



International Environmental
Law Research Centre

Liability and Redress in Biotechnology

Towards the Development of Rules at the National and International Levels

COP/MOP 1 Biosafety Protocol – Background Paper
IELRC Side-events on liability, February 2004

Dr Philippe Cullet

This paper can be downloaded in PDF format from IELRC's website at
<http://www.ielrc.org/Content/WP04011P.pdf>

Table of Content

Executive Summary	iii
I. Introduction	1
II. Liability and Environmental Damage	1
A. Environmental Liability in General	1
B. Biotechnology and Environmental Liability	2
III. Socio-Economic Aspects and Patent Liability	4
A. Socio-economic Aspects	4
B. Patent Liability	4
IV. Relevance of Existing Regimes	6
A. Responsibility and Liability in International Law	6
B. National Implementation: Case of the Swiss Gene Technology Law	8
V. Towards the Development of Liability and Redress Regimes	9
A. Need for Liability and Redress Regimes at the National and International Levels	9
B. Towards Liability and Redress in Biotechnology	10
C. Final Remarks	11

Executive Summary

The question of liability and redress in the field of biotechnology is discussed primarily because of the concerns related to environmental damages that may occur as a result of the introduction of genetically modified organisms (GMOs) into the environment. It can, however, not be examined only from an environmental point of view. In fact, there are at least three other elements which must be taken into account.

- Firstly, the introduction of GMOs into the environment has the potential to cause significant socio-economic disruption. One of the most visible socio-economic impacts at present is the potential for organic farmers to lose their organic certification if their fields are contaminated by GMOs with the immediate loss of income that this brings up.
- Secondly, there are a number of unknowns concerning the potential impacts of the introduction of GMOs into the environment on human health.
- Thirdly, most GMOs are protected by intellectual property rights. As a result, concerns have emerged with regard to the question of patent liability. Some of the main questions that concern the relationship between intellectual property rights and real property rights, for instance, in situations where farmers have been sued by patent holders for breach of a patent even where the disputed seeds are the result of contamination from other fields.

The specificity and significance of the types of damages that may occur as a result of the introduction of GMOs into the environment indicate that individual states and the international community must take specific action in this field and must ensure that all types of damages are covered by the rules adopted. This is also borne out by other factors:

- The international community has amply demonstrated the need for liability regimes in the case of hazardous activities by adopting a number of specific binding liability instruments in such varied fields as nuclear energy, hazardous wastes or oil pollution.
- Reliance on sectoral regimes linked to individual treaties may not be the most ideal solution but it reflects the sectoral development of international environmental law and member states have no choice but to keep building the system up in this way as the centralisation of environmental rules and principles is neither realistic nor necessarily desirable at this point.
- There is no generally binding framework concerning environmental liability in international law and the only general convention is a regional convention of the Council of Europe which is not yet in force

The development of liability and redress rules is called for by Article 27 of the Biosafety Protocol. Besides this formal mandate, a liability and redress framework also constitutes a logical and necessary complement to the existing framework put in place by the Protocol. This is due to the fact that the role of liability rules does not stop at providing a compensatory mechanism for situations where harm occurs but also provides a mechanism promoting the taking of preventive measures. In the case of the Biosafety Protocol, liability rules will thus directly and indirectly contribute to the implementation of the precautionary approach which constitutes the central paradigm around which the whole Protocol is articulated.

The development of a liability and redress regime can thus be based narrowly on Article 27 or on a broader platform which takes into account and emphasises the role of liability rules in fostering preventive and precautionary conduct. Member states will also have to consider two further points in this regard. Firstly, Article 14(2) of the Biodiversity Convention should not be seen as a *quid pro quo* for not developing liability rules under the Protocol. This is due in particular to the fact that the Protocol gives a specific mandate to member states which is the result of the negotiations undertaken by states adopting the Biosafety Protocol in full knowledge of the existence of Article 14 of the Convention. Secondly, it is implied in most discussions that the liability framework to be adopted will focus on the civil liability of entities introducing GMOs into the environment or exporting them to other countries. Member states should nevertheless either consider the development of a framework for state responsibility in this field or ensure that the liability rules applied also apply in situations where states are directly involved.

The adoption of a liability and redress framework for biotechnology does not occur in a vacuum. A number of general principles already exist in international law. Further, a number of specific treaties, in particular in the environmental field, already include evolved liability regimes which constitute a perfect basis for the development of liability rules in the context of the Biosafety Protocol. In addition, some individual countries have already adopted biosafety legislation including liability rules. The recent Gene Technology Act adopted by Switzerland illustrates that the adoption of a strict liability framework is both feasible and necessary to provide a comprehensive regulatory framework for biotechnology. Member states to the Biosafety Protocol, on the basis of existing national and international liability frameworks, should find it relatively straightforward to adopt an effective liability and redress regime which will strengthen the Protocol and significantly contribute towards the realisation of the goals of the Biodiversity Convention.

