GMO Statutory Liability Regimes: An International Review

December 2004

Canadian Institute for Environmental Law and Policy

Thank you to the representatives of the Canadian Institute for Environmental Law and Policy, specifically Anne Mitchell and Susan Holtz and Michelle Swenarchuk from CELA for their assistance with this report and many other organizations and individuals for their interest and valuable comments.

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ISBN 1-896588-47-6

Founded in 1970, CIELAP is an independent, not-for-profit research and education organization whose mission is to provide leadership in the research and development of environmental law and policy that promotes the public interest and sustainability.

CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY

L'INSTITUT CANADIEN DU DROIT ET DE LA POLITIQUE DE L'ENVIRONNEMENT

TABLE OF CONTENTS

Executive Summary

Several nations have recognized the uniqueness of Genetically Modified Organisms (GMOs) and the potential inability of traditional civil liability regimes to deal with this unique technology. Consequently, multiple national statutory instruments have been created to address GMO-related liability and redress. As regards a Canadian policy to meet the new and complex legal challenges related to GMOs, the Canadian Institute for Environmental Law and Policy (CIELAP) offers the following eight recommendations, which are presented in context within this paper:

- Canada should recognize the uniqueness of GMO technology and the limits of the common law system, and implement a statutory liability instrument.

- Canada should ratify the *Cartagena Protocol*, as this/the forthcoming liability and redress regime will assist in the creation of an encompassing system of liability and redress within the country.

- The proposed Canadian statutory liability instrument should offer redress for both public and private damage.

- The proposed Canadian statutory liability instrument should provide a broad definition of private damage that specifically protects economic loss resulting from contamination due to cross-pollination.

- The proposed Canadian statutory liability instrument should protect harm to the environment and biodiversity, and the harm should be specifically defined within the legislation.

- The proposed Canadian statutory liability instrument should channel both public and private liability to the industrial producers of the technology, as they are best suited to internalize the costs of harm

- The proposed Canadian statutory liability instrument should implement a strict liability regime.

- The proposed Canadian instrument should ease the burden of proof on causation through the creation of a rebuttable presumption.

CIELAP also believes it is important Canada provide an effective legal response to the scientific and economic realities – an increase in incidents of contamination versus the rise in organic agriculture, for example – of GMOs as soon as possible.

Conclusion

It is recommended Canada act now to enact legislation dealing with both public and private damage caused by the rapid spread of GMO technology. [GMO-related damage.] This instrument should provide a broad definition of private damage that specifically protects economic loss resulting from contamination due to cross-pollination, as well as provide a workable definition of harm to the environment and biodiversity. Liability should be strict, and channeled to industrial producers who are the best suited to internalize costs. And, as the final recommendation states, to further advance the public interest, the burden of proof on causation should be eased through the creation of a rebuttable presumption.

1.0 Introduction

The release of Genetically Modified Organisms (GMOs) into the environment raises questions of liability and redress in both the public and private law realm. Traditionally, the discussion of legal responsibility, duty and obligation has focused on potential environmental damage associated with GMO release. This focus has expanded to include private law concerns including the socio-economic effects of cross-pollination contamination. Producers, suppliers, and users of GMOs are subject to the rules of civil liability, specifically the common law of negligence, the strict liability torts of nuisance, and the rule in *Rylands v. Fletcher*[1]. Negligence provides redress to individuals who have suffered harm resulting from a careless act. In the absence of a careless act, nuisance or the rule in *Rylands* may afford redress. Nuisance is available when a defendant uses his or her own land to carry out an activity that causes something harmful or offensive, which affects the land of a neighbour. The rule in *Rylands* protects one against damage caused by any isolated escape of something harmful to their land, when a defendant is making unnatural use of his or her land.

There is debate regarding the appropriateness of traditional civil liability systems to deal with the unique features of GMO technology. Debate also surrounds the uniqueness of the technology itself. Multiple international bodies and nations have created statutory GMO liability instruments, thus recognizing the uniqueness of GMOs, and the inadequacy of traditional liability regimes. Canada has taken the stance that the rules of civil liability are sufficiently flexible to deal with GMO technology. This paper will explore the policy implications of creating a statutory liability regime and will discuss the appropriateness of Canada's stance and provide recommendations on how it has to proceed.[2]

2.0 Potential Damage

The release of GMOs may have adverse affects on the environment and biodiversity. Once released, a GMO may become an invasive species, harm non-target organisms, or have its inserted genes flow to natural species.[3] Release may also cause property damage through cross-contamination of neighbouring crops, which may have related socio-

[1] (1868), L.R. 3 H.L. 330 (U.K. H. L.), affirming (1866), L.R. 1 Exch. 265 (Eng. Exch.) [*Rylands*].
[2] As this paper focuses on legal liability associated with environmental and socio-economic damage, it will not explore possible regulatory sanctions that applicants may be exposed to if they violate the conditions of GMO regulatory laws, unless the sanctions deal directly with environmental or socio-economic damage. The discussion also excludes legal liability that may arise from intellectual property law.
[3] For a complete discussion of potential environmental damage see Bjorkquist S. & Winfield M., "The Regulation Of Agricultural Biotechnology In Canada" (1999) Canadian Institute of Environmental Law and Policy.

economic effects. Three distinct scenarios may lead to economic loss: Firstly, an unapproved crop grown within a field trial may contaminate a commercial crop. This would prevent the commercial crop from entering the market; secondly, a commercial GMO crop may contaminate a non-GMO commercial crop. If this contamination induces a 'genetically modified' labeling requirement, a crop price premium may be lost;[4] and thirdly, a GMO crop may contaminate an organic crop, leading to the loss of an organic designation and consequential destruction of any price premium the designation may bring.[5]

3.0 The civil liability system

In Canada, Europe and the United States, producers and users of GMOs are subject to the traditional rules of civil liability. That is, if a GMO causes damage to a person, their property, or associated economic interest, the producer or user of that GMO may be held liable for that damage. Actions may be brought under the common law of negligence, or under the traditional strict liability torts of nuisance, and the rule in *Rylands v. Fletcher.*[6] It is not the intention of this paper to discuss the application of the common law to GMOs, thus, each of these heads of damage will only be discussed briefly.[7]

3.1 Negligence

Individuals who believe their crops or property have been damaged as a result of a neighbour growing GMO crops who failed to take adequate precautions, may have an

[4] Currently, this head of damages is significant outside of Canada in nations where labeling is mandatory. In April of 2004, the EU enacted new legislation on the labeling of genetically modified food. EC, Regulation 1829/2003 of 22 September 2003 on genetically modified food and feed [2003] O.J.L. 268/1 [*EC Labeling Regulation*] at Article 12(2) and EC, Regulation 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [2003] O.J.L. 268/24 [*EC Labeling Regulation II*] at Article 7(2), introduce a labeling threshold of 0.9%. If a food product contains >0.9% genetically modified ingredients it must be labeled as 'genetically modified'. The threshold exists to take account of accidental contamination that might arise during cultivation, harvesting, transport and processing.

