



International Environmental
Law Research Centre

LIABILITY AND GMOS

TOWARDS A REDRESS REGIME IN BIOSAFETY PROTOCOL

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39/7 Economic & Political Weekly (14 February 2004), p. 615.

This paper can be downloaded in PDF format from IELRC's website at
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The development and the commercialisation of genetically modified plant varieties such as Bt cotton have drawn a lot of attention over the past few years. While most attention has concentrated on the pros and cons of the introduction of genetically modified organisms (GMOs) into the environment, little consideration has been given to the potential negative consequences of the legal or illegal introduction of GMOs into the environment. Today, it is increasingly clear that some GMOs will be introduced into the environment, some with the sanction of the Genetic Engineering Approval Committee (GEAC) and some without, as in the case of the Bt cotton illegally planted in Gujarat. It is therefore imperative to address not only the conditions under which GMOs should be commercialised – an issue which is still under debate – but also to devise specific rules concerning liability for damage that may occur as a result of their introduction into the environment.

The question of liability must be addressed simultaneously at the international and at the national level. At the international level, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity which entered into force in September 2003 does not provide rules for liability. The issue proved too contentious in the run-up to the adoption of the Protocol and states agreed to defer the consideration of liability rules.¹ As a result, the first Meeting of the Parties to the Protocol which will take place in the last week of February 2004 has been given the task to start negotiations on the development of liability rules which must be completed by 2008. At the national level, the regulatory framework which governs GMOs, starting with the Biosafety Rules,² does not directly address the issue of liability which is governed by the general rules on liability applicable in India. This article seeks to highlight some of the important concerns that need to be addressed in the development of liability rules for GMOs. It argues that despite the existence of general liability rules at the national level and some general principles applicable to liability at the international level, it is necessary to develop separate liability rules for biotechnology because of the specific and novel challenges linked to the introduction of GMOs into the environment. This is done in part by examining the response given by Switzerland which adopted in 2003 a Gene Technology Law with a strong liability regime.³

LIABILITY FOR ENVIRONMENTAL HARM

Liability rules can be developed for different reasons. Liability is often conceived as a mechanism through which harm caused in the context of a legal or illegal activity can be compensated. Liability regimes 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.⁴ 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. Finally, liability rules can also be seen as an incentive to promote the implementation of existing environmental rules.

Different types of liability schemes exist at present. The basic system provides that individuals or entities are 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. In this case, promoters of hazardous activities are deemed to be liable for damage caused regardless of fault. Absolute liability does not provide for any excuses at all while strict liability usually provides that some external events such as natural disasters or war constitute factors which can exonerate the promoter of the activity.

At present, both domestic and international law provide basic rules for liability and redress. The general rules are, however, insufficient to deal with certain kinds of specific environmental damage. This is illustrated at the national level where existing tort law proved insufficient in the case of the Bhopal gas disaster,⁵ and led to the development

1 Article 27 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, January 20, 2000, 39 *International Legal Materials* 1027 (2000).

2 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells, 1989.

3 Swiss Federal Law relating to Non-human Gene Technology, March 21, 2003, *Recueil systématique* 814.91 (hereafter Swiss Gene Technology Law).

4 This is, for instance, the approach adopted in Article 1 of the Common Position (EC) No 58/2003 adopted by the Council on September 18, 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 (November 18, 2003).

5 In particular, the principle of strict liability developed in *M C Mehta vs Union of India (Shriram Gas Leak case)*, (1987) 1 SCC 395 was not applied in the Bhopal case. See *Union Carbide Corporation vs Union of India* (1991) 4 SCC 584.

of statutory instruments such as the Public Liability Insurance Act, 1991.⁶ At the international level, specific liability regimes have been adopted to supplement general rules for hazardous activities such as nuclear energy, the transboundary movement of hazardous wastes or the carriage of oil.⁷ Existing regimes concerning hazardous activities provide for strict liability in recognition of the dangerous nature of the activity undertaken.

The development of genetic engineering and the introduction of GMOs into the environment raise questions concerning the legal consequences of the potential negative outcomes arising from GMOs' introduction into the environment.