I. Introduction

The question of liability and redress in the context of the legal or illegal introduction of genetically modified organisms (GMOs) into the environment has been the object of increasing attention in recent years.¹ However, there is as yet no operative international legal framework which could be used in the case of serious damage resulting from the introduction of GMOs into the environment. The development of a liability regime has been called for by negotiating states to the Biosafety Protocol which specifically entrusted member states with the task of developing rules on liability and redress in the first four years after the entry into force of the Protocol.²

Liability and redress in the context of biotechnology remains a relatively novel area at the international level and in most countries which are yet to adopt national rules. However, the development of a liability and redress regime does not occur in a complete vacuum. At the international level, states have developed an increasing number of liability regimes for individual treaty regimes, such as in the case of hazardous wastes. At the national level, some countries have already attempted to address the question of liability in the biosafety legislation they adopt.

This Background Paper starts from the premise that the introduction of GMOs into the environment is going to become increasingly common in years to come. This is in part linked to the coming into force of the Biosafety Protocol which encourages member states not to completely ban GMOs. This is also linked to the fact that the illegal or uncontrolled spread of GMOs into the environment is going to become increasingly common as their use increases around the world. This Paper therefore analyses the question of liability and redress from the perspective of the development of national and international rules, taking into account existing regimes. It first examines the question of liability within the context of environmental damage which has been the most common starting point for debates on liability. It then moves on to analyse issues related to socio-economic damage and the question of patent liability as it relates to the introduction of GMOs into the environment. The third section then examines some of the elements from existing regimes which could be used in the development of a liability and redress regime in the context of the Biosafety Protocol. The last section makes some suggestions concerning the development of liability and redress regimes at the national and international levels.

II. Liability and Environmental Damage

A. Environmental Liability in General

At the outset, it is useful to recall some of the reasons leading to the introduction of liability regimes. Liability is often conceived as a mechanism through which harm caused in the context of a legal or illegal activity can be compensated. It is, however, not limited to compensation and can also 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.³ In other words, liability regimes contribute to the implementation of the polluter pays principle by imposing the integration of environmental and social costs of a given activity. Further, liability rules can also act as an incentive to promote the implementation of existing environmental rules. This indicates that liability regimes can have a much broader objective than simple compensation for damage having occurred and can generally contribute to damage prevention, a fundamental aspect of environmental law.⁴

Liability schemes have traditionally been used to compensate injury to property and persons. Environmental damage has over time become another increasingly acceptable head of damage either as a factor causing personal injury or property loss or in itself. 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 includes 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 only in monetary form. Where no direct economic loss is registered, the restoration of the environment is one possible solution. 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 as exceptions for exceptional cases. The different problems linked to environmental damage may not all be relevant in the case of the introduction of GMOs into the environment but most aspects need to be debated in the formulation of a liability regime given that the full extent of potential damage is not yet known.

Depending on the gravity of the harm caused, different liability schemes have been developed. The basic system provides that a given individual or entity is liable for damages they cause if they are at fault. In the case of hazardous activities, the fault element is often waived in favour of a regime of strict or absolute liability.

Most countries of the world have developed basic rules for liability and redress. In a number of countries, liability rules may also extend to damage caused outside of a contractual relationship. Some environmental damage can, for instance, be effectively compensated through the law of torts. However, exclusive reliance on torts as a liability mechanism tends to be insufficient to tackle environmental damage generally, in part because torts tend to focus on reparation more than prevention.

At the international level, there is a very general framework for state responsibility.⁵ These rules tend, however, to be lacking in specificity when it comes to addressing environmental damage. States have responded to this problem by adopting specific liability regimes for certain hazardous activities such as nuclear energy, the transboundary movement of hazardous wastes or the carriage of oil.⁶ Apart from giving clear indications to operators of the consequences of potential damage arising from the activities they undertake, sectoral liability regimes are noteworthy for generally imposing strict liability on operators in recognition of the dangerous nature of the activity undertaken.

B. Biotechnology and Environmental Liability

The preceding introduction to issues related to environmental liability in general provides the background for an analysis of the specific case of liability for environmental damage in the case of the introduction of GMOs into the environment. The questions raised in the context of environmental damage by GMOs are only partly similar to other environmental damage and therefore warrant special examination.

A few features specific to the introduction of GMOs into the environment can be highlighted. Firstly, concerning potential damage, several specific issues can be highlighted. These include dangers linked to the instability of the genetic material and the possibility of further changes in the 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.⁷ Secondly, there remain significant uncertainties concerning the extent of potential harm and its timeline. The recently completed UK field trials have 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.⁸ 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.

These elements indicate that the liability regime for GMOs must take into account the specificities of this new technology. However, in general it is expected that the regime adopted in the context of the Biosafety Protocol will be modelled after existing liability regimes. On this basis, a few remarks can be made concerning certain general characteristics of liability regimes in the specific context of GMOs.