[5] The National Standard of Canada – Organic Agriculture, 1999 (CAN/CGSB-32.310-99) sets out the requirements to obtain an organic designation. Section 10.1.2 of the standards states, "The use of the term organic, and similar terms having the same meaning, is permitted on the principle display panel of a food product, only if 95% or greater of ingredients, excluding added water or salt, are obtained from certified sources of organic production in conformity with this standard."

[6] (1868), L.R. 3 H.L. 330 (U.K. H. L.), affirming (1866), L.R. 1 Exch. 265 (Eng. Exch.). [*Rylands*]

[7] For a comprehensive review of GMO liability arising in American tort law see, Kershen D.L., "Legal Liability Issues in Agricultural Biotechnology" (2002) The National Agricultural Law Center. For a detailed perspective from the United Kingdom see, "GM Crops Coexistence and Liability - Annex D" (November 2003) Agriculture and Environment Biotechnology Commission (AEBC) [*ABEC*].

actionable claim in negligence. Negligence provides redress for harm resulting from a careless act. It consists of three main elements: Firstly, a duty to take care; secondly, a breach of that duty; and thirdly, harm suffered by another person as a result of the breach.[8] A duty is only owed to foreseeable victims.[9] Thus, it may be difficult for a farmer to bring an action against a seed supplier and/or a producer of a GMO. The question of whether a duty of care exists is largely a policy concern, which may best be decided by parliament.

3.2 Nuisance

Nuisance establishes strict liability, hence, there is no fault requirement. It is available when a defendant uses his or her own land to carry out an activity that causes something harmful or offensive, which affects the land of a neighbour.[10] Protection is conferred for both actual damage, and, for unreasonable interference with the plaintiff 's enjoyment of their land. The common law has yet to decide if the planting of GM-crops constitutes a harmful or offensive activity, and if contamination from cross-pollination is an unreasonable interference with the enjoyment of one's own land.

3.3 The rule in Rylands v. Fletcher

The rule in *Rylands* establishes strict liability for damage caused by any isolated escape of something harmful to the plaintiff's land, when the defendant is making unnatural use of his or her land.[11] For the rule to be applicable in the context of GMOs, courts would have to conclude that producing or growing GMOs is a "non-natural" use of one's land.

4.0 Statutory Liability Regimes

The common law may inadequately deal with GMO liability. Furthermore, many of the policy issues surrounding GMO liability may be best suited for parliament and not the judiciary. Inadequacies may be remedied through the creation of a statutory liability regime. In determining if a unique statutory regime is required, one must first determine

[8] See *ABEC, Ibid* at para. 36.
[9] *Donoghue v. Stevenson*, [1932] A.C. 562 at p. 580.
[10] New Zealand Law Commission Report, "Study Paper 14: Liability for Loss Resulting from the Development, Supply, or use of Genetically Modified Organisms" (May 2002) New Zealand Law Commission [*New Zealand Law Commission*] at para. 42.
[11] Mark Wilde, *Civil Liability for Environmental Damage: A Comparative Analysis of Law and Policy in Europe and the United States* (The Hague: Kluwer Law International, 2002) at p.41.

if genetic engineering technology is unique. For instance, is agriculture involving GMOs at its core different from traditional agricultural breeding technologies? An affirmative answer then leads one to ask if the evolving common law has the flexibility and capacity to deal with this uniqueness. Legislative intervention is required if the potential harm is deemed to create new challenges that cannot be met by the common law.

The issue of GMO uniqueness has been explored by many nations. Proponents of GMOs often argue that the power of genetic engineering is unique, but the risks are conventional.[12] Genetic modification is hailed as a great power because it allows for species barriers to be crossed. At the same time it is argued this power creates no new risks. Rhetorically speaking, these appear to be conflicting claims, as this position implies the tremendous new power is no different than traditional breeding technologies.[13] The United States has adopted the position that GMOs in an agricultural context are not unique.[14]

Of course, speaking scientifically, this new ability to cross the species barrier does indeed permit the potential for specific risks. The new legal question is, whether the new risks are enough like the old risks to be addressed in the same way. Many countries, however, have recognized the uniqueness of GMOs and subsequently must decide if their common law can adapt to the uniqueness. *The New Zealand Law Commission* summarized the features of GMOs that may cause problems within the current common law. These features, although not all necessarily unique to GMOs, were deemed to make current civil liability regimes ill fitted to deal with GMOs:

- Difficulty in estimating the level of risk posed by GMOs
- Difficulty in assessing the magnitude of potential damage
- Potential for catastrophic levels of harm
- Potential for irreversible damage
- Potential for negative effects to manifest in the long term and be diffuse in nature
- Difficulty and expense plaintiffs may face in establishing causation and proving the extent of any damage.[15]

[12] Michael Baram *et al.,* "1997 Symposium Transgenic Agriculture: Biosafety and International Trade" (1997) 4 B.U. J. SCI. & TECH. L. 4 at para. 17.
[13] *Ibid.* at para. 14.
[14] The "Coordinated Framework for Regulation of Biotechnology" (June 26, 1986) 51 Fed. Reg. 23302, developed by The Office of Science and Technology Policy in the United States, concluded that agricultural biotechnology does not differ in essence from traditional breeding techniques.
[15] *Supra* note 10 at para. 144. It must be noted that the Law Commission's stance on the uniqueness of GMOs countered the view previously expressed by the New Zealand Royal Commission on Genetic Modification. The Royal Commission stated that from a liability perspective there is nothing radically different in genetic modification to require new or special remedies, Royal Commission on Genetic Modification, "Report of the Royal Commission on Genetic Modification" (Wellington, 2001) 2, Chapter 12, at para. 80.

