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Agricultural Biotechnology:  
Legal Liability Regimes from Comparative and International Perspectives  
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**Introduction**

As agricultural biotechnology has become an agronomic alternative, discussion has emerged about what legal liabilities, if any, exists for those who create, distribute, and produce transgenic seeds and crops. Many governments have debated legal liability as related to agricultural biotechnology.<sup>1</sup> This debate has also been informed by numerous commentators -- academics from several disciplines, government lawyers, and representatives from non-governmental organizations or industry. The authors of this article – a Canadian academic and an American academic – have participated in this discussion about legal liability and agricultural

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<sup>1</sup> For example, governmental bodies of New Zealand have produced several documents on legal liability. In chronological order these documents are: Royal Commission on Genetic Modification, Report, Chapter 12, “Liability Issues” (2001); Ministry of Research, Science & Technology, Review of Chen, Palmer & Partners and Simon Terry Associates, *Who Bears the Risk?* (Oct. 2001) available at [www.morst.govt.nz/hot/biotechRCGM.html](http://www.morst.govt.nz/hot/biotechRCGM.html); NZ Law Commission Report, “Liability for Loss Resulting from the Development, Supply or Use of Genetically Modified Organisms” (May 2002); Ministry for the Environment, “Public Discussion Paper: Improving the Operation of the HSNO Act for New Organisms,” Chapter 8 “Liability Issues” (Sept. 2002) available at [www.mfe.govt.nz](http://www.mfe.govt.nz); and Ministry for Environment, “Summary of Submissions: Improving the Operation of the HSNO Act for New Organisms,” Chapter B8 “Liability Issues” (Feb. 2003) available at [www.mfe.govt.nz](http://www.mfe.govt.nz).

biotechnology.<sup>2</sup>

To our knowledge, the published academic literature on this topic has primarily focused on domestic law of particular nations<sup>3</sup> with some discussion about liability proposals at the international level.<sup>4</sup>

In this article, the authors hope to offer fresh insights on legal liability from comparative law and international law perspectives. The article begins by comparing Canadian and American legal liability regimes in agricultural biotechnology. Using this North American comparison as background, the article then discusses liability issues by contrasting the statutory regimes from Denmark and Germany. Once the comparisons and contrasts between Canadian, American, Danish, and German law have been presented, the article focuses on the on-going discussion of legal liability and agricultural biotechnology at the Meeting of the Parties (MOP) of the

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<sup>2</sup> S. SMYTH et al, REGULATING THE LIABILITIES OF AGRICULTURAL BIOTECHNOLOGY (CABI Pub. 2004), especially Chapter 2 “Innovation and Liability” that focuses on legal liability issues; L. Khoury & S. Smyth, Reasonable Foreseeability and Liability in Relation to Genetically Modified Organisms, 9<sup>th</sup> ICABR Int’l Conf. on Agric. Biotechnology (Ravello, Italy, July 2005); and S. Smyth, A Decade of Regulating Agricultural Biotechnology Liability in Canada: A Case Study from 1994-2004 (Ph.D. Thesis, Univ. of Saskatchewan, Jan. 2005).

D. Kershen, Legal Liability Issues in Agricultural Biotechnology, National Agricultural Law Center Research Article (2002), [www.nationalaglawcenter.org](http://www.nationalaglawcenter.org); D. Kershen, Proposed Liability for Transgenic Crops, 10 (#2) Agric. Mngt. Newsletter 7 (ABA-SEER, Feb. 2006).

<sup>3</sup> *E.g.*, J. Glenn, Footloose: Civil Responsibility for GMO Gene Wandering in Canada, 43 WASHBURN L. J. 547 (2004); B. Endres, “GMO:” genetically modified organism or gigantic monetary obligation? The liability schemes for GMO damage in the United States and the European Union, 22 LOYOLA L.A. INT’L & COMP. L. REV. 453 (2000). Both these articles provide a survey of the possible legal claims that might exist to establish legal liability related to agricultural biotechnology.

<sup>4</sup> *E.g.*, E. Duall (Note), A Liability and Redress Regime for Genetically Modified Organism under the Cartagena Protocol, 36 GEO. WASH. INT’L L. REV. 173 (2004).

Cartagena Protocol on Biosafety (BSP).<sup>5</sup> The authors posit that understanding the comparisons and contrasts between Canada, the United States, Denmark, and Germany assists greatly in understanding the issues and debates about legal liability and agricultural biotechnology at the international level at the BSP negotiations.

By providing comparative descriptions of the legal liability regimes for agricultural biotechnology in Canada, Denmark, Germany, and the United States, the authors desire to clarify the quite different alternatives available to the participants in the Cartagena Biosafety Protocol (BSP) negotiations. Moreover, by discussing and explaining the options facing the BSP negotiators, the authors have confidence that policy-makers from the various nations should gain a better understanding of how they might fashion domestic legal liability regimes to best fit their own particular nations.

### **Legal Liability: Canada and the United States of America**

In the Canadian and American legal systems, legal liability can be classified into three general types: civil liability, administrative liability, and criminal liability.<sup>6</sup>

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<sup>5</sup> The Cartagena Protocol on Biosafety (BSP) entered into force on 29 December 2003. The Meeting of the Parties is the governing entity of the BSP. Article 27 titled “Liability and Redress” states:

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

<sup>6</sup> For an excellent brief discussion of these three classifications, read R. Burnett-Hall, Annex D – Liability for Damage Caused by Genetically Modified Organisms: The Existing Law in UK AGRICULTURE AND ENVIRONMENT BIOTECHNOLOGY COMMISSION REPORT (Nov. 2003), especially pp. 125-129. Although this Annex D is for the United Kingdom, Canada and the

## Civil Liability

Civil liability means that one person (plaintiff) brings a private claim for a legal remedy (usually monetary damages, but at times for an injunction) against another person (defendant) by claiming that the person or property of the plaintiff has suffered harm caused by the defendant.<sup>7</sup> Thus, a Canadian or American plaintiff potentially could bring a private lawsuit against the company that created a transgenic crop or a farmer who grew a transgenic crop claiming that the plaintiff has suffered harm to her body, her land, or her crop caused by the transgenic crop of the company or the farmer.

In both Canada and the United States, a plaintiff claiming civil liability harm caused by a transgenic crop has several causes of action (torts) from which to choose for the legal pleadings that formally present the case (plaintiff v. defendant) to the court. In both Canada and the United States, the plaintiff can bring more than one cause of action in the same case, if the plaintiff has a reasonable basis to believe that the plaintiff can prove facts that establish each cause of action set

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United States share a common heritage from the English legal system, including the tripartite classification of legal liability.