Firstly, one of the usual conditions for triggering of liability regimes is that actors must be directly identifiable. This can be a source of significant 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 is not a suitable mechanism for compensation and other mechanisms such as insurance should then be relied upon. One of the solutions to this problem is to provide that the person/entity – including public entities where applicable – which receives the authorisation from the state to introduce a specific GMO into the environment or to export it is liable for all damages caused by this organism.⁹ This would allow the identification of the person/entity liable relatively easily since in an increasing number of cases, commercialised GMOs are protected by patent rights. The absence of a rule focusing the liability on the patent holder would soon render GMOs unattractive to farmers who might see themselves sued by their neighbours for contamination of their fields while farmers whose fields have been contaminated by GMOs run the risk of being sued for infringing the patent rights of the company commercialising the GMO.¹⁰

Secondly, the question of which damage will be covered is also a delicate issue. In general, there may be in some cases a problem of causality where the negative environmental consequences cannot easily be traced to one particular cause or a problem where the damage is too diffuse to be traceable. 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 the damage included in the liability rules ultimately determines the viability of the industry. In other words, the definition of damages in the specific regime will have a direct influence on the development of the biotechnology industry. In principle, from an environmental point of view, it is logical to take into account all damages as is done in some treaties.¹¹ In reality, it is likely that states will seek to provide a narrower definition of damage which may, for instance, be limited to damage directly caused by the properties of GMOs, their reproduction or modification, and the transfer of genetic material from these organisms.¹²

Thirdly, the question of causality is one which has been widely discussed in the context of environmental damage. Various questions concerning the difficulties which can surface concerning the identification of the link between the source of the contamination of the environment and the felt impacts have been debated. The problem first surfaced in the context of the environmental contamination by sources which are either distant in space or time from the impacts. Examples include the case of damage 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. However controversial these issues may have been in the past, the adoption of a number of liability regimes in international environmental law and their implementation confirms that causality is not a significant obstacle to the development of liability regimes. In the case of GMOs, the question of causality should not pose any major hurdle to the development of a liability regime. The main issues are similar to other environmental contamination.

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. However, on the basis of the precautionary principle which is the main operative principle in the biosafety protocol, the forthcoming liability regime should also adopt the principle of strict liability because of the current uncertainties concerning the magnitude of the possible damages and the extent to which they may occur over a long period of time.

While a civil liability regime should constitute the backbone of a regime addressing potential damage caused by GMOs, it may also be supplemented by a penal regime. This is an approach which has already been proposed at the international level in the Convention on the Protection of the Environment through Criminal Law.¹³ In terms of biosafety, the Brazilian law constitutes one example of a regime that favours a criminal approach.¹⁴

III. Socio-Economic Aspects and Patent Liability

As noted above, liability issues in the context of biotechnology are not widely different from issues arising in the case of other activities causing environmental damage. Further, there is already a significant number of existing environmental liability regimes which provide models for the development of a liability and redress rules for environmental damage caused by GMOs. Liability and redress concerning the introduction of GMOs into the environment raises, however, other questions which go beyond the field of strict environmental liability. These include two broad set of issues which will be considered in turn in this section: socio-economic aspects and the question of patent liability.

A. Socio-economic Aspects

The main question debated in the context of liability and GMOs has been that of the potential environmental harm caused by GMOs. There are, however, also a number of negative socio-economic impacts which must be taken into account. In practice, there may be an immediate link between environmental harm and socio-economic harm but this is not necessarily the case in all situations.

The first case 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 whether through cross-pollination, dispersion or any other method. In the situation where the plots contaminated belong to farmers who are organic farmers, the simple fact of contamination by GMOs immediately has 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.¹⁵ The recent report of the UK Biotechnology Commission indicates 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.¹⁶ 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.¹⁷ 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 has not only a negative impact on biodiversity generally but may also have a directly negative impact 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 potentially significant problem relates to the potential of 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.

B. Patent Liability

Liability issues in the context of GMOs go beyond environmental and socio-economic issues to include issues related to property rights. This is due to the fact that most GMOs are protected by patent rights or other intellectual property rights. In fact, questions related to patent liability are among the most innovative and serious questions raised by the introduction of GMOs into the environment. This is because the question of patent liability turns on its head existing principles concerning liability: while under environmental liability principles

the promoter of an environmental harmful activity is liable for the resulting damage, under patent liability rules, 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.