These features of GMOs make a claim in negligence, nuisance or under the rule in *Rylnands v. Fletcher*, difficult and uncertain. An additional problem with the common law is that it does not directly address questions of environmental damage. Tort focuses on interests in bodily integrity or property, and environmental interests are at most an incidental issue.[16] Private law ignores unowned environmental resources; thus, it does not cover many of the potential damages associated with the release of GMOs.

Canada has taken the stance that the Canadian common law is sufficiently robust and flexible to deal with the potential harm of GMOs.[17] Many other countries have adopted the same position, including Australia[18] and, as noted above, the United States.[19] However, governments, in effect, assign major policy decisions to the judiciary through the adoption of such a stance. By contrast, a growing number of nations and international bodies have recognized the uniqueness of GMOs, and the limits of current common law regimes, through the development of specific GMO legislation.

> **RECOMMENDATION 1:** Canada should recognize the uniqueness of GMO technology and the limits of the common law system, and implement a statutory liability instrument.

5.0 International Liability Regimes

A number of international directives, conventions and protocols are relevant to the discussion of GMO-related public and private liability. The following is a discussion of some of these regimes.

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[16] Maria Lee, "Regulatory Solutions for GMOs in Europe: The Problem of Liability" (November, 2003) Journal of Environmental Law and Practice, 311.

[17] Canada has no statutory GMO liability legislation. The Canadian Biotechnology Advisory Committee report, "Patenting of Higher Life Forms and Related Issues" (June 2002) 14, stated that liability issues are adequately addressed by the common law of negligence and the civil law of obligations, and thus specific provisions for biotechnology are not required.

[18] During the development of the *Gene Technology Act* 2000 (Cth), the Australian legislature concluded that potential harms of GMOs could be dealt with using the common law and current legislation. Submission no. 77 to the Senate Community Affairs Reference Committee, Parliament of Australia, Canberra, October 2000 (Interim of the Gene Technology Regulator, Department of Health and Aged Care), 146; accepted by the Senate Community Affairs Reference Committee (cited to Science and Economic Policy Branch Australian Government Department of Agriculture, Fisheries and Forestry: *Liability Issues Associated with GM Crops in Australia*, September 2003).

[19] The *Coordinated Framework for Regulation of Biotechnology*, Supra note 14, concluded that agricultural biotechnology does not differ in essence from traditional breeding techniques. Accordingly, the United States has not developed a unique legal liability regime for genetically modified crops.

5.1 International Public Liability Regimes

Various international directives, conventions and protocols are relevant to the discussion of GMO-related public liability. Of these international instruments, the Cartagena Protocol on Biosafety[20] has the potential to have the greatest reach. This stems from the 107 countries in five continents that have ratified the protocol.[21] However, this reach is limited because major signatory nations like Australia, Canada and China have yet to ratify the protocol, while others, including the Russian Federation and the United States, have never signed on.[22]

The objective of the protocol is to ensure protection exists in the transfer, handling and use of living modified organisms that may adversely affect the conservation and sustainable use of biological diversity.[23] Liability and redress are envisioned as tools to ensure this adequate level of protection is met. The original protocol deferred establishing a liability regime, but stated that rules would be adopted within four years of the protocol coming into force, and would be based on an elaboration of current international rules and procedures on liability taking into account ongoing processes in international law.[24] With the protocol coming into force on 11 September 2003, it is expected rules of liability and redress should be in place by 2008.[25] The impact of the rules will be limited since they will only involve trans-boundary damage, and will not touch liability that is purely an internal matter.[26]
Other international laws, such as the European Union's Environmental Liability Directive,[27] are not limited to trans-boundary damage. The *EU Liability Directive* establishes an environmental public liability framework based on the "polluter pays" principle.[28] The directive covers environmental damage caused by GMOs.[29] However, the scope of the coverage is limited by the directive's narrow definition of environmental

[20] The Catagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 Jan. 200, 39 *Int'l Leg. Mat.* 1027 (2000) [*Cartagena Protocol*].
[21] Online: Convention on Biological Diversity <http://www.biodiv.org/biosafety/ratification.asp>
[22] Online: Convention on Biological Diversity <http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt>
[23] *Supra* note 20, Article 1.
[24] *Supra* note 20, Article 27.
[25] Online: Convention on Biological Diversity <http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt>
[26] *Supra* note 20, Article 14(2).
[27] EC, Council Directive 2004/35/CE of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage [2004] O.J.L. 143/56 [*EU Liability Directive*].
[28] *Ibid.* at Article 1.
[29] *Ibid.* at Article 3(1) states that the directive applies to environmental damage caused by any of the activities laid out in Annex III. Included in the activities of Annex III is (10) the contained use of GMOs, and (11) the deliberate release, transport and marketing of GMOs.

damage. The definition only includes damage to protected species and natural habitats,[30] and land contamination that creates a significant risk of adversely affecting human health.[31] It is likely that the possible harmful effects of GMOs will occur outside of protected habitats. For instance, farmland biodiversity is ignored unless the farm is within a protected natural habitat.[32] In addition, adverse effects may have no impact on protected species or human health. Although the directive does not confer protection for all potential damages, it is significant that it recognizes the release of GMOs as a possible activity leading to environmental harm.

The Cartagena liability drafters may be inclined to consider non-legally binding documents, such as the *Lugano Convention*.[33] The convention addresses environmental liability and is based on the ”polluter pays” principle.[34] The convention covers activities associated with GMOs.[35] A broad definition of environmental damage is adopted, which is wider then that contained within the *EU Liability Directive*. Damage is simply defined as impairment of the environment.[36] The broadness of this definition is enlarged since the environment is deemed to include:

> [N]atural resources both abiotic and biotic, such as air, water, soil, fauna and flora and the interaction between the same factors; property which forms part of the cultural heritage; and the characteristic aspects of the landscape.[37]

These broad definitions of ”damage” and ”environment” are likely to capture the majority of potential environmental damage associated with GMOs.