<sup>7</sup> Civil liability also encompasses one party (plaintiff) claiming private damages against another party (defendant) caused by defendant's infringement of the intellectual property rights (e.g. trade secrets, plant variety certificates, patents) of the plaintiff. Although Canadian and American intellectual property laws are similar, comparing the significant decisions of the Supreme Court of Canada with those of the Supreme Court of the United States also reveals important differences. *Compare* Commissioner of Patents v. President and Fellows of Harvard College, 2002 SCC 76 (patenting of living matter, higher life forms are not a patentable subject) *with* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (patenting of living matter, all life forms are patentable subject) and *compare* Monsanto Canada Inc. v. Schmeiser, 2004 SCC 34 (genes and cells of plants, but not the plants themselves, are patentable) *with* J.E.M. AgSupply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001) (genes, cells, and the plants themselves are patentable). This article does not address the issues of civil liability arising from claims of intellectual property infringement.

forth in the legal pleadings. In both Canada and the United States, a plaintiff's possible causes of action for damages suffered reflect the shared Common Law system of jurisprudence originating in England. More specifically, the following four Common Law causes of action<sup>8</sup> have received the most attention in the academic literature<sup>9</sup>.

- Negligence.<sup>10</sup> Negligence exists when a defendant fails to act as a reasonable person would have acted in the factual situation and the defendant's unreasonable conduct causes damages to the person or property of the plaintiff. With respect to the negligent act alleged against the defendant by the plaintiff, the courts examine three specific elements of the negligence cause of action: defendant's foreseeability of harm from defendant's conduct (an act or a failure to act); whether defendant owed plaintiff a duty of care; and, if a duty of care exists, the standard of care that the law expects the defendant to honor in fulfilling that duty.

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<sup>8</sup> The authors give very brief descriptions of the four Common Law causes of action. The authors have checked their brief descriptions for accuracy against widely-used one volume treatises on torts in Canada and the United States, specifically G. FRIDMAN, *THE LAW OF TORTS IN CANADA* (2<sup>nd</sup> ed. 2002) and D. DOBBS, *THE LAW OF TORTS: HORNBOOK SERIES* (2000). However, the brief descriptions come from the authors, not the treatise writers who have devoted many pages of careful detail to their discussions of each Common Law cause of action.

<sup>9</sup> For Canada and United States, see the literature citations *supra* notes 2 & 3. For other Common Law countries with emphasis also on the same four Common Law causes of action, *see* M. Barber, *Managing genetically modified crops in Australia: GM crops, segregation and liability in Australian agriculture* (Avcare, Sept. 2005), [www.avcare.org.au](http://www.avcare.org.au); D. Dalton, *Liability Issues Associated with GM Crops for Australia*, Dept. of Agriculture, Fisheries and Forestry (Sept. 2003); Peter Lloyd, *Report of the Independent Reviewer to the Government of Victoria on Market Impacts of Genetically Modified Canola and Industry Preparedness* (Dec. 2003), [www.dpi.vic.gov.au/dpi/nrensr.nsf](http://www.dpi.vic.gov.au/dpi/nrensr.nsf); for New Zealand, the citations *supra* note 1; (UK) R. Burnett-Hall, *supra* note 6, esp. pp. 133-136 and D. Howarth, *Civil liability for GM farming: GM crops and the existing law*, 12 *ENVIR'L LIAB.* 185 (2004).

<sup>10</sup> G. FRIDMAN *supra* note 8, Ch. 12, *The Tort of Negligence*; D. DOBBS *supra* note 8, Ch. 6, *The Negligence Cause of Action*.

Negligence is considered a fault-based cause of action because the plaintiff must prove that the defendant was at fault for failing to act like a reasonable person – an objective standard of fault as opposed to a subjective standard of fault.

- Trespass.<sup>11</sup> Trespass involves the direct physical entry upon the property of plaintiff by defendant or things (animals, equipment, substances, or particles) under defendant's control.

Trespass exists against defendant from the act of direct entry, regardless of fault on the part of the defendant. Plaintiff is entitled to nominal damages for the act of trespass itself. However, if the plaintiff desires to gain an injunction or monetary (more than nominal) damages, the plaintiff must prove a specific harm or specific injury from the act of trespass.

- Nuisance.<sup>12</sup> Private nuisance involves the unreasonable interference by defendant's conduct with the plaintiff's possessory use and enjoyment of her own land with emphasis more on the plaintiff's possessory use and enjoyment than on the defendant's conduct. However, with the emphasis on plaintiff's possessory use and enjoyment, the plaintiff must be claiming a reasonable use and enjoyment reflective of the character of the locality where plaintiff's land lies and reflective of what normal persons, as opposed to especially sensitive persons, may reasonably expect from neighbors. Nuisance exists against defendant from the unreasonable interference, regardless of fault on the part of the defendant. Nuisance is a cause of action in which courts attempt to accommodate both plaintiff and defendant and to achieve a neighborly coexistence.

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<sup>11</sup> G. FRIDMAN *supra* note 8, Ch. 3, Trespass – General Principles; D. DOBBS *supra* note 8, Ch. 4, Direct and Intentional Interference with Property.

<sup>12</sup> G. FRIDMAN *supra* note 8, Ch. 8, Nuisance; D. DOBBS *supra* note 8, Ch. 34 Nuisance.

The Common Law also recognizes a public nuisance. Public nuisance exists when a defendant engages in conduct that unreasonably interferes with a recognized public right (such as the right of the public to access and to use a public highway). As a public nuisance interferes with a public right, a public official (e.g. a Provincial or a State Attorney-General) ordinarily is the proper party to bring a legal action against the defendant to abate the public nuisance. If an individual plaintiff can show a specific, special damage from the public nuisance that is not suffered by members of the general public, the individual plaintiff may have a legal claim for the special, specific damages by using a public nuisance claim.<sup>13</sup>

- **Strict Liability.**<sup>14</sup> Strict liability exists when a defendant brings or does something on his land that is abnormally dangerous or not natural and the “abnormally dangerous” or “not natural” something causes harm to the person or property of plaintiff. Strict liability exists regardless of fault on the part of the defendant in order to make the defendant internalize the cost of harms caused by defendant’s “abnormally dangerous” or “not natural” something. Although Canada and the United States have similar strict liability doctrines, Canadian jurisprudence seems to place more emphasis in its case law upon the foundational precedent of *Rylands v. Fletcher*<sup>15</sup> and its implications so that strict liability may at times be called The Rule of Rylands

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<sup>13</sup> G. FRIDMAN, *supra* note 8, Ch. 8 Nuisance at 8.8 Private Actions for Public Nuisance; D. DOBBS, *supra* note 8, Ch. 24, § 467 Public Nuisance. For a law review article that emphasizes the public nuisance claim in the agricultural biotechnology context, T. Redick & G. Bernstein, Nuisance Law the Prevention of “Genetic Pollution”: Declining a Dinner Date with Damocles, 30 ENV’L L. REPT. 10328 (2000).

