the national level. In an international transaction concerning GMOs, a number of actors can be involved. These include the producer or developer of the GMO, the entity notifying an intention to export, the exporter, the carrier or the importer. In principle, in accordance with the precautionary principle, the main burden of liability should fall on the developer and producer of the GMO. Further, it would be best from an environmental point of view if liability fell mostly on the side of actors in the exporting country which initiate the transboundary movement and are best able to address damage in case the risk is realised. In practice, a system channelling all liability to the producer and developer would only work if the Biodiversity Secretariat was given a strong role in the implementation of the liability and redress regime allowing it to ensure that the country of import can enforce the liability rules in the country of export. Alternatively, it may be appropriate to ensure that injured parties are able to claim for damages in their own jurisdiction against the importer. The liability and redress regime should then provide a system identifying actions that can be taken by the importer if it wants the liability to be channelled back upstream to the exporter, notifier or producer. In other words, all the relevant actors would be jointly and severally liable.

B. Environmental Liability and Patent Liability: Towards a Comprehensive Liability Framework

As noted in Section 2, patent liability does not directly fall within the scope of Article 27, largely because the Biosafety Protocol does not deal with intellectual property rights issues. Similarly, patent laws and treaties do not address biosafety concerns because the patent regime is in general conceived as fulfilling a different function. Nevertheless, there are increasing links between the two fields which need to be taken account at different points in the regulatory framework. In terms of liability, the central issue is that there are different 'liabilities' for different actors that may be triggered in the context of a single event. These liabilities may be complementary or may be opposed. This is why a comprehensive liability regime for modern biotechnology needs to consider all dimensions of the issue.

The question of the respective liabilities of the company commercialising GMOs for environmental contamination and the liability of farmers who are found in possession of GM seeds without having purchased them from a licensed dealer is best illustrated in a judgment of the Canadian Supreme Court in *Monsanto Canada Inc. v Schmeiser* which provides an appropriate basis for discussing these issues at the national and international levels.⁸⁴

81 See respectively Convention on the Protection of the Environment through Criminal Law, Strasbourg, 4 November 1998, 38 Int'l Leg. Mat. 259 (1999) and Article 13, Brazil: lei de biossegurança, 1995.

82 Cf. M. Faure, *The International Regime for the Compensation of Oil Pollution Damage: Are they Effective?*, 12/3 Rev. Eur. Community & Int'l Env'tl. L. 242 (2003) at p. 250 highlighting advantages and disadvantages of this solution.

83 Cf. Section 36(a), Germany: Gesetz zum Neuordnung des Gentechnikrechts, 2004. See also Canadian Institute for Environmental Law and Policy, *GMO Statutory Liability Regimes: An International Review* (Toronto: CIELAP, 2004).

84 *Monsanto Canada Inc. v Schmeiser*, Supreme Court of Canada, Judgment of 21 May 2004, 2004 SCC 34.

The background to this case is the development by Monsanto of a genetically modified variety of canola which is resistant to the application of Roundup Ready, a herbicide that kills most plants. Mr Schmeiser had been growing canola for many years. In the 1990s a number of his neighbours decided to use the Monsanto canola variety on their fields. Mr Schmeiser seems to have decided not to introduce the genetically modified variety. However, Mr Schmeiser was found in possession of Roundup Ready Canola even though he had never purchased it. Following the discovery of genetically modified seeds on his fields, Monsanto brought an action against Mr Schmeiser for infringement of their patent on Roundup Ready Canola. More specifically, Monsanto asserted that Mr Schmeiser had used, reproduced and created genes, cells, plants and seeds containing the genes and cells claimed in Monsanto's patent without authorisation. The Supreme Court found that the patent had been violated but that Mr Schmeiser did not owe anything to Monsanto.⁸⁵

This judgment raises a number of questions from the point of view of patent law which are not explored here. Besides patent issues, the judgment raises broader questions since it fails to address other important issues related to the introduction of genetically modified seeds into the environment. Thus, it does not consider questions related to biosafety, or questions related to the environmental liability of the company commercialising the genetically modified seeds, or questions related to farmers' rights or privileges.

With regard to biosafety, an important dimension of the case not addressed by the judges is the relationship between patent liability and environmental liability. While patent protection is one of the main legal incentives for the development of modern biotechnology in the private sector, biosafety regulations are the main instrument through which environmental and health impacts of GMOs are examined. One of the main reasons why biosafety should be considered in a case like this is that it brings up different but complementary aspects to the dispute. The patent dispute looked exclusively at the question of whether Mr Schmeiser had infringed a patent. A biosafety dispute would also have looked at the issue of whether Monsanto should be deemed responsible for introducing into the environment a genetically modified construct which has the potential to self-replicate.⁸⁶

Seen from this broader perspective, the dispute between Mr Schmeiser and Monsanto becomes a question of the respective liability of Mr Schmeiser concerning the patent infringement versus Monsanto's liability for the contamination of his property. This raises problems which were not addressed by the court.

Firstly, there is a need for clarity concerning the responsibility of the different entities and individuals involved in the introduction of genetically modified seeds into the environment. As noted above, an appropriate solution is to provide that the entity which has been given the authorisation to introduce a GMO into the environment is solely liable for damage that is a result of the modification of the genetic material. Should a different solution prevail, the legal framework should at least clearly demarcate the responsibility of the entity marketing the genetically modified organism and the responsibility of other users. In *Monsanto v Schmeiser* where the farmer is deemed to have infringed the patent even if his fields were in fact contaminated, this would seem to absolve the entity marketing the seeds from any liability and shift the burden to users. On the basis of the Schmeiser decision, the principle established would appear to be that the only legal relationship that farmers have with Monsanto is with regard to patent protection. In a situation where their fields are contaminated, they would only be able to sue their neighbours for the contamination.