No international public liability regime exists that sufficiently offers redress for the potential environmental harms of GMOs. The *Cartagena Protocol* limits its application to trans-boundary damage, the *EU Liability Directive's* narrow definition of damage

[30] *Ibid.* at Article 2(1)(a). Protected species and natural habitats are defined in Article 2(3)(a-c) as those species and habitats mentioned in EU Directive 79/409/EEC and EU Directive 92/43/EEC.
[31] *Ibid.* at Article 2(1)(c).
[32] *Supra* note 16.
[33] *Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment* Lugano, 21.VI.1993. [*Lugano Convention*]. The *Lugano Convention* is a Council of Europe Convention. The Council of Europe is an organization consisting of 40 members, including all 15 EU Member States. The Organization is independent of the EU and even if all 15 Member States sign Council Conventions they have no legally binding effect. EU Member states, Italy, Luxembourg, the Netherlands, Greece, and Finland were original signatories. Portugal subsequently signed onto the convention. Bryan Endres, "GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union" (August, 2000) 22 Loy. L.A. Int'l & Comp. L. Rev. 453.
[34] *Lugano Convention*, *Ibid*, Preamble.
[35] *Ibid*. at Article 2(1)(b) states that "dangerous activity" includes the production, storage, use, disposal or release of genetically modified organisms.
[36] *Ibid.* at Article 2(7)(c).
[37] *Ibid.* at Article 2(10).

allows potential harm to escape coverage, and the *Lugano Protocol* is not legally binding. The only international public liability regime that may impact Canada is the *Cartagena Protocol*.

5.2 International Private Liability Regimes

GMO-associated private liability is ill defined at an international level. Unlike public liability regimes, few international instruments have attempted to deal with private liability.

Originally, it was proposed that the *EU Liability Directive* would cover private liability.[38] The drafters of the Environmental Liability *White Paper* felt it was essential to include private liability within the framework because often private and public damage will result from the same event. In the absence of a private law element, inequitable results could occur since compensation may not occur for a private element of damage while compensation would occur for the public element.[39] However, the inclusion of private liability was met with resistance as both Germany[40] and the United Kingdom[41] expressed the view that the directive should not cover private damage. Opposition stemmed from the possible effects on civil procedure in Member States and national insurance arrangements and compensation schemes.[42]

The European Parliament (EP) was in favor of including private liability within the *EU Liability Directive*, and attempted to steer the EU in this direction by adopting a *Co-existence Report*[43] calling for the creation of a community-wide private liability regime dealing with financial damages associated with co-existence.[44] The report went even further and called for all Member States to implement a moratorium on GMO crop approvals until a liability system based on the ”polluter pays” principle was in place.[45] Despite the attempts of the EP, private liability was dropped in the final version of the *EU Liability Directive*.

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[38] White Paper on environmental liability, COM(2000) 66 final 9 February 2000. [*White Paper*] at p.16.
[39] *Ibid.* at pg. 16.
[40] German Government’s response to the *White Paper*, Online: Europa <http://europa.eu.int/comm/environment/wel/main/commentator_detail.cfm?n_cmt_id=404>
[41] The United Kingdom’s response to the *White Paper*, Online: Europa <http://europa.eu.int/comm/environment/wel/main/commentator_detail.cfm?n_cmt_id=234>
[42] The United Kingdom’s response to the *White Paper*.
[43] Friedrich - Wilhelm GRAEFE zu BARINGDORF (Greens/EFA, D) *Report on coexistence between genetically modified crops and conventional and organic crops* 2003/2098(INI). [*Co-existence Report*]. Adopted by the European Parliament in the plenary session on 18 December.
[44] *Ibid.* at para. 8.
[45] *Ibid*. at para. 9.

With no European private law regime in place, EU Member States are responsible for implementing their own private liability regimes through the common law or statute. The EU Directive on the deliberate release into the environment of genetically modified organisms affords this power to Member States.[46]

It is likely the liability and redress regime being developed under the *Cartagena Protocol* will encompass private liability, as the protocol deals with many socio-economical and human-health related issues.[47] As with public liability, the regime will only cover trans-boundary damage.

> **RECOMMENDATION 2:** Canada should ratify the *Cartagena Protocol*, as the forthcoming liability and redress regime will assist in the creation of an encompassing system of liability and redress within the country.

6.0 Statutory Liability Instrument Design

Many nations have drafted their own national liability regimes in recognition of common law limits and the general lack of international protection. Once a nation has decided legislative intervention is required, it must be determined if the intervention will touch on public, private, or both public and private liability. The majority of countries that have enacted GMO liability legislation have chosen instruments that singularly implement a public law regime.[48] The sole protection of the public interest in a national regime expresses a realization of the inability of tort to deal with environmental damage and an acceptance of the adequacy of the civil system to deal with private damage. The private law is unable to deal with environmental harm because the system is essentially a forum for private dispute resolution, which is not concerned with third party objectives such as environmental protection.[49] Thus, the classic model of the tort system imposes limits on the system's ability to mitigate the risks of GMOs.[50] When this is combined with the belief that private dispute resolution is sufficiently flexible to deal with new private harms, a public statutory regime will be implemented.

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[46] EC, Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1990] O.J.L. 117/15 at para. 16 of the preamble.
[47] See *Supra* note 20 at Article 11 (adoption of economic and social incentive measures), and Article 20 (Financial resources).
[48] Bulgaria, Estonia, Indonesia, Slovakia, Slovenia, and South Africa have each enacted public law liability regimes that encompass GMOs.
[49] *Supra* note 11 at p. 9.
[50] "Designer Genes that Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products" (1987) 100 HARV. L. REV. 1086 at page 1093.

Increasingly, nations have questioned the flexibility of the classic civil system and have combined private elements into their public liability regimes.[51] Other nations have adopted less comprehensive combination regimes that are tied to regulatory instruments.[52] Whether legislation covers public or private liability, drafters must consider the following policy questions when creating the instrument:

- What damage will be covered by the legislation?
- Who will be liable?
- Should there be a fault requirement?
- How will the burden of proof on causation be dealt with?