<sup>14</sup> G. FRIDMAN *supra* note 8, Ch. 9, Strict Liability for Dangerous Things; D. DOBBS *supra* note 8, Ch. 23, Strict Liability for Animals, Abnormal Conditions, and Special Dangers.

<sup>15</sup> (1866), L.R. 1 Ex. 265, *aff’d* (1868), L.R. 3 H.L. 330. In *Rylands v. Fletcher*, defendant built a pond on his land which ultimately broke into mining shafts beneath defendant’s



v. Fletcher.<sup>16</sup>

Using these four Common Law causes of action, several potential scenarios for damage claims exist. Reported decisions of various courts of Canada and the United States have addressed several of these scenarios. Reported decisions do not exist for all the potential scenarios but other information makes it possible to sensibly comment about liability in these scenarios in Canada and the United States, even without the existence of reported decisions. To our knowledge, there are no reported decisions (and no filed cases) where the parties to the lawsuit are farmer against farmer.<sup>17</sup> The reported decisions all involve a claim against a developer of transgenic seed.

Scenario One: Claim for damages arising from an unapproved transgenic crop mixing with commercial agricultural crops.

The United States has had one situation – StarLink™ – in which reported decisions have dealt with legal liability arising from an unapproved transgenic crop commingling with commercial agricultural crops. StarLink™ was a transgenic corn approved for animal feed and ethanol production, but not approved for human food.<sup>18</sup> When StarLink™ became commingled with corn for human food, farmers and elevators filed lawsuits against Aventis Cropscience

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land and thereby flooded the plaintiff's mine. The English courts held the defendant liable to plaintiff for damages to the mine caused by this indirect, unintended escape of water.

<sup>16</sup> Compare G. FRIDMAN, *supra* note 8 pp. 217-237 (discussing the doctrine of *Rylands v. Fletcher*) with D. DOBBS *supra* note 8 pp. 950-952 (discussing the rule of *Rylands v. Fletcher*).

<sup>17</sup> B. Endres, Revising Seed Purity Laws to Account for the Adventitious Presence of Genetically Modified Varieties: A First Step Towards Coexistence, 1 J. FOOD L. & POLICY 131, 135 & 138 (2005).

<sup>18</sup> In re StarLink Corn Products Liability Litigation, 211 F. Sup.2d 1060, 1062 (N.D. Ill. 2002).

USA, the developer.<sup>19</sup> The numerous law suits were consolidated into a single class action lawsuit in the United States Federal Court for the Northern District of Illinois.<sup>20</sup>

In the legal proceedings that followed, the trial judge ultimately ruled that plaintiffs who could prove that their crop or stored grain had been physically contaminated<sup>21</sup> by unapproved StarLink™ – making their crops and grain unmarketable as food corn because adulterated by an unapproved substance<sup>22</sup> – had a viable legal claim through negligence, private nuisance, and public nuisance.<sup>23</sup> After these rulings, the parties to the litigation reached a settlement of the legal claims.<sup>24</sup>

Although the Canadian courts have not faced a Scenario One factual situation, the similarity between the successful causes of action in the StarLink™ litigation to Canadian Common Law causes of action make it quite likely that Canadian courts would reach a similar result.

Scenario Two. Claim for damages arising from an approved transgenic crop mixing with

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<sup>19</sup> *Id.* at 1064.

<sup>20</sup> *In re StarLink Corn Products Liability Litigation*, 212 F. Supp.2d. 828, 833 (N.D. Ill. 2002).

<sup>21</sup> *Id.* at 842-843.

<sup>22</sup> *Id.* at 835.

<sup>23</sup> *Id.* at 852. The trial court also recognized a possible claim under a state (Tennessee) consumer protection statute.

<sup>24</sup> *In Re StarLink Corn Products Liability Litigation, Proposed Settlement and Fairness Hearing Document* at p. 3, MDL Docket No. 1403, (N.D. Ill. Feb. 14, 2003) (proposed settlement of \$100 million in principal plus accrued interest); T. Redick, *Stewardship for Biotech Crops: Strategies for Improving Global Consumer Confidence*, 44 *JURIMETICS* 5, 23-26 (2003) (discussing the StarLink™ case and reporting a settlement for \$110 million).

non-transgenic crops resulting in a loss of a premium for a person or company who intended to sell a non-transgenic commodity or food product.

There are no reported Canadian or American cases addressing issues that would be raised by a Scenario Two fact pattern. There are likely several reasons why Scenario Two fact patterns have not come before the Canadian and American courts.

First, Scenario Two is most likely to involve a premium price related to tolerance levels for the legal requirement to label a product as “genetically modified.” Although the European Union’s 0.9% standard for labeling are difficult to meet, these tolerance standards may not require farmers to adopt agronomic practices significantly different than those farmers presently use, at least for maize, cotton, and sugar beet.<sup>25</sup> Moreover, a Scenario Two situation related to labeling requirements does not exist in the domestic markets of Canada and the United States because there are no laws requiring transgenic ingredients or foods to bear a “genetically modified” label.

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<sup>25</sup> G. Brookes & P. Barfoot, Co-existence of GM and non GM arable crops: the non GM and organic context in the EU (May 2004). Brookes and Barfoot write, “The evidence to date shows that non GM crops growing commercially in the EU and in North America have co-existed with conventional and organic crops without economic and commercial problems – only isolated instances have been reported of adventitious presence of GMOs occurring in organic crops, even in North America where GM crops dominate production of soybeans, maize and canola.” *Id.* at 3.

W. Weber & T. Bringezu, Test of coexistence under German field conditions – results from the “Erprobungsanbau” 2004 with Bt-maize, Proc. 2<sup>nd</sup> Int’l Conf. on Co-Existence between GM and non-GM based agricultural supply chains 327, 329 (Montpellier, Nov 2005) (Table 2, by using a 20 meters separation distance between transgenic and non-transgenic fields, the adventitious presence in the non-transgenic field was below the European threshold (0.9%) for labeling at all 27 farm locations). *See also*, European Commission, Joint Research Centre Institute for Prospective Technological Studies, New case studies on the coexistence of GM and non-GM crops in European agriculture (2006) and European Commission Joint Research Centre Institute for Prospective Technological Studies, Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture (2002).