The normal situation under patent law is that patent holders have rights over an invention and have the possibility to stop everyone else from doing anything with this invention without their consent. Wherever someone uses an invention protected by patent rights, s/he can be held liable if s/he does not have the consent of the patent holder where this consent is required under the relevant national patent law. In the case of patent protected GMOs, an entirely different situation obtains. The patent holder has the possibility to ensure that farmers who buy GM seeds also sign a contract stopping them from using the seeds for more than one crop and stopping them from saving, distributing and selling the same. However, the patent holder is not in a position to stop GM seeds intentionally introduced into the environment from contaminating other fields and the environment in general. This is an environmental question of the type analysed in the first section above. This is also a question of patent liability in the situation where the seeds contaminate the fields of other farmers who have not purchased the seeds from the patent holder. 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 simple presence of a GM seed on the land of a farmer who has not purchased the seeds is an infringement of the patent. This situation is not a theoretical one but one which has been the object of litigation in recent years.

In the case of *Schmeiser v. Monsanto*, the company is claiming damages from Mr Schmeiser because he was found in possession of genetically modified canola seeds even though he never purchased seeds from Monsanto. More specifically, it was contended 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 decisions of the trial judge and the appeal judge both went in favour of Monsanto.¹⁸ Two main features of the decision must be highlighted. Firstly, the judge has sought to define the condition under which a farmer is responsible for the presence of patented seeds on his land. He pointed out that

*a farmer whose field contains seed or plants originating from seed spilled into them, or blown as seed, in swaths from a neighbour's land or even growing from germination by pollen carried into his field from elsewhere by insects, birds, or by the wind, may own the seed or plants on his land even if he did not set about to plant them. He does not, however, own the right to the use of the patented gene, or of the seed or plant containing the patented gene or cell.*¹⁹

The judge indicates that the rights of the patent holder prevail over real property rights in land and the farmer must pay a licence fee under all circumstances.²⁰ In fact, the judgment goes further since it indicates that Mr Schmeiser is to pay a licence fee even if he did not benefit from the specific characteristics of the patented product. The judge concludes that

*Mr. Schmeiser knew or can be taken to have known [that the seed] was Roundup tolerant. That seed was grown and ultimately the crop was harvested and sold. In my opinion, whether or not that crop was sprayed with Roundup during its growing period is not important. Growth of the seed, reproducing the patented gene and cell, and sale of the harvested crop constitutes taking the essence of the plaintiffs' invention, using it, without permission. In so doing the defendants infringed upon the patent interests of the plaintiffs.*²¹

This is significant since farmers can only take advantage of the features of Roundup ready seeds if they spray the crop with this herbicide. Otherwise, the crop is generally similar to the non-GM variety.

The appeal goes further with regard to the adventitious presence of patented seeds. The judges accept that where landowners ignore the specific properties of a patented seed, '[t]here is considerable force to the argument that it would be unfair to grant Monsanto a remedy for infringement where volunteer Roundup Ready Canola grows in a farmer's field but its resistance to glyphosate remains unknown, or if that characteristic

becomes apparent but the seeds of the volunteer plants are not retained for cultivation'.²² No decision is taken on this point because it is assumed that Mr Schmeiser knew or should have known that the seeds he saved in 1997 were glyphosate resistant seeds.

The Schmeiser case has significant implications for the development of liability regimes in the field of biotechnology. *Schmeiser v. Monsanto* shows that liability regimes need to address the relationship between intellectual property rights and property rights such as land rights as well as the relationship with other rights such as the fundamental human right to food. The judgment avoids the issue by concentrating exclusively on the question of the violation of patent rights. In the narrow context of patent law, the decision reached is acceptable since strict liability usually constitutes the basis for judging violations of the patent.²³ In the case of patented seeds, other elements need to be taken into account. Where possession is unintentional and where the properties of the invention are not used, different principles should apply. Further, other relevant factors should be taken into account. In this situation, there is a conflict between the principles of patent law which protect the patent holder and real property rights which protect the landowner. Tort law has, for instance, long provided a basis for addressing issues related to trespass and nuisance and recognises that even the intrusion caused by microscopic particles can be the basis of a tort action.²⁴ It is surprising to see that the Schmeiser judge does not even analyse the issue from the perspective of tort law before possibly dismissing the argument. If the Schmeiser precedent was to be followed more generally, it would lead to significant consequences not only for farmers but more generally for the management of all land. In following the judge's reasoning, Mr Schmeiser must not only be held liable to pay for the loss of earnings that Monsanto is claiming but he could also be held liable for damage subsequently caused by GMOs originating from his land and contaminating other tracts of land. From a broader perspective, this would lead to the conclusion that the landowner is both responsible for the unwanted intrusion on his/her land and for the damage that may occur as a result of this unwanted possession. In other words, landowners would become responsible for the damage caused by a substance introduced on their land against their will.