Secondly, the issue of a balance of liabilities raises the question of the control that farmers have or can have over the land they own or use. Different farmers may take different decisions concerning the kind of agriculture they want to undertake and some decide to pursue organic agriculture. Since the definition of organic agriculture implies that there should be no genetically modified plants, contamination by genetically modified seeds would immediately disqualify organic farmers from selling their crops as organic and would lead to a loss of earnings since organic products in general fetch a higher price than non-organic ones. Unless there is a clear decision to forgo organic or conventional agriculture, contamination of crops should be compensated by the entity causing the contamination. The entity which benefits from the commercialisation of the genetically modified seed should be the one shouldering the costs related to the contamination of the environment.

Thirdly, this also raises the issue of farmers' rights. The situation can be divided between the rights of farmers who purchase genetically modified seeds and other farmers. In the case of farmers who purchase, for instance, Roundup Ready Canola from Monsanto, they have to sign a technology-use agreement which contractually restricts the rights they have over the seeds they purchase. These agreements have, for instance, been challenged in some cases

⁸⁵ *Id* at §§ 97 and 105.

⁸⁶ This goes beyond and is not related to the decision allowing Monsanto to commercialise Roundup Ready Canola.

in the United States but the courts have found that even if they deprive farmers of some statutory rights this does not invalidate the contract which they voluntarily sign as part of the purchase agreement with the company.⁸⁷ While the situation of farmers who are bound by a technology-use agreement seems clear at least in North America, these contractual provisions should not, in principle, affect the rights of other farmers. Farmers who do not purchase these seeds should have the rights they customarily enjoy as part of the ‘farmer privilege’ enjoyed under the plant breeders’ rights system. These farmers should theoretically have the right to save and use seeds that they have grown even if they have been pollinated by genetically modified pollen. *Monsanto v Schmeiser*, however, seems to indicate that unless a farmer had no inkling of the potential presence of genetically modified seeds, s/he would be liable. In practice, this means that the onus of the proof is on farmers. This also implies that if farmers grow non-genetically modified crops in an area where genetically modified crops are grown, there could be a presumption that they ‘ought to know’ of the possible presence of protected genetically modified seeds on their fields.

Overall, *Monsanto v Schmeiser* is an important decision. On the one hand, it acts as a clear warning to other farmers in Canada that they have to watch their fields for the presence of genetically modified seeds. It also indicates that patent protection seems to prevail today over the rights that landowners have and that issues concerning biosafety, co-existence and liability are of low importance. On the other hand, the finding that the patent-holder can in principle assert its rights on all transgenic seeds used in a commercial context whatever their origin may make the link between environmental contamination and the patent-holder easier to establish.

In an international perspective, the Schmeiser case can be seen in two different ways. On the one hand, the case may remain an isolated decision and its impacts may stop at Canadian borders. This will be the case if all other countries adopt strict biosafety frameworks which make it clear that the entity marketing the genetically modified organism is solely liable for all consequences arising from its introduction into the environment. On the other hand, there remain at present a number of countries where the legal framework is not specific enough to ensure that similar cases will never occur in the future.

C. Final Remarks

Liability and redress is a mechanism that seeks to strengthen the effectiveness of the underlying legal regime. The adoption of a liability and redress regime does not indicate a desire to foreclose the development of a new technology but rather to promote it while ensuring that all eventualities are taken care of. In the case of technologies whose harmful capacity has been established, preventive measures require the adoption of strong liability regimes. The same is true for modern biotechnology on the basis of the precautionary principle which provides the legal basis for addressing the uncertainties linked to this still relatively novel technology.

The development of a liability and redress regime for modern biotechnology can be linked in part to existing environmental liability and redress treaties developed over the past couple of decades since a number of basic issues are similar. Further work needs to be carried out in certain areas that have not been adequately covered earlier or that are specific to modern biotechnology. These include the question of socio-economic damage and the necessity to address the potential clash between the environmental, health and socio-economic liability of the entity introducing GMOs into the environment and the patent liability linked to the fact that most GMOs introduced on the market are protected by patents or other intellectual property rights.

Existing international liability regimes provide a basis for the development of liability rules concerning traditional and environmental damage in the case of modern biotechnology. Existing national biotechnology-specific liability regimes such as Switzerland’s Gene Technology Law provide a model for some of the specific issues that need to be addressed in the context of GMOs. However, existing regimes neither cover the question of the link between environmental and patent liability nor satisfactorily address the question of socio-economic damage. There remains scope for significant and constructive debates in the context of the process started under Article 27 of the Biosafety Protocol. The development of a comprehensive and adequate liability and redress regime under the Protocol and in all individual countries is critical in view of the uncertainties surrounding the impacts of the introduction of GMOs into the environment. The successful conclusion of the process started under Article 27 of the Protocol is critical for the effectiveness of the international law regime adopted. The adoption of individual liability regimes in all states where GMOs are introduced will be the necessary complement to the international law regime.

⁸⁷ See, for example, *Monsanto v McFarling*, United States Court of Appeals – Federal Circuit, 23 August 2002, 302 F.3d 1291.

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