Second, the conventional legal rule is that a person who signs a contract promising to satisfy product quality specifications is the person who bears the costs and the responsibilities to fulfill those voluntarily accepted specifications. The person who seeks a premium by promising product quality specifications must earn that premium.<sup>26</sup>

Leaving aside the premium paid for organic products, the evidence is thin that markets pay a premium price for non-organic, non-transgenic farm products. The demand for non-organic, non-transgenic farm products exists to satisfy international markets but it is not clear that the demand translates into a price premium.<sup>27</sup>

While these three reasons may explain why Canadian and American courts have not faced

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<sup>26</sup> G. Brookes & P. Barfoot, Co-existence in North American agriculture: can GM crops be grown with conventional and organic crops? (June 2004). Brookes and Barfoot write, “Overall, co-existence of GM and non GM, including organic, crops have been occurring in North America. ... In effect there has been recognition that if producers wish to avoid GM events in their production systems the onus for implementing measures to facilitate this falls on the specialty producers (including organic) which are, in turn rewarded via price premia for incurring costs associated with meeting requirements of their customers and certification bodies.” *Id.* at 4.

Report of the Working Group of the Department of Agriculture and Food, Coexistence of GM and non-GM Crops in Ireland, Ch. 8 Economic loss, liability and redress (Sept. 2005), [www.agriculture.gov.ie](http://www.agriculture.gov.ie). The Irish Working Group wrote, “Where non-GM crop growers voluntarily choose to impose additional or stricter requirements on their production systems over and above the legal minimum, in order to gain market or price advantage, then non-GM crop growers are responsible for ensuring those requirements are met and for meeting their associated costs, if any.” *Id.* at 119. *See also*, Endres Revising Seed Purity Laws, *supra* note 17 at 135-137. (agreeing that historically the specialty producer, including organic producers, must bear the cost of meeting voluntarily accepted contract specifications for product standards).

<sup>27</sup> G. Brookes & P. Barfoot, Co-existence ... in the EU, *supra* note 25 at pp. 6-7 shows at the farm gate “very little development of a price differential” between conventional and transgenic crops. *See also*, G Brookes, N. Craddock, B. Kniel, The EU non-GM Market: Labelling requirements, market dynamics and cost implications for the EU feed and food supply chains (Sept. 2005); Rural Industries Research and Development Corporation (Australian Government), Global Responses to GM Food Technology (Feb. 2005) at pp. ix, 45, & 46 states “Where price premiums for non-GM varieties exist they are small ...”

Scenario Two situations, these three reasons also hint at the difficulty that plaintiffs may have in proving the elements of negligence, trespass, nuisance, and strict liability and, particularly, the existence of economic damages. But exactly how Canadian and American courts would resolve legal claims for Scenario Two situations is presently unknown because no reported cases opine on these issues.

Scenario Three. Claim for damages arising from an approved transgenic crop mixing with organic crops resulting in a loss of the organic label for the specific organic crop or of organic certification for the organic farmer's farm.<sup>28</sup>

There are no reported decisions in Canada or the United States addressing issues that would be raised by a Scenario Three fact pattern. However, a straightforward answer explains why – no organic farmer has lost certification for products or farm due to the adventitious presence<sup>29</sup> of transgenic material.

In Canada, Saskatchewan organic farmers filed a class action lawsuit against transgenic seed developers<sup>30</sup> that relate to Scenarios Four and Five to be discussed shortly. In early pleadings, however, the plaintiffs sought to prove the Scenario Three fact pattern. The plaintiffs abandoned the effort because they could present no proof that any organic farmers had lost organic certification.<sup>31</sup> Canadian organic certification bodies have also indicated that organic

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<sup>28</sup> M. Migus, *GMO Statutory Liability Regimes: An International Review* (Canadian Institute for Environmental Law and Policy, 2004) (suggesting Scenarios One, Two, and Three).

<sup>29</sup> Adventitious presence means the inadvertent presence of transgenic seeds or other material in conventional and organic crops. CAST Commentary QTA2005-1 on Adventitious Presence (July 2005).

<sup>30</sup> *Hoffman v. Monsanto Canada, Inc.*, 2005 SKQB 225.

<sup>31</sup> *Id.* at ¶ 218.

farmers will not lose organic certification for adventitious presence of transgenic crops.<sup>32</sup>

The United States Department of Agriculture (USDA) confirmed to National Association of State Departments of Agriculture that no organic farmer had lost organic certification for the adventitious presence of transgenic material.<sup>33</sup> Moreover, the USDA-National Organic Program (NOP) regulations make it clear that organic products and farms would lose certification only if the organic farmer intentionally used transgenic material or failed to take reasonable precautions to avoid transgenic material. Organic farmers who abide by their approved organic production plans by so doing produce organic products regardless of the adventitious presence of transgenic material.<sup>34</sup>

Canada does not have national organic standards by law. The United States does have national organic standards by law and implementing regulations. Yet both the Canadian and American approaches to organic certification are very similar. Organic agriculture is a set of production standards and not product standards. Consequently, an organic farmer who follows an approved production plan produces organic products on an organic farm regardless of adventitious presence of transgenic material. Hence, in Canada and the United States there will be no legal claim for Scenario Three fact patterns because these fact patterns involve adventitious

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<sup>32</sup> K. Briere, Organic Grower will keep certification, *THE WESTERN PRODUCER* (Sept. 8, 2003); The Conseil d'accréditation du Québec, Press Release on launches organic/GMO investigation (8 Sept. 2003) (indicating that the organic certification requires that organic producers must not intentionally use transgenic materials and take precautions to avoid negligent contamination).

<sup>33</sup> USDA-NOP letter to National Association of State Departments of Agriculture (Dec. 21, 2004).

<sup>34</sup> USDA-NOP Final Rules 2002 at pp. 33-35 available at <http://www.ams.usda.gov/nop/NOP/standards/FullText.pdf>.

presence that does not adversely affect organic certification.

Scenario Four. Claim for damages arising from the loss of market access. For example, where a buyer decides against buying a farmer's crop even though there was no evidence of transgenic material or the evidence of transgenic material was below legally-set thresholds.