Each of these policy questions will be discussed in more detail below.

RECOMMENDATION 3: The proposed Canadian statutory liability instrument should offer redress for both public and private damage.

6.1 What type of damage will be covered?

Once it is decided a statutory regime is needed to offer protection for GMO-related damage, the protected damage must be defined. A review of the types of private and public damage enumerated in various national instruments follows.

6.1.1 What type of private damage will be covered?

If a statutory regime is put in place to offer protection for private GMO-related damage, that protected damage must be defined. Austria,[53] Germany,[54] Nigeria,[55] Norway[56] and Switzerland[57] have adopted liability legislation that covers broad areas of private damage. The *German Act* provides the most detailed definition of damage. Originally, damage was described as harm to health and property.[58] An amendment to the Act in 2004 expanded this definition through the introduction of detailed heads of financial damage.[59] The following three cross-contamination scenarios that would possibly lead to

[51] Austria, Germany, Nigeria, Norway, and Switzerland, have each combined private and public liability into their regimes.
[52] China, and New Zealand, require a breach of regulatory guidelines to create a cause of action.
[53] *Austrian Gene Technology Act*, 1994 (BGBL. Nr. 510/1994). (unofficial translation) [*Austrian Act*].
[54] *Gentechnikgesetz* vom 16. Dezember 1993 (Amended June 18, 2004). [*German Act*].
[55] *Nigeria Biosafety Guidelines*, 2001. [*Nigerian Guidelines*].
[56] The Act relating to the production and use of genetically modified organisms (Gene Technology Act), 1993. [*Norwegian Act*].
[57] Swiss Federal Law relating to Non-human Gene Technology, March 21, 2003, Recueil systématique 814.91. [*Swiss Law*].
[58] *Supra* note 54 at Section 32(1).
[59] *Supra* note 54 (Amended June 18, 2004).

compensation were outlined: one, contamination leading to a crop being prevented from entering the market; two, contamination inducing a genetically modified labeling requirement; and three, contamination destroying an "organic" distinction.[60] With this amendment, the *German Act* casts a broad definition of damage and essentially erases any uncertainty surrounding the type of damages for which one will be liable.

Although the *Nigerian Guidelines* definition of damage is not as detailed as that in the *German Act*, the definition is broader. Strict liability is imposed for any harm, injury or loss caused directly or indirectly by GMOs, and it is specified that the harm encompass personal injury, damage to property, and financial loss.[61] Essentially, *any* damage, direct or indirect, is covered, and compensation for cross-contamination related financial loss should be easily obtainable, as it is under the inclusive heads of financial loss spelled out in the *German Act*. Such a wide definition of damage may potentially be crippling to the biotechnology industry within Nigeria.

Norwegian and Swiss legislation also put forth strong definitions of damage. The *Norwegian Act* assigns liability when "damage, inconvenience or loss" occurs.[62] The *Swiss Law* employs the wording "damage that occurs to agricultural or forestry enterprises."[63] Although not as specific as the wording in the German or Nigerian instruments, damage to agricultural enterprises would likely be interpreted to include the financial heads associated with contamination. Austrian legislation covers all harm to health and property that would encompass financial loss attached to property damage through cross-pollination contamination.[64]

Other nations, including China[65] and New Zealand,[66] provide private liability regimes through GMO application/registration regulations. The reach of these regimes is limited because a breach of the country's application or registration procedures is required for redress. Thus, if a GMO is approved through a country's registration process, no legislation exists to protect private parties from subsequent harm. The Chinese regulations are an interesting example of the move to include economic loss as a head of damage. This head was added in subsequent, agricultural specific legislation.[67] The

[60] *Supra* note 54 Online: Federal Ministry of Consumer Protection, Food and Agriculture <http://www.verbraucherministerium.de/index-000265812B89107E9DEC6521C0A8D816.html>
[61] *Supra* note 55 at Section 14(a).
[62] *Supra* note 56 at Section 21.
[63] *Supra* note 57 at Article 30(2).
[64] *Supra* note 53 at Section 79(a)(1).
[65] China provides private liability redress through the Safety Administration Regulation on Genetic Engineering, 1993 [*Chinese Genetic Regulation*] and the Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering, 1996 [*Chinese Agricultural Regulation*].
[66] Hazardous Substances and New Organisms Act, 1996 (amended October 2003) [*New Zealand* Act] at Part 7 (117) and Part 7A.
[67] The *Chinese Genetic Regulation*, *Supra* note 65 at Chapter 5, Principle 28, provides protection from environmental pollution, risks to ecological balance and harm to public health. Subsequent *Chinese*
(Footnote continued on next page)

regulation is also unique in that it contains a damage threshold, and only provides redress for damage that causes "great" economic loss.[68] Unfortunately, the threshold quantifier of "great" is undefined.

Other nations, including Hungary[69] and the Russian Federation,[70] offer no statutory protection from potential GMO-related private damage, yet state in GMO specific legislation that their civil systems will deal with such harms. Although no statutory protection is afforded, these regimes entrench the uniqueness of GMOs within legislation and also mandate that the civil system should hear cases involving such damage.

> **RECOMMENDATION 4:** The proposed Canadian statutory liability instrument should provide a broad definition of private damage that specifically protects economic loss resulting from contamination due to cross-pollination.

6.1.2 What type of public damage will be covered?

Many countries have adopted statutory public liability regimes that cover the potential harmful impacts of GMOs on the environment. Increasingly, nations are including protection for harm to biodiversity or biosafety in their public regimes. Bulgaria,[71] Indonesia,[72] Nigeria,[73] Slovakia[74] and Slovenia[75] each include harm to biodiversity as a specific head of damage. Unfortunately, Indonesia is the only country that offers a definition of this term.[76] Similarly, many nations leave the definition of environmental harm legislatively undefined, simply stating that parties will be responsible for harm to the environment.[77] With such an approach, the judiciary is left to define these terms. Consequently, they will determine the scope and impact of the regime. Problems are likely to arise around the meaning of harm to biodiversity, as this concept, especially in a legal context, is relatively new and ill defined. Since one purpose of introducing a

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Agricultural Regulation, *Supra* note 66 at Chapter 6, Principle 32, provided additional protection for great economic loss.