Firstly, the introduction of GMOs into the environment can have negative environmental impacts. Possible environmental harm includes: dangers linked to the instability of the genetic material and the possibility of further changes in the genetically modified organisms, 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.⁸ The potential extent of the harm and its timeline remain a matter of uncertainty at this point. The recently completed UK field trials 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.⁹

Secondly, potential harm caused by the introduction of transgenic seeds into the environment is not only limited to environmental harm but also includes socio-economic aspects. In the context of agriculture, one of the main potential impacts which is already visible in some countries is the contamination of organic crops by transgenic seeds.¹⁰ In situations where this happens, organic farmers lose their certification and consequently must sell their crops at the lower price fetched by non-organic crops. Socio-economic concerns also arise where GMOs contribute to displacing existing plants. Where displaced plants are basic food crops, their disappearance may have negative consequences for the fulfilment of basic food needs. Similarly, the substitution of agricultural commodities grown in the south by transgenic varieties which can grow in the north will have direct negative consequences for everyone involved in the production of the specific cash crop involved.

Thirdly, the question of liability in the context of GMOs must be seen in a broader context which takes into account the property rights attached to these organisms. In most cases, GMOs are protected by intellectual property rights, most often patent rights. This has important implications because under normal circumstances, a patented invention can only be used with the consent of the patent holder. In practice, GMOs introduced into the environment can find their way beyond the environment into which they have been introduced. Where the protected organism is a seed and where these seeds find their way to the lands of farmers which do not grow transgenic crops and therefore do not pay royalties to the company holding the patent, the patent holder may be tempted to claim for infringement of the patent. This has already happened in Canada where Monsanto sued a farmer, Schmeiser, for infringement of a patent. The judgment made it clear that Schmeiser was liable to pay Monsanto whether he was aware of the presence of the protected seeds or not.¹¹

6 See, e.g., Usha Ramanathan, 'Hazard and Compensation' (on file with the author, 2002).

7 See respectively *Convention on Civil Liability for Nuclear Damage*, Vienna, May 21, 1963 as amended by the Protocol of September 12, 1997; *Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal*, Basel, December 10, 1999; and *International Convention on Civil Liability for Oil Pollution Damage*, London, November 27, 1992 and *Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage*, London, November 27, 1992.

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

9 Maria Burke, *GM Crops – Effects on Farmland Wildlife* (London: Farmscale Evaluations Research Team and the Scientific Steering Committee, October 2003).

10 Farmers have reacted to this. In Canada, for instance, some organic farmers are currently trying to sue the companies having introduced genetically modified canola which contaminated their organic canola crops. See L Hoffman and D Beaudoin et Monsanto and Aventis, Statement of claim, Saskatoon, January 10, 2002.

11 *Monsanto Canada Inc v Schmeiser (CA)*, September 4, 2002, [2003] 2 FC 165. An appeal is currently being considered by the Supreme Court.

NEED FOR A LIABILITY AND REDRESS REGIME

Liability in the context of GMOs brings up a number of specific elements. Concerning environmental damage, GMOs present specific problems because there remain significant uncertainties concerning their potential adverse effects on the environment in the long run. It is therefore necessary to provide specific rules for environmental liability in the case of the introduction of GMOs into the environment which take into account the special nature of GMOs. Further, issues of liability cannot be looked at only from the point of view of adverse impacts on the environment; potential negative socio-economic impacts must also be addressed. Finally, the question of liability is linked to the existence of patents over most GMOs. This brings up a whole new set of issues which must also be addressed in the overall development of a liability regime for biotechnology.

The need for a specific liability regime in the field of biotechnology is borne out at the national and at the international level. In both cases, existing rules provide at most a general framework which is not specific enough to either take into account all relevant situations or to provide a legal framework which is specific about the consequences of certain situations, such as genetic contamination. At the national level, torts can provide an answer in some situations, but they neither have a preventive function nor alleviate the case of environmental damage and, as noted above, this has led states to develop sectoral regimes.