Scenario Five. Claim for damages arising from a decision by a farmer to forgo planting a particular crop because of concern about proximity to transgenic crops or market perception about transgenic crops.<sup>35</sup>

Scenarios Four and Five are grouped together because they share the following common characteristics: lack of physical damage to the plaintiff's property; the claims relate to disappointed commercial expectations; and the plaintiff and defendant are relational strangers who, therefore, have not allocated risks between themselves in a contractual relationship. In factual situations sharing these characteristics, tort law has often denied recovery because the potential plaintiffs are an unnumbered, unbounded group whose damage claims would be speculative and limitless because dependent on third party (customer, market) behaviors. The rubric applied to these situations in Canadian and American law is the "pure economic loss" doctrine.<sup>36</sup>

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<sup>35</sup> UK AGRICULTURE AND ENVIRONMENT BIOTECHNOLOGY COMMISSION REPORT: GM CROPS? COEXISTENCE AND LIABILITY (Nov. 2003) at p. 4 suggesting Scenarios Four and Five. [hereafter UK REPORT: GM Crops?].

<sup>36</sup> The discussion of pure economic loss in the text is a summary of the discussion of pure economic loss in a transgenic crop context from *In re StarLink Corn Products Liability Litigation*, 212 F. Supp.2d 828, 838-843 (N.D. Ill. 2002). (The *StarLink*<sup>TM</sup> trial judge ruled that the pure economic loss doctrine did not apply because the plaintiffs had alleged adequate proof of physical damage to plaintiff's crops.) For discussion of pure economic loss in Canadian torts, G. Fridman, *supra* note 8 at pp. 373-383. In Professor Fridman's discussion of pure economic loss for Canadian torts, he also discusses the same doctrine in the jurisprudence of Australia, New Zealand, and the United Kingdom.

For a thorough discussion of pure economic loss in multiple jurisdictions, E. BANAKAS (ed.), *CIVIL LIABILITY FOR PURE ECONOMIC LOSS* (Kluwer Law Int'l, 1996). The Banakas book has chapters, among others, on pure economic loss in three of the four jurisdictions comparatively discussed in this article: Canada (Ch. 6), the United States of America (Ch. 5),

There are three reported cases in Canadian and American jurisprudence that present Scenario Four and Scenario Five fact patterns.

In Canada, Saskatchewan organic farmers brought a class action on behalf of all organic grain farmers in the province against Bayer Cropscience, Inc. and Monsanto Canada, Inc. for damages arising from the commercialization of transgenic canola.<sup>37</sup> Although the plaintiffs at first focused on loss of organic certification (Scenario Three),<sup>38</sup> the plaintiffs refocused their claims to concentrate on loss of the European market<sup>39</sup> for organic canola (Scenario Four) and the loss to organic farmers of the practical option to choose to grow organic canola (Scenario Five).<sup>40</sup> In addition while refocusing the lawsuit, the plaintiffs added a claim for damages for removal of volunteer transgenic canola growing on their lands.<sup>41</sup>

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and Germany (Ch. 3). The Banakas book does not have a chapter on pure economic loss in Danish law. Although the Banakas book was published ten years ago, other information and research gives the authors of this article substantial confidence that the discussions on pure economic loss in the Banakas book continue to be accurate about the current state of the law in Canada, the United States and Germany.

<sup>37</sup> Hoffman v. Monsanto Canada, Inc., 2005 SKQB 225 at ¶ 1.

<sup>38</sup> Read the text accompanying notes 28-32 *supra*.

<sup>39</sup> Hoffman at ¶ 218.

<sup>40</sup> Hoffman at ¶ 219.

<sup>41</sup> Hoffman at ¶ 220. Louise Schmeiser also filed a claim for costs of removing volunteer transgenic canola from her organic garden against Monsanto Canada, Inc. Mrs. Schmeiser sought \$C 140 in damages. Pat Peckover, Supreme Court Duo Battle in Small Claims Court, HUMBOLDT JOURNAL (March 31, 2005). After trial proceedings, the Provincial Court of Saskatchewan ruled that Mrs. Schmeiser had failed to prove her claims and dismissed the case. Louise Schmeiser and Monsanto Canada Inc., Provincial Court of Saskatchewan (Humboldt) # 18/04, ¶ 51 (15 June 2005) (copy of opinion in possession of authors).



In a lengthy opinion,<sup>42</sup> Judge G.A. Smith discussed and ruled upon each of plaintiff's plead causes of action: negligence,<sup>43</sup> the rule in *Rylands v. Fletcher*,<sup>44</sup> nuisance,<sup>45</sup> trespass,<sup>46</sup> and three environmental claims based on Saskatchewan statutes.<sup>47</sup>

With respect to the negligence claim, Judge Smith denied the claim giving three reasons. First, the plaintiffs did not plead facts showing that it was foreseeable that markets would reject organic products or that farmers would decline to grow organic grains due to adventitious presence of transgenic material.<sup>48</sup> Second and more serious, the plaintiffs had not alleged adequate relational proximity – i.e. expectations/reliance/communicated representations, or any physical damage to property, or a special relationship between the parties.<sup>49</sup> Third, even if the first two reasons could be overcome, policy reasons related to pure economic loss would bar recovery under a negligence claim.<sup>50</sup> As Judge Smith wrote,

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<sup>42</sup> The *Hoffman* opinion consists of 340 paragraphs and is 100+ pages in print. The authors provide only a brief discussion, focused on particular paragraphs, of this complex, detailed opinion.

<sup>43</sup> Hoffman at ¶¶ 37-88.

<sup>44</sup> Hoffman at ¶¶ 89-97.

<sup>45</sup> Hoffman at ¶¶ 98-124.

<sup>46</sup> Hoffman at ¶¶ 125-133.

<sup>47</sup> Hoffman at ¶¶ 134-193. The authors discuss these environmental claims later in this article under the heading of **Legal Liability: Canada and the United States of America Administrative Liability**.

<sup>48</sup> Hoffman at ¶¶ 64-66.

<sup>49</sup> Hoffman at ¶¶ 67-70.

<sup>50</sup> Hoffman at ¶¶ 71-80.

“It is my conclusion that the case before me does not present a situation in which the courts would extend the categories for recovery of pure economic loss, for all the policy reasons traditionally cited in support of the exclusion of this recovery (liability in an indeterminate amount for an indeterminate time to an indeterminate class) are in play in the case.”<sup>51</sup>

With respect to the rule of *Rylands v. Fletcher*, Judge Smith opined that the companies would be liable only if an escape of a substance came from property owned or controlled by the companies. The judge ruled that a commercial release of the approved transgenic crop is not reasonably arguable as such an escape.<sup>52</sup>

With respect to nuisance, Judge Smith ruled that there were no allegations that transgenic canola was harmful per se or made organic canola unfit for consumption or that the transgenic seed developers has failed to conform to requirements for commercial release. Hence, the judge concluded that there was no evidentiary support for a finding that “defendants substantially caused the nuisance (interference with certified organic grain farmers’ use and enjoyment of their land) alleged.”<sup>53</sup>

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<sup>51</sup> Hoffman at ¶ 80 with parenthetical insert from ¶ 73.