[68] *Chinese Agricultural Regulation*, *Supra* note 66 at Chapter 6, Principle 32(4).

[69] Hungarian Act No. XXVII of 1998 on Biotechnology Activities at Article 27.

[70] Federal Act of the Russian Federation on State Regulation of Genetic Engineering Activity, 1996 [*Russian* Act] at Article 12.

[71] Environmental Protection Act – Bulgaria (State Gazette No. 86/18 October 1991, Amended SG No. 100/1992; 31 & 63/1995; 13/1997) Additional Provision 6.

[72] Decree of the Minister of Agriculture Number: 856/Kpts/HK.330/9/1997 On The Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products at Article 42 confers protection for harm to biosafety.

[73] *Supra* note 55 at Section 14(a) protects harm to biological diversity.

[74] 151/2002 Act on use of genetic technologies and genetically modified organisms, 2002 at Article 2(a) and Article 14(2).

[75] Management of Genetically Modified Organisms Act, 2002 (unofficial translation) at Article 1(1) and Article 3(9) which stress the importance of protecting biological diversity.

[76] *Supra* note 72 at Article 1(2).

[77] See e.g. *Russian Act*, *Supra* note 70 at Article 12.

statutory regime is to eliminate the uncertainties of common law, such uncertainty produces a weaker legal instrument.

An all-inclusive definition of environmental harm will limit uncertainty. The *Austria Act* employs this tactic by including a provision that a party is responsible for *any* harm to the environment.[78] As with private liability regimes, some nations such as China,[79] Indonesia[80] and New Zealand[81] offer redress for public harm only when application/ registration procedures have been violated. Thus, no environmental protection is provided under these regimes if registration and GMO release procedures are met. The Chinese regime provides a threshold for environmental and biodiversity damage, in that the damage must cause "serious" environmental pollution or cause "severe" damage to biological diversity.[82] These undefined qualifiers further limit the reach of the liability regime. Estonia offers a regime that is even further limited in scope, in which redress is only provided for harm caused by accidents associated with GMOs approved solely for contained use.[83]

> **RECOMMENDATION 5:** The proposed Canadian statutory liability instrument should protect harm to the environment and biodiversity, and the harm should be specifically defined within the legislation.

6.2 Channeling of Liability

In the common law of tort, it is unlikely that one could establish a basis to distinguish between producers, suppliers, and farmers when dealing with harm caused by a GMO, because all would be liable if they breached their relevant duty.[84] Thus, when developing a statutory liability regime, one must decide if liability will be channeled to one party or appropriated amongst multiple parties. Legal channeling means that liability is exclusively concentrated, and allocated to a pre-defined party. The law will then exclude the liability of any other person contributing to the damage. If appropriation is chosen, one must decide between proportionate liability or joint and several liability.[85] Arguably, proportionate liability is the most consistent with the "polluter pays" principle, as a

[78] *Supra* note 53 at Section 79(a)(1) and 79(a)(2).
[79] The *Chinese Genetic Regulation*, Supra note 65 at Chapter 5, Principle 28(1) and 28(3) and *Chinese Agricultural Regulation*, *Supra* note 65 at Chapter 6, Principle 32(1) and 32(3).
[80] *Supra* note 72 at Article 42.
[81] *Supra* note 66 at Part 7 (117) and Part 7A.
[82] The *Chinese Genetic Regulation*, *Supra* note 65 at Chapter 5, Principle 28(1) and 28(3) and *Chinese Agricultural Regulation*, *Supra* note 65 at Chapter 6, Principle 32(1) and 32(3).
[83] Contained Use of Genetically Modified Micro-Organisms Act, 2001. Section 14.
[84] *Supra* note 10 at para. 86.
[85] *Supra* note 10 at para. 88. In proportionate liability, each defendant is only responsible for the damage the plaintiff shows was caused by that defendant. In joint and several liability, each defendant is liable for the full amount of the damage caused. This is of importance in the event other defendants cannot be identified or are not worth suing.

plaintiff is only responsible for the damage they caused. However, proportionate liability raises great issues of causation that may put an undue burden on a plaintiff. Thus, a policy decision must be made that balances the equitable treatment of defendants and the burden placed on plaintiffs.

6.2.1 Channeling of Private Liability

The majority of statutory GMO private liability regimes channel liability, however decisions vary as to which party liability will be channeled. Austria and Switzerland channel liability to producers. In Austria, the "releasing company" is singled out as the party that will be held liable for harm caused by GMOs.[86] Switzerland identifies the person seeking marketing authorization as the party who is solely liable.[87] Similarly, countries, such as China[88] and New Zealand,[89] which offer redress through regulatory regimes, channel liability to producers, as they are the party subject to regulation. Channeling liability to producers of the technology in this manner may hinder the scientific advancement of a potentially useful technology. Regardless, such a channeling seems appropriate as liability is being channeled to the party that is ultimately profiting economically from the technology, and is thus best suited to internalize the costs.

It may be argued that other stakeholders "profit" from the benefits of GMO technology. The first generation of agricultural GMO products were designed to offer a benefit to farmers (e.g., farmers received cost savings that were attributed to a reduction in pesticide use) and future generations promise to confer benefits to the end consumers. When one considers that multiple stakeholders or society as a whole may "profit" from GMO technology, it blurs the issue as to who is best suited to bear the costs of harm.