It has been argued that there is no need for a separate liability regime either at the national level or at the international level.¹² At the international level, arguments against the development of a separate regime do not fit with the general pattern of development of international environmental law. Treaties have been developed for the past several decades mostly on a sectoral basis and as a result there is very little coordination among the various areas of international environmental law. This explains why states have developed separate liability regimes in each relevant sectoral area. In an ideal world, environmental 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, arguments against the development of separate liability regimes have been trumped by the adoption of the Gene Technology Law in Switzerland. It is interesting that 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.¹³ 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.¹⁴

The Gene Technology Law constitutes the result of a long political process. The Act 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. The liability regime is therefore central to the overall balance of the act. Overall, the act, in keeping with the recognition of the hazardous nature of the introduction of GMOs into the environment, establishes a regime of strict liability.¹⁵ Interestingly, the person who must seek the authorisation from the government to market a GMO is solely liable for resulting damages in situations where the organisms are contained in agricultural or forestry additives.¹⁶ This implies that the company marketing the GMO cannot exonerate itself by claiming that the harm has been caused,

12 See, e.g. Malcolm Forster and Daniel Lawrence, 'The Cartagena Protocol: Moves towards Establishing an International Liability Regime for Living Modified Organisms', 15 *Envtl L and Management* 5 (2003).

13 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, October 7, 1983, *Recueil systématique* 814.01 (hereafter Environment Protection Act).

14 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 April 30, 2001.

15 Exclusion clauses include 'acts of God' or gross misconduct of the injured party or a third party. See Article 30(8) of the Swiss Gene Technology Law, n 3.

16 Article 30(2) of the Swiss Gene Technology Law, n 3.

for instance, by the farmer having planted the genetically modified seed.¹⁷ The Act specifically provides that the person who is liable for handling 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. Apart from providing for strict liability, the Act is also noteworthy for establishing a 30-year time limit for the injured party to claim damages after the event causing the damage or the date on which the GMOs were marketed.¹⁸ The Gene Technology Law does not establish a compulsory insurance scheme for persons marketing GMOs but authorises the central government to take measures to protect the interests of injured parties.¹⁹

The Swiss Act reflects the specific conditions and needs of Switzerland and has not been developed as a model for other countries. It is, however, of interest to other countries, in the north and south, which are considering authorising the commercialisation of GMOs. First, it is the result of a broad debate having taken place in a country which is both known for its multinational companies like Novartis which have a big stake in the development of gene technology and for its generally progressive environmental policies. As a result, the act does not stop the development of gene technology but provides a rather strict legal framework within which it can take place. The liability regime is central to this balance. This is an aspect which cannot be ignored in India given the apparent uncertainties and controversies in the case of the commercialisation of Bt cotton.

The Swiss Act also provides another interesting lesson of immediate relevance in the context of the development of liability rules in the Biosafety Protocol. A strict liability framework at the national level is a major step forward in ensuring that the potential negative consequences of the release of GMOs are taken into account by relevant actors and fully compensated for should they occur. This is, however, insufficient to address transboundary aspects. The latter include transboundary damage of the same type identified at the national level, such as the spread of transgenic seeds beyond the plot where they are sown. They also include problems linked to legal or illegal international transactions in GMOs. One such case is the not so infrequent situation where food aid comes in the form of a genetically modified variety. Should this variety find its way into the environment of the receiving country and cause damage to the receiving country, domestic liability rules would be insufficient to deal with this transboundary issue involving another state. In other words, it is imperative for India – and the south in general – providing or considering the commercialisation of GMOs to develop a national liability regime alongside and to push for the development of a similar regime at the international level. The occasion of the first meeting of the parties of the Biosafety Protocol provides an excellent opportunity to focus governments' attention on the issue of liability and the need to develop liability and redress regimes at the national and international levels at the same time.

Overall, even if the Biosafety Protocol does not yet include rules on liability and does not impose on member states their introduction at the national level, their development is a necessary by-product of the ratification of the Protocol. The Protocol, by its very nature, contributes to the adoption of GMOs in member states since it imposes the introduction of procedures for the importation of GMOs. While member states retain some control over the import decision since they can base their decisions on the precautionary principle, they cannot introduce regulations which ban GMOs altogether. Following the coming into force of the Protocol in September 2003, it is imperative that the system proposed in the Protocol which promotes the adoption of genetic engineering around the world should be supplemented by liability rules. This is a task that each individual country and the international community of states must undertake as soon as possible.

17 The only exception to this rule is where GMOs have been handled inappropriately or where the person using the GMO has otherwise contributed to the occurrence or exacerbation of the damage. See Article 30(3) of the Swiss Gene Technology Law, n 3.

18 The right to claim damages further expires three years from the time the injured party becomes aware of the damage and of the person liable. See Article 32 of the Swiss Gene Technology Law, n 3.

19 Article 34 of the Swiss Gene Technology Law, n 3.

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