As for the general Canadian law on pure economic loss, Bruce Feldthusen, Dean of the University of Ottawa Faculty of Law, wrote in concluding remarks to his Canadian chapter in the Banakas book as follows: “In summary, the Canadian position on relational loss is totally uncertain, both because of the unusual split among the judges, and because of the inherent uncertainty in the judgment of McLachlan J. [in *CNR v. Norsk Pacific Steamship Co.*]. I would predict that the majority of relational loss claims will continue to fail, but that considerable time will be wasted litigating supposedly special cases of proximity.” B. Feldthusen, *The Recovery of Pure Economic Loss in Canada: Proximity, Justice, Rationality and Chaos*, Ch. 6 at 147 in E. BANAKAS *supra* note 36. *See also*, Joost Blom, *Tort, Contract and the Allocation of Risk*, 17 S.C.L.R.2d 189 (2002) (“Pure economic loss, while certainly an area of growth in the last four decades, remains the exception.” *Id.* at 290.)

<sup>52</sup> Hoffman at ¶ 97.

<sup>53</sup> Hoffman at ¶¶ 121-122 with parenthetical insert from ¶ 98.

With respect to trespass, plaintiffs alleged that the commercial release of transgenic canola set in motion the events leading to transgenic canola pollen or transgenic canola volunteers eventually reaching plaintiffs' organic farmlands.<sup>54</sup> Judge Smith ruled that this chain of events did not constitute the direct, with emphasis on the word "direct," physical entry required by the trespass cause of action.<sup>55</sup>

In the United States growers of conventional soybeans (plaintiffs) and corn filed a class action lawsuit against transgenic seed developers (Monsanto Company, Pioneer Hi-Bred International, Inc., and Syngenta, Inc.) pleading public nuisance and negligence and alleging damages to conventional markets because of the commercial release of transgenic crops.<sup>56</sup> Plaintiffs abandoned claims of direct physical injury to their crops and instead alleged only loss of markets due to concerns about commingling (actual or perceived) between conventional and transgenic soybeans and corn in marketing channels.<sup>57</sup>

In the opinion granting a summary dismissal of plaintiff's tort claims, Judge Sippel applied the pure economic loss doctrine to both the public nuisance and negligence causes of action.<sup>58</sup> Judge Sippel distinguished the *Sample* tort claims from the *StarLink*<sup>TM</sup> tort claims

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<sup>54</sup> Hoffman at ¶ 128.

<sup>55</sup> Hoffman at ¶ 133.

<sup>56</sup> *Sample v. Monsanto Co.*, 283 F. Supp.2d 1088, 1090 (E.D. Mo. 2003).

<sup>57</sup> *Sample* at 1091-1093.

<sup>58</sup> *Sample* at 1093-1094. Applying the pure economic loss doctrine to negligence is consonant with Canadian jurisprudence. Applying the pure economic loss doctrine to nuisance, including public nuisance, is a broader use of the doctrine in American jurisprudence than may be so from the case precedents of Canadian jurisprudence.

precisely because the *Sample* plaintiffs did not claim direct physical injury to their personal crops.<sup>59</sup> Judge Sippel followed the *StarLink*<sup>TM</sup> opinion’s discussion of the pure economic loss doctrine<sup>60</sup> to emphasize that the doctrine would bar claims solely for loss of market access.<sup>61</sup>

The *Sample* decision barring recovery for Scenarios Four and Five has received indirect support in a subsequent *StarLink*<sup>TM</sup> litigation opinion. In *Agra Marke, Inv. v. Aventis Cropscience USA LP*,<sup>62</sup> Agra Marke claimed damages for loss of a premium for conventional corn and asserted that its damages were covered by the *StarLink*<sup>TM</sup> settlement.<sup>63</sup>

In deciding *Agra Marke*, Judge Moran determined that Agra Marke’s claim related to conventional corn that became commingled with *StarLink*<sup>TM</sup> corn only after the conventional corn was sold and entered the stream of commerce for the international market.<sup>64</sup> Judge Moran ruled that the *StarLink*<sup>TM</sup> settlement applied to those whose crops had suffered direct physical injury

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<sup>59</sup> *Sample* at 1093.

<sup>60</sup> For the *StarLink* opinion’s discussion of pure economic loss, read *supra* note 36.

<sup>61</sup> *Sample* at 1093-1094.

As for the general American law on pure economic loss, Professor Gary Schwartz began his chapter in the Banakas book by stating, “The first section of this chapter describes the leading issues in American tort law since 1960 that bear on tort recoveries for economic loss. It shows that the traditional rule denying recovery for the negligent infliction of economic loss – though it has been subject to a variety of challenges – has held up reasonably well.” G. Schwartz, *The Economic Loss Doctrine in American Tort Law: Assessing the Recent Experience*, Ch. 5 at 103 in E. BANAKAS *supra* note 36.

<sup>62</sup> 2005 WL 327020 (N.D. Ill. 2005) (not reported in the official reporter of federal decisions).

<sup>63</sup> *Id.* at \*2.

<sup>64</sup> *Id.* at \*4.

while owned by the claimant<sup>65</sup> and, therefore, ruled that Agra Marke had no claim under the *StarLink*<sup>TM</sup> settlement.<sup>66</sup> Implied in Judge Moran’s ruling is that the pure economic loss doctrine bars recovery for claims related to loss of access to international markets. Judge Moran had foreshadowed (but not predetermined) the *Agra Marke* ruling in his *StarLink* opinion when he decided that no legally viable claim would exist for those who claimed harm to property “because the corn was commingled after they had relinquished their ownership interest in it.”<sup>67</sup>

Taking into account the *Hoffman* case<sup>68</sup> in Canada and the *Sample* and *Agra Marke* cases in the United States, Scenarios Four and Five are unlikely to be legally viable claims using Common Law causes of action in Canadian and American courts.

#### Administrative Liability

Whereas civil liability is liability flowing from litigation between private parties asserting private claims, administrative liability is liability flowing from legislatively enacted regulatory statutes. In the enacted regulatory statutes, the legislature delegates administrative duties, including enforcement, to specified administrative agencies. Within a particular regulatory statute, the legislature may allow private citizens to initiate legal actions to enforce the regulatory statute against private persons alleged to be violating the statute. However, administrative

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<sup>65</sup> *Id.* at \*3.