Germany has taken an alternative route to that of Austria and Switzerland, and holds "operators" liable for private damage.[90] In an agricultural context, an operator is the farmer that grows a GM crop. By choosing to channel liability to farmers, it may be that the German government perceives farmers to be the party that profits the most from GMO technology. However, the German government has expressed opposition to agricultural GMO technology and it is more likely that the government decided to channel liability to farmers because they are the least able to internalize costs.[91] This

[86] Su*pra* note 53 at 79(a)(1) and 79(a)(2).
[87] *Supra* note 57 at Article 30(2).
[88] The *Chinese Genetic Regulation*, *Supra* note 65 at Chapter 5, Principle 28 and *Chinese Agricultural Regulation*, *Supra* note 65 at Chapter 6, Principle 32.
[89] *Supra* note 66 at Part 7 (117) and Part 7A.
[90] *Supra* note 54 at Section 32(1).
[91] Minister Kuenast of the German Ministry of Consumer Safety, Food and Agriculture (BMVEL), has made it very clear that she is not a proponent of GMO technology and in her view the country does not need this technology. USDA Foreign Agricultural Service - GAIN Report, *European Commission not Happy with Germany Genetech Law*, 2004.

would effectively force farmers to plant GM-free crops to avoid liability. This effect is strengthened by the fact that liability is joint and several between operators.[92] Thus, a plaintiff may choose from which neighbouring farmer to seek compensation.

Liability is appropriated within the *Nigerian Guidelines*. Liability is attached to the applicant filing for governmental regulatory approval, the person responsible for the harmful activity, and the provider, supplier or developer of the GMO.[93] Essentially, the industrial producer, farmer and every other individual within the supply chain, may be held liable for a single incident of harm. In addition, corporate officers will be held individually liable for harm caused by an associated corporate body.[94] Liability is joint and several. Thus, if other defendants cannot be identified, or are not worth suing, each defendant is liable for the full amount of the damage caused.[95] Assigning liability in this fashion may ultimately have the same effect as channeling liability to producers, as producers are most likely to be in the best financial position. One difference is that a joint and several regime will deter participation in the field of genetic modification at every level since all parties are potentially liable. Of all liability regimes, the *Nigerian Guidelines* provide the strongest deterrence to entrance into GMO research and development.

Unfortunately, some countries, such as Norway, have implemented private GMO liability regimes that channel liability in a vague manner.[96] It is essential in the creation of a statutory liability instrument that the channeled or appropriated parties are clearly defined.

6.2.2 Channeling of Public Liability

Countries that have enacted combination regimes channel liability in the same manner for both private and public heads of damage.[97] As with private damage, the producer or releasing company is best suited to internalize costs that stem from public environmental damage. Consequently, Bulgaria[98] and Indonesia,[99] which have pure public liability regimes, have enacted legislation that channels liability to producers.

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[92] *Supra* note 54 at Section 36(a).
[93] *Supra* note 55 at Section 14(b).
[94] *Supra* note 55 at Section 14(c).
[95] *Supra* note 55 at Section 14(d).
[96] *Supra* note 56 at Section 21 states that remediation may be performed at the expense of the person responsible for the activity. The Act does not define 'person responsible' and thus leaves the definition up for debate.
[97] Austria, China, Germany, New Zealand, Nigeria, Norway, and Switzerland each channel liability consistently for private and public heads of damage (see the section entitled: Channeling of private liability to see which party liability is channeled to).
[98] *Supra* note 71 at Chapter 4, Article 14.
[99] *Supra* note 72 at Article 42.

South Africa has a unique and perplexing system that channels liability to the end-user or consumer.[100] Thus, a consumer may be liable for harm caused by a GMO product that they have consumed. Channeling of this sort also provides no incentive for producers of GMO products to exert appropriate levels of caution.[101] Interestingly, some countries have recognized the problems with such a system and have made specific provisions to exclude end-users and consumers from liability. Slovakian GMO liability legislation channels liability to "users" which encompasses all "natural persons" using genetic technologies *except* final consumers.[102] "Natural persons" is undefined in the legislation, and it appears, in an agricultural setting, liability would be channeled to farmers.

In Slovenia, the public liability regime employs terminology that raises uncertainty as to the potential liability of the various parties involved.[103]

> **RECOMMENDATION 6:** The proposed Canadian statutory liability instrument should channel both public and private liability to the industrial producers of the technology, as they are best suited to internalize the costs of harm

6.3 Should there be a fault requirement?

Negligence is the cornerstone of the Anglo-American tort model. In this system liability is contingent upon the need to establish some degree of fault. This requirement places an evidential burden on the plaintiff to show that a defendant breached a duty of care that was owed to the plaintiff. Such a burden may hinder the ability to efficiently compensate victims. If this hindrance is deemed to be too great, a strict liability system may be adopted to facilitate compensation by foregoing the examination of fault. A strict liability regime should be implemented when the need to protect the public and provide effective compensation outweighs the need to establish the moral culpability of the defendant.[104] With the rapidly changing nature of biotechnology, it is difficult to define a socially optimal duty of care and assess when that duty has been breached. When a strict liability system is in place, the search for a socially optimal duty is unnecessary.[105] The majority of nations that have implemented GMO liability legislation have recognized the pitfalls of a fault-based system and have implemented strict liability regimes. Countries may

[100] Genetically Modified Organisms Act, 1997 [*South African Act*] Section 17(2) states that liability caused by the release of a GMO shall be bourn by the user. Section 1 includes end-users and consumers in its definition of user.
[101] Environmental Affairs And Tourism Portfolio Committee; 8 May 2001: Genetically Modified Organisms Legislation: Briefing.
[102] *Supra* note 74 at Section 9(1).
[103] *Supra* note 75 at Article 3(9) states that the legal or natural person may be responsible for remediation costs. 'Legal or natural person' is not defined within the Act.
[104] *Supra* note 11 at p. 197.
[105] *Supra* note 50 at p. 1095.

explicitly state that strict liability applies or may imply that this is the case through the simple exclusion of any fault requirement.[106]

A strict liability system is especially appropriate in a situation where a party derives an economic benefit from the risk it creates. If this justification is to be used, one must ensure liability is channeled to those deriving economic benefit. Additionally, a strict liability regime appears to be justified as it parallels the strict liability torts of nuisance and the rule in *Rylands*, which appear to have potential applications to GMO liability.

RECOMMENDATION 7: The proposed Canadian statutory liability instrument should implement a strict liability regime.