Another issue is the question of the exhaustion of intellectual property rights. The main question raised is whether the patent holder should be able to assert its rights beyond the first sale of the seeds. In North America, the Schmeiser decision indicates that the patent holder's rights are not exhausted even if the seed has not been acquired voluntarily. This has been confirmed as well in the case of seeds acquired contractually. Recent United States decisions indicate that the contractual restrictions imposed by the patent holder on the purchasers are valid and consequently do not leave space for the application of the doctrine of exhaustion.²⁵

IV. Relevance of Existing Regimes

Liability rules have been successfully developed in a number of areas and contexts over time. The development of liability rules in the context of biotechnology should thus seek to build on existing regimes at the international and national levels, as appropriate. There is, as yet, no international liability framework directly applicable to biotechnology. However, there are some general rules of state responsibility and liability which can be used and there are a number of sectoral regimes which can be used as a model for developing rules for biotechnology. Further, some countries have already developed liability rules at the national level for the specific case of biotechnology. This section examines the extent to which existing international rules and frameworks can be used in the context of biotechnology and analyses the specific case of the Swiss Gene Technology Law as one of the national frameworks that may guide developments at the international level.

A. Responsibility and Liability in International Law

International law has developed two different types of relevant rules and principles, some concerning the responsibility of states, some concerning the liability of actors engaged in hazardous activities.

At the level of inter-state relations, there exist a number of basic principles concerning state responsibility. States are generally responsible for all wrongful acts.²⁶ In an environmental context, they also have the duty to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of national jurisdiction.²⁷ A legal regime concerning activities not prohibited is also being considered.²⁸ In other words, while there are some general principles concerning state responsibility, there is at present no binding framework in general international law. As a result, this is a question which needs to be addressed specifically in the context of the development of a liability regime.

Potential problems include the question of the responsibility of a state that exports GMOs to another country. Should these GMOs subsequently cause damages in the country where they are introduced or to a neighbouring country, the question of the responsibility of the exporting state will have to be determined. Without a binding framework concerning state responsibility in this field which would, for instance, channel responsibility to the exporting state, the only alternative is to rely on existing general principles. These principles are similar to the principles concerning liability highlighted above. Under existing principles, the importing country would find it difficult to hold the exporting state responsible for the damages. This is due to the fact general rules of state responsibility tend to be quite unspecific especially when it comes to environmental damage. Further, the aggrieved state would probably have to show that the damage has significant adverse impacts and that the exporting state is at fault.²⁹ Where state responsibility is confirmed, the state causing the damage has an obligation to repair, for instance, through compensation.³⁰ Overall, not only are rules of state responsibility rather vague but states have generally refrained from using them in the case of environmental harm.³¹

Despite the primacy of inter-state relations in international law, states have resorted – partly because of their reluctance to adopt strict frameworks for state responsibility – to the development of civil liability rules at the international level. It is in this category that the most interesting legal developments have taken place. Several treaties include specific liability regimes in the case of activities deemed particularly hazardous such as hazardous waste disposal, nuclear energy and oil pollution damage. These treaties are based on relatively similar principles. 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.³² This is assorted of the usual exclusions such as war or acts of god.³³ In certain cases, the strict liability framework is supplemented by a fault-based liability for individuals contributing to causing the damage through negligence or premeditation.³⁴ Some treaties provide a possibility for the entity to which the liability is channelled to have recourse against other actors,³⁵ 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.³⁶ 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. 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 slow move towards the inclusion of other elements, such as the costs of preventive measures and the costs of restoration of a degraded environment.³⁷

Besides existing sectoral international liability regimes, the Council of Europe has made a significant contribution to this field by adopting a convention specifically devoted to liability and environmental damage (Lugano Convention).³⁸ While the Lugano Convention is a regional instrument and has not yet come into force, it should be taken into account by member states to the Biosafety Protocol in the development of a liability regime. 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’.³⁹ 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.⁴⁰

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, 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 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, there exists at present a general framework for state responsibility proposed by the International Law Commission. Even though it is not environment-specific, it provides the basic framework for developing rules in the context of biotechnology. Fourthly, questions concerning state responsibility and civil liability should be addressed separately even though the basic principles are similar.

B. National Implementation: Case of the Swiss Gene Technology Law

The liability and redress regime under the Biosafety Protocol will undoubtedly borrow a lot from existing international treaties. However, since there is little in existing frameworks which is directly relevant in the case of biotechnology, member states may wish to also draw on the experience of member states which have already adopted liability regimes at the national level in this field. Switzerland is one of the countries that has already gone through a whole legislative exercise and adopted a biosafety act with a strict liability regime.⁴¹ While Switzerland is only one small country among many others, the regime adopted is quite significant. 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 both to the industry and environmental NGOs. This is probably the most important lesson for the international community.

Turning to the specificities of the Swiss Gene Technology Law, the central characteristic of the liability regime is the adoption of a strict liability framework. 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.*⁴²

The person who has been given the authorisation to introduce GMOs into the environment is also 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.⁴³ 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 Law also specifically considers the question of environmental damages. 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.⁴⁴

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.⁴⁵

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.⁴⁶ This constitutes one question which the international community must address as well since there are relatively vast areas of the world which do not fall under national sovereignty. In particular, the direct or indirect introduction of GMOs in seas will lead to important legal issues which should rather be solved a priori since international law is at present poorly equipped to deal with the question of damage to zones not falling under the sovereignty of any state.