<sup>66</sup> *Id.* at \*4.

<sup>67</sup> *In re StarLink Corn Products Liability Litigation*, 212 F. Supp.2d 828, 842 (N.D. Ill. 2002).

<sup>68</sup> On August 30, 2005, the Hoffman plaintiffs (organic farmers) were granted the right to appeal to the Saskatchewan Court of Appeal. *Hoffman v. Monsanto Canada Inc.*, 2005 SKCA 105.

liability is primarily a public liability – i.e. liability for harms to the public caused by violation of the regulatory statute that are enforced by a governmental agency. The public harms that are most often mentioned in the debate about agricultural biotechnology are claimed impacts on the environment and on biodiversity.<sup>69</sup>

Administrative regulation of agricultural biotechnology at the federal level in Canada can best be expressed by quoting from an official document::

The Government of Canada considers that the use of existing Acts ... has value and a number of advantages over redrafting legislation to address technological advances such as new techniques of biotechnology. ... Accordingly, it has instituted regulatory assessment processes based on sound science and the generally accepted premise that it is the product itself, rather than the technology or process, that should trigger the need for regulation.<sup>70</sup>

When focusing on products, Canada regulates all plants and food products that are deemed to have novel traits. In other words, novel traits in plants or foods triggers regulatory review by whatever process the plant or the food acquired the novel trait. Plants with novel traits can be produced by genetic engineering, mutagenesis or can be plants not previously grown in Canada.<sup>71</sup>

The regulation of products of biotechnology in Canada most predominately falls into the

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<sup>69</sup> M. Migus, *supra* note 28.

<sup>70</sup> Canadian Food Inspection Agency (CFIA), Response of the Federal Departments and Agencies to the Petition Filed May 9, 2000 by the Sierra Legal Defence Fund under the *Auditor General Act*: Review of Federal Laws, Regulations and Policies on Genetically Modified Organisms, ¶ 61 (2000) available at [www.inspection.gc.ca/english/sci/biotech/enviro/sierrae.shtml](http://www.inspection.gc.ca/english/sci/biotech/enviro/sierrae.shtml) [hereafter Response to Petition].

<sup>71</sup> *Id.* at ¶¶ 15, 18.

domain of two different agencies of government.<sup>72</sup> The Canadian Food Inspection Agency (CFIA), using the *Seeds Act*, *Feeds Act*, *Fertilizers Act*, *Plant Protection Act*, and the *Health of Animals Act*, regulates for environmental assessment (including biodiversity) and for livestock feed safety assessment for all plants with novel traits (PNTs).<sup>73</sup> Health Canada is responsible for human health and safety in relation to food biotechnology and does this through the *Food and Drugs Act* and *Pest Control Products Act*.<sup>74</sup> This includes all novel foods produced through genetic engineering and that are intended for human consumption.

The federal Canadian regulatory system and the federal American regulatory system have three significant traits in common. Both focus on product, not process, though the Canadian system regulates more broadly than the American because the Canadian system regulates all novel plants and foods. Both use existing regulatory statutes and agencies rather than creating a specialized statutory and administrative regime for agricultural biotechnology. Both use sound science (scientific rationality) as an underpinning policy orientation towards the regulation of

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<sup>72</sup> Two other federal agencies of the Government of Canada – the Department of Fisheries and Oceans, and Environment Canada – also have regulatory obligations related to biotechnology. However, these two agencies have not yet had to become active in their regulatory obligations. *Id.* at Table 1 and ¶¶ 35-39. Three other federal agencies of the Government of Canada – Agriculture and Agri-Food Canada, Natural Resources Canada, and Industry Canada – have no regulatory authority regarding biotechnology but these three agencies do provide expertise and advice to those agencies with direct regulatory obligations. *Id.* at Table 1 and ¶¶ 40-44.

<sup>73</sup> *Id.* at ¶¶ 86 & 89. *See also*, CFIA, Regulating Agricultural Biotechnology in Canada: An Overview, available at [www.inspection.gc.ca/english/sci/biotech/reg/bioage.shtml](http://www.inspection.gc.ca/english/sci/biotech/reg/bioage.shtml); CFIA, Regulating Agricultural Biotechnology in Canada: Environmental Questions, available at [www.inspection.gc.ca/english/sci/biotech/enviro/envrege.shtml](http://www.inspection.gc.ca/english/sci/biotech/enviro/envrege.shtml).

<sup>74</sup> Response to Petition *supra* note 70 at ¶¶ 29-31.

agricultural biotechnology.<sup>75</sup>

In addition to the federal Canadian regulatory system, the Province of Saskatchewan has enacted three environmental statutes that have been applied to transgenic crops in the reported decision (previously discussed) of *Hoffman v. Monsanto Canada Inc.*<sup>76</sup>

With regard to the Environmental Management and Protection Act of 1983-84,<sup>77</sup> the statute allows any person “a right of compensation from (a) the owner of the pollutant or the person having control of the pollutant for loss or damage incurred as a result of: (i) the discharge of a pollutant; ... without proof of fault, negligence or wilful intent.”<sup>78</sup> In applying this statutory language to transgenic canola, Judge Smith considered the definitions of the words “discharge,” “environment,” “owner of a pollutant,” “person having control of a pollutant,” “pollutant,” and “pollution.”<sup>79</sup> After discussing the pleadings and the definitions, Judge Smith concluded:

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<sup>75</sup> S. MacLauglin (Note), *Food for the Twenty-First Century: An Analysis of Regulations for Genetically Engineered Food in the United States, Canada, and the European Union*, 14 INDIANA INT’L & COMP. L. REV. 375 (2003); G. Isaac & J. Hobbs, *GM Food Regulations: Canadian Debates*, 3 ISUMA 105 (Autumn 2002) available at [www.isuma.net/vo3no2/isaac/isaac\\_e.pdf](http://www.isuma.net/vo3no2/isaac/isaac_e.pdf).

<sup>76</sup> *Hoffman* at ¶¶ 134-193. For previous discussion of the *Hoffman* case in this article, read text related to Scenarios Four and Five under the Civil Liability heading of **Legal Liability: Canada and the United States of America**.

Canada also has a federal Canadian Environmental Protection Act (CEPA) that has several liability provisions. However, the liability sections of the CEPA appear to relate to toxic substances, international air pollution, and international water pollution. It is unlikely that transgenic crops, particularly if approved for commercial release in Canada, would be listed as substances within the liability provisions of the CEPA. S.C. 1999 c. 33 §§ 1-355.1.