6.4 How will the burden of proof on causation be dealt with?

It may be immensely difficult for a plaintiff to establish causation and receive compensation for harm suffered. The difficulty may arise because of the possible time lapse before damage is discovered or in the difficulty of obtaining scientific evidence establishing a causal link.[107] For instance, if damage is caused by the combined effects of multiple GMOs from various neighbouring fields, it may be difficult or impossible to establish that any individual GMO caused the damage.[108] A statutory liability instrument may implement means to ease the burden of causation placed on plaintiffs. The policy objective of protecting harmed plaintiffs must be balanced against the concern of finding defendants liable for damage, to which they did not actually contribute.[109]

The *Austria Act* provides an example of an extreme relaxation of the burden of proof on causation. When a GMO is involved in an isolated incident, and the damage is observable, it will be assumed that the GMO caused the damage.[110] However this provision is one of strict, not absolute, liability. That is, the *Austrian Act* allows for this assumption to be disproved if the operator can show that the damage was *not* caused by the GMO.[111] Germany has a similar provision in its GMO legislation.[112] Such a shift in

[106] For an example of an explicated statement of strict liability see the *Nigerian Guidelines*, *Supra* note 55 at Section 14(a) which states "strict liability for any harm" applies and the *Norwegian Act*, *Supra* note 56 at Section 23, which states liability is "regardless of any fault". Strict liability is implied within the *Swiss Act*, *Supra* note 57 at Article 30(2).
[107] *Supra* note 10 at para. 21.
[108] Thornton J., "Genetically Modified Organisms: Developing a Liability Regime" (2001) 6 Env Liability 267, 272. from *New Zealand Law Commission*, *Supra* note 10 at para. 78.
[109] M. Wilde at p. 233.
[110] *Supra* note 53 at 79(d).
[111] *Supra* note 53 at 79(d).
[112] *Supra* note 54 at Section 34.

the burden of proof is appropriate since it is likely that the defendant has a greater knowledge of the possible adverse effects of GMOs.

RECOMMENDATION 8: The proposed Canadian instrument should ease the burden of proof on causation through the creation of a rebutable presumption.

8.0 Bibliography

Legislation

151/2002 Act on use of genetic technologies and genetically modified organisms, 2002.

Austrian Gene Technology Act, 1994 (BGBL. Nr. 510/1994).

Contained Use of Genetically Modified Micro-Organisms Act, 2001. Section 14.

Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment Lugano, 21.VI.1993.

EC, Council Directive 2004/35/CE of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage [2004] O.J.L. 143/56.

EC, Regulation 1829/2003 of 22 September 2003 on genetically modified food and feed [2003] O.J.L. 268/1.

EC, Regulation 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [2003] O.J.L. 268/24.

Environmental Protection Act – Bulgaria (State Gazette No. 86/18 October 1991, Amended SG No. 100/1992; 31 & 63/1995; 13/1997).

Federal Act of the Russian Federation on State Regulation of Genetic Engineering Activity, 1996.

Genetically Modified Organisms Act, 1997.

Gentechnikgesetz vom 16. Dezember 1993 (Amended June 18, 2004).

Hazardous Substances and New Organisms Act, 1996 (amended October 2003).

Hungarian Act No. XXVII of 1998 on Biotechnology Activities.

Nigeria Biosafety Guidelines, 2001.

Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering, 1996.

Safety Administration Regulation on Genetic Engineering, 1993.

Swiss Federal Law relating to Non-human Gene Technology, March 21, 2003, Recueil systématique 814.91.

The Act relating to the production and use of genetically modified organisms (Gene Technology Act), 1993.

Legislation (Continued)

The National Standard of Canada – Organic Agriculture, 1999 (CAN/CGSB-32.310-99).

The Catagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 Jan. 200, 39 *Int'l Leg. Mat.* 1027 (2000).

Jurisprudence

Donoghue v. Stevenson, [1932] A.C. 562.

Rylands v. Fletcher (1868), L.R. 3 H.L. 330 (U.K. H. L.), affirming (1866), L.R. 1 Exch. 265 (Eng. Exch.).

Secondary Material: Articles

Bjorkquist S. & Winfield M., "The Regulation Of Agricultural Biotechnology In Canada" (1999) Canadian Institute of Environmental Law and Policy.

Bryan Endres, "GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union" (August, 2000) 22 Loy. L.A. Int'l & Comp. L. Rev. 453.

"Designer Genes that Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products" (1987) 100 HARV. L. REV. 1086 at page 1093.

Kershen D.L., "Legal Liability Issues in Agricultural Biotechnology" (2002) The National Agricultural Law Center.

Maria Lee, "Regulatory Solutions for GMOs in Europe: The Problem of Liability" (November, 2003) Journal of Environmental Law and Practice, 311.

Michael Baram *et al.*, "1997 Symposium Transgenic Agriculture: Biosafety and International Trade" (1997) 4 B.U. J. SCI. & TECH. L. 4 April 17.

Secondary Material: Reports

Canadian Biotechnology Advisory Committee report, "Patenting of Higher Life Forms and Related Issues" (June 2002) 14.

Environmental Affairs And Tourism Portfolio Committee; 8 May 2001: Genetically Modified Organisms Legislation: Briefing.

Friedrich - Wilhelm GRAEFE zu BARINGDORF (Greens/EFA, D) *Report on coexistence between genetically modified crops and conventional and organic crops* 2003/2098(INI).

"GM Crops Coexistence and Liability" (November 2003) Agriculture and Environment Biotechnology Commission (AEBC).

"Coordinated Framework for Regulation of Biotechnology" (June 26, 1986) 51 Fed. Reg. 23302.

Secondary Materials: Reports (Continued)

Royal Commission on Genetic Modification, "Report of the Royal Commission on Genetic Modification" (Wellington, 2001) 2.

Submission no. 77 to the Senate Community Affairs Reference Committee, Parliament of Australia, Canberra, October 2000 (Interim of the Gene Technology Regulator, Department of Health and Aged Care), 146; accepted by the Senate Community Affairs Reference Committee (cited to Science and Economic Policy Branch Australian Government Department of Agriculture, Fisheries and Forestry: *Liability Issues Associated with GM Crops in Australia*, September 2003).

USDA Foreign Agricultural Service - GAIN Report, *European Commission not Happy with Germany Genetech Law*, 2004.

Secondary Material: Books

Mark Wilde, *Civil Liability for Environmental Damage: A Comparative Analysis of Law and Policy in Europe and the United States* (The Hague: Kluwer Law International, 2002).