Overall, the Swiss Law includes a number of features that member states of the Biosafety Protocol may wish to consider in the development of an international liability regime. Significant elements include the decision to adopt a regime based on strict liability, the thirty-year period for bringing claims and the channelling of the liability exclusively to the person being given the authorisation to introduce GMOs into the environment.

V. Towards the Development of Liability and Redress Regimes

A. Need for Liability and Redress Regimes at the National and International Levels

Member states to the Biosafety Protocol have in Article 27 a clear mandate to develop a liability and redress regime. Nevertheless, it has sometimes been argued that the development of a separate liability regime for biotechnology is unnecessary.⁴⁷ As the preceding analysis demonstrates, there are strong arguments in favour of the development of a liability regime for biotechnology besides the mandate given to member states in Article 27. Firstly, biotechnology brings up a number of unusual elements to the question of liability. Concerning environmental damage, GMOs present specific problems in part because there remain significant uncertainties concerning their potential adverse effects on the environment in the long run. Further, adverse impacts are not limited to environmental impacts but extend to different socio-economic impacts that must also be addressed. Additionally, patent liability is another dimension which must be taken into account in the case of GMOs.

The need for specific liability regimes is borne out at the international and national levels. At the international level, existing general rules do not provide sufficient guidance in the case of environmental damage. This has led states to develop sectoral liability regimes, on the basis of existing sectoral treaties. This may not be the most ideal situation but the lack of coordination among existing environmental treaties is a fact which cannot be wished away. In a perfect world, environmental liability rules would be common to all areas of international environmental law but in the real world, it is necessary to contend with the inadequacies of the existing international system and keep building the system up sectorally. This implies that states cannot afford to delay the development of an international liability regime until a broader environmental liability is possibly adopted many years hence.

At the national level, in systems of common law, torts can provide an answer in some of situations. Thus, a progressive reading of the traditional rule of *Rylands v. Fletcher* about what constitutes a natural use of land could, for instance, give torts a more important role to play in the context of GMOs.⁴⁸ However, this role remains at best partial since torts neither have a preventive function nor alleviate the need for statutory regimes providing for strict or absolute liability for hazardous activities. Further, there is the risk that environmental contamination could be reduced to a problem between two landowners that would fail to involve the person or entity holding patent rights and/or commercialising the GM product.⁴⁹ More specifically, arguments against the development of separate liability regimes have largely been trumped by the adoption of laws like the Swiss Gene Technology Law. In fact, the Swiss Parliament specifically debated the need for a separate regime. The first draft of the law did in fact propose to make a series of amendments to the pre-existing Environment Protection Act.⁵⁰ Eventually, 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.⁵¹ It is also noteworthy that the liability regime is a central component of the biosafety regime adopted in Switzerland. The Law is in part the result of a compromise whereby Switzerland would not commit itself to a moratorium on GMOs but would provide a legal framework providing strict conditions for the release of GMOs and a strong liability regime.

B. Towards Liability and Redress in Biotechnology

The development of a liability and redress regime at the international level is directly a consequence of the adoption of Article 27 of the Biosafety Protocol. At the national level, the development of liability and redress regimes is linked to the implementation of the Biosafety Protocol but is necessary in all states which plan to introduce GMOs even if they are not parties to the Protocol.

Liability and redress regimes should be related to the underlying instruments. In this case, the development of a liability and redress regime should be related to the main objective of the Biosafety Protocol which is to ensure an adequate level of protection concerning the transfer, handling and use of GMOs. In fact, the development of a liability regime is directly related to the precautionary principle insofar as it constitutes one indirect instrument to ensure that precaution remains the basis of all decisions concerning the use of GMOs.

The liability and redress regimes adopted should 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 should contribute to conserving biodiversity, conserving soil fertility and the integrity of living organisms. Besides, liability rules should also have socio-economic objectives, including the realisation of the right to food and generally fostering access to food as a basic need. Beyond the issue of basic needs, liability rules should also contribute to ensure consumer choice between organic –and generally non-GM products– and GM products. In other words, the development of liability rules has a lot to do with ensuring that co-existence of GM and non-GM crops can be a reality in the long-term in all countries where GMOs are introduced into the environment. Further, liability rules should also integrate considerations related to patent liability and the issues considered above with regard to the potential for a complete reversal of the rationale for liability in countries that would follow the model provided by the existing Canadian case law.⁵² In other words liability rules should aim at determining the responsibility of the different actors with a view to channel liability to the person obtaining the authorisation to introduce GMOs into the environment.

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 biotechnology reinforce the need for a separate statutory liability scheme. Leaving liability issues to existing general principles will neither allow the orderly development of the biotechnology industry nor provide an adequate level of protection to the environment and human health. In particular, it is of the utmost importance to ensure that questions of liability in the field of biotechnology are not left to rules and principles developed to address claims between landowners.

With regard to the level of protection necessary in the context of biotechnology, it is necessary on the basis of the precautionary principle which is itself the cornerstone principle of the Protocol to adopt a strict liability approach. This is the approach chosen, for instance, by Switzerland in view of the significant uncertainties concerning potential harm that may occur as a result of the introduction of GMOs into the environment. In this context, it is noteworthy that in parliamentary debates in Switzerland, the adoption of a strict liability framework was seen as a response to proponents of a complete moratorium on the introduction of GMOs into the environment.⁵³ Given the significant uncertainties concerning the actual impacts of GMOs once introduced into the environment, one of the only ways to ensure opposition to their commercialisation diminishes is to provide a strong liability framework at the international level as well.

Concerning damages, the liability and redress regime should build upon existing principles in the field of liability and take into account the specificities of biotechnology. This implies providing a definition of damages which includes damages to the environment, to human health, to property and to economic interests. 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. Further, in developing rules concerning damages, states should take special care of centres of origin of diversity. In fact, the liability and redress regime to be adopted should 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. In other words, an even stricter regime should be adopted for zones that are either known to be ecologically sensitive or known to be of great importance for biodiversity conservation.

C. Final Remarks

The Biosafety Protocol is a treaty whose main aim is the management of transboundary movements of GMOs. It is based on the principle of conservation of biodiversity and its main operative principle the precautionary principle. In other words, it seeks to reconcile the aim of promoting biotechnology with the need to avoid adverse impacts on the environment. This balance can only be achieved meaningfully if the whole system is bound by a strong regulatory mechanism to ensure that actors involved comply with the rules in place. The adoption of a strong liability and redress regime seeks to achieve this aim. It is not a dispensable appendage but part of the basic architecture of a regulatory framework for biosafety which is sustainable in the long-term. This is a task which must be undertaken simultaneously at the international and national levels because the international law framework to be adopted in the context of the Biosafety Protocol will not address all relevant issues at the national level. The development of a liability and redress regime does alleviate the need for prevention and precaution concerning the introduction of GMOs into the environment which should remain the main preoccupation of all states. However, as soon as some states decide to introduce GMOs, it becomes imperative to provide liability rules to ensure that preventive measures are taken and to provide a clear framework for compensation should harm occur.

Endnotes

- ¹ Note that in this paper, GMO is used as a generic term which also covers Living Modified Organisms (LMOs).
- ² Article 27 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 Jan. 2000, 39 *Int'l Leg. Mat.* 1027 (2000).
- ³ This is, for instance, the approach adopted in Article 1 of the Common Position (EC) No 58/2003 adopted by the Council on 18 September 2003 with a view to the adoption of a Directive 2003/. . . /EC of the European Parliament and of the Council of . . . on environmental liability with regard to the prevention and remedying of environmental damage, *Official Journal* 2003/C 277 E/02 (18 Nov. 2003).
- ⁴ See, e.g., Case Concerning the Gabcikovo-Nagymaros Project (Hungary/Slovakia), International Court of Justice, Judgment of 25 Sept. 1997, 37 *Int'l Leg. Mat.* 162 (1998) at § 140.
- ⁵ 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).
- ⁶ See below at p. 10 for more details.
- ⁷ See, e.g., 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.
- ⁸ Maria Burke, *GM Crops – Effects on Farmland Wildlife* (London: Farmscale Evaluations Research Team and the Scientific Steering Committee, October 2003).
- ⁹ This is the solution adopted by Switzerland. See Federal Law relating to Non-human Gene Technology, 21 March 2003, *Recueil systématique* 814.91 [hereafter Gene Technology Law]
- ¹⁰ On the question of patent liability, see below at p. 6.
- ¹¹ See, e.g., Article 3 of the International Convention on Civil Liability for Oil Pollution Damage, London, 27 November 1992.
- ¹² Cf. the solution chosen by Switzerland at Article 5(3) of the Gene Technology Law, note 9 above.
- ¹³ Convention on the Protection of the Environment through Criminal Law, Strasbourg, 4 Nov. 1998, 38 *Int'l Leg. Mat.* 259 (1999).
- ¹⁴ Article 13, Brazil: lei de biossegurança, 1995.
- ¹⁵ See, e.g., Department for Environment, Food and Rural Affairs, *Compendium of UK Organic Standards* (Version 3.5, 2003).
- ¹⁶ Agriculture and Environment Biotechnology Commission, *GM Crops? – Coexistence and Liability* (London: Biotechnology Commission, 2003).
- ¹⁷ See L. Hoffman & D. Beaudoin v. Monsanto & Aventis, *Statement of claim*, Saskatoon, 10 Jan. 2002.
- ¹⁸ Note that the case is currently before the Supreme Court of Canada.
- ¹⁹ Monsanto v. Schmeiser, 29 March 2001, 2001 *FCT* 256 at § 92.
- ²⁰ This was confirmed in appeal where the judge indicated that ‘there is no authority for the proposition that ownership of a plant must necessarily supercede the rights of the holder of a patent for a gene found in the plant. On the contrary, the jurisprudence presents a number of examples in which the rights of ownership of property are compromised to the extent required to protect the patent holder’s statutory monopoly’. See *Monsanto Canada v. Schmeiser*, 4 Sept. 2002, [2003] 2 *F.C.* 165 at § 51.
- ²¹ Monsanto v. Schmeiser, 29 March 2001, 2001 *FCT* 256 at § 123.
- ²² Monsanto Canada v. Schmeiser, 4 Sept. 2002, [2003] 2 *F.C.* 165 at § 56.
- ²³ See, e.g., Roger D. Blair & Thomas F. Cotter, ‘Strict Liability and its Alternatives in Patent Law’, 17 *Berkeley Tech. L.J.* 799 (2002).
- ²⁴ *Martin v. Reynolds Metal Company*, 29 July 1959, 221 *Or.* 86, 342 *P.2d* 790.
- ²⁵ See, e.g., *Monsanto v. William Trantham*, 16 Aug. 2001, 156 *F.Supp.2d* 855 and *Monsanto v. McFarling*, United States Court of Appeals, Federal Circuit, 23 Aug 2002, 302 *F.3d* 1291.
- ²⁶ Article 1, International Law Commission, note 5 above.
- ²⁷ Principle 2 of the Rio Declaration on Environment and Development, 14 June 1992, UN Doc. A/CONF.151/26/Rev.1 (Vol. 1), Annex I.

- 28 See, e.g., Pemmaraju Sreenivasa 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).
- 29 States have usually refrained from imposing strict liability on themselves. One exception is the Convention on International Liability for Damage Caused by Space Objects, London, 29 March 1972, 961 *UN Treaty Series* 187.
- 30 Permanent Court of International Justice, Case Concerning the Factory at Chorzów, 13 Sept. 1928, Series A, No 17.
- 31 One of the few exceptions concerns a claim by Canada against the USSR for Damage Caused by Soviet Cosmos 954. See 18 *Int'l Leg. Mat.* 899 (1979).
- 32 See, e.g., Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Basel, 10 Dec. 1999, UN doc. UNEP/CHW.5/29, Annex III (1999) [hereafter Basel Convention Protocol].
- 33 See, e.g., Article 4(5) of the Basel Convention Protocol, note 32 above.
- 34 See, e.g., 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 [hereafter Vienna Convention].
- 35 Article 8 of the Basel Convention Protocol, note 32 above.
- 36 See, e.g., Article 6 of the Vienna Convention, note 34 above.
- 37 See, e.g., Article 1(k) of the Vienna Convention, note 34 above.
- 38 Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, Lugano, 21 June 1993, 32 *Int'l Leg. Mat.* 1228 (1993) [hereafter Lugano Convention].
- 39 Article 2(1) of the Lugano Convention, note 38 above.
- 40 Article 2(7) of the Lugano Convention, note 38 above.
- 41 For another example, see, e.g., Norway, Act Relating to the Production and Use of Genetically Modified Organisms, 1993.
- 42 Article 30(2) of the Gene Technology Law, note 9 above.
- 43 Article 30(4) of the Gene Technology Law, note 9 above.
- 44 Article 31 of the Gene Technology Law, note 9 above.
- 45 Article 32 of the Gene Technology Law, note 9 above.
- 46 Article 31(2) of the Gene Technology Law, note 9 above.
- 47 See, e.g., Malcolm Forster & Daniel Lawrence, 'The Cartagena Protocol: Moves Towards Establishing an International Liability Regime for Living Modified Organisms', 15 *Env'tl. L. & Management* 5 (2003).
- 48 See, e.g., Cambridge Water Company v. Eastern Counties Leather plc, House of Lords, 9 Dec. 1993, [1994] 2 A.C. 264.
- 49 Cf. Richard Burnett-Hall, 'Liability for Damage Caused by Genetically Modified Organisms: The Existing Law', in Agriculture and Environment Biotechnology Commission, *GM Crops? – Coexistence and Liability* at Annex D (London: Biotechnology Commission, 2003).
- 50 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 Oct. 1983, *Recueil systématique* 814.01.
- 51 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.
- 52 See above at p. 6.
- 53 See Pierre-Alain Gentil/Conseil des Etats, Session d'été 2001, huitième séance, 14 juin 2001.

www.ielrc.org