<sup>77</sup> SASK. ST. 1983-84, c. E-10.2 (hereafter EMPA 83/84).

<sup>78</sup> EMPA 83/84 § 13(3) quoted in *Hoffman* at ¶ 137.

<sup>79</sup> *Hoffman* at ¶¶ 137-158.



“It is my conclusion that, even if the plaintiffs were permitted to amend the statement of claim once again to assert facts sufficient to provide some support to the allegation that GM canola is inherently harmful or unsafe and is a “pollutant” within the meaning of the Act, the facts alleged in the statement of claim still would not be sufficient in law to sustain a claim under s. 13 of the EMPA, for they do not reasonably support the conclusion that the defendants owned or controlled the “pollutants” at the time they were discharged into the environment. At best, the action would lie against farmers who cultivate GM canola.”<sup>80</sup>

Beginning in 2002, Saskatchewan adopted a new Environmental Management and Protection Act (EMPA 2002).<sup>81</sup> Under EMPA 2002, the word “substance” replaced the word “pollutant” and other relevant definitions (the responsible persons, loss and damages, environment) were substantially broadened.<sup>82</sup> With these changes, Judge Smith ruled that plaintiffs had pled sufficient facts to state a claim under EMPA 2002.<sup>83</sup> However, plaintiffs’ success has significance primarily for future commercial releases of transgenic crops because Judge Smith also ruled, as conceded by plaintiffs, that EMPA has no retroactive effect.<sup>84</sup> Without retroactive effect, plaintiffs did not have any claim for loss of markets because the loss of markets, if any, occurred prior to 2002.<sup>85</sup> Consequently, the plaintiffs can recover, if

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<sup>80</sup> Hoffman at ¶ 158.

<sup>81</sup> SASK. ST. 2002, c. E-10.21 (hereafter EMPA 2002).

<sup>82</sup> Hoffman at ¶¶ 162-163. In light of these broadened definitions, Judge Smith stated that “the scope for potential liability imposed, on a literal reading of this section, is staggering” and could include even kindly, gentle, favorable, and beneficial environmental effects. *Id.* at ¶ 163.

<sup>83</sup> Hoffman at ¶ 168.

<sup>84</sup> Hoffman at ¶ 169.

<sup>85</sup> *Id.*

ultimately successful legally and factually at trial proceedings, only for “alleged clean-up costs related to the presence of volunteer GM canola found on the land of organic farmers after the Act came into effect.”<sup>86</sup>

In the *Hoffman* case, the plaintiffs also plead causes of action under the Environmental Assessment Act<sup>87</sup> (EAA) that allows a civil liability remedy to a private person “who suffers loss, damage, or injury as a result of the development [that has not received provincial ministerial approval] and that ... person is not required to prove negligence or intention to inflict loss, damage or injury.”<sup>88</sup> Judge Smith ruled that the plaintiffs could try to prove that the commercial release of transgenic canola was a “development” that “caused widespread public concern because of potential environmental changes” or that through cross-pollination was a “significant impact” on plant life in the environment.<sup>89</sup> Judge Smith ruled that the plaintiffs had pled sufficient facts to establish a cause of action under the EAA, but whether the cause of action will result in provable monetary damages payable by the defendants is subject to subsequent, further trial proceedings.<sup>90</sup>

In the United States, three federal agencies share the administrative duties related to

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<sup>86</sup> *Id.*

<sup>87</sup> SASK. ST. 1979-80, c. E-10.1, as amended 1983, c. 77; 1988-89, c. 42; and 1996, c.F-19.1.

<sup>88</sup> *Hoffman* at ¶ 171.

<sup>89</sup> *Hoffman* at ¶ 191.

<sup>90</sup> *Hoffman* at ¶ 192. In a later part of the *Hoffman* opinion, Judge Smith ruled that plaintiffs could not pursue their two allowed environmental claims through a class action lawsuit. Each plaintiff would have to file an individual lawsuit to pursue claims for damages unique to each plaintiff. *Id.* at ¶¶ 191-192.

agricultural biotechnology.<sup>91</sup> The United States Department of Agriculture regulates transgenic crops for their agronomic properties related to whether or not a particular transgenic crop poses a plant pest or noxious weed risk that could harm other crops, the environment, or public health.<sup>92</sup> The Food and Drug Administration regulates transgenic crops as food or feed for the purpose of determining the safety of these crops when consumed by humans or animals.<sup>93</sup> The Environmental Protection Agency regulates transgenic crops that possess pesticidal qualities<sup>94</sup> to assure that the transgenic crop will grow “without unreasonable adverse effects on the environment.”<sup>95</sup>

In the United States, the federal legislature has not enacted any special regulatory statute specifically targeted towards biotechnology, including agricultural biotechnology. Moreover, in the United States, the federal legislature has not enacted any administrative liabilities uniquely applicable to agricultural biotechnology for potential damages to the environment or to

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<sup>91</sup> For an overview of the regulatory system for agricultural biotechnology through USDA-Biotechnology Regulatory Services (BRS), read the fact sheets at [www.aphis.usda.gov/publications/biotechnology](http://www.aphis.usda.gov/publications/biotechnology). Two fact sheets – “Biotechnology, Federal Regulation, and the U.S. Department of Agriculture” and “National Environmental Policy Act and Its Role in USDA’s Regulation of Biotechnology” – specifically discuss the BRS consideration of environmental impacts, including issues related to threatened and endangered species, by the preparation of either an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) as part of the regulatory process.

For an overview of the entire regulatory system for agricultural biotechnology in the United States, D. Uchtmann, *StarLink*<sup>™</sup> – A Case Study of Agricultural Biotechnology Regulation 7 DRAKE J. AGRIC. L. 159, 160-174 (2002).

<sup>92</sup> Plant Protection Act, 7 U.S.C. §§ 7701-7772 (2005).

<sup>93</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-394 (2005).

<sup>94</sup> Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (2005).

<sup>95</sup> *Id.* at § 136a(c)(5).

biodiversity. While there have been administrative actions related to agricultural biotechnology in the United States – the StarLink™ matter being the most prominent<sup>96</sup> – obviously no reported decisions exist in the United States about agricultural biotechnology and administrative liability for allegations of environmental or biodiversity harms because no statutory provisions authorize claims related to environmental or biodiversity once transgenic crops receive regulatory approval for commercialization.<sup>97</sup>

### Criminal Liability

Criminal liability means that the sovereign, through a public prosecutor, brings charges against a person (the criminal defendant) that the criminal defendant has violated public penal law(s). If convicted of the charges, Canadian and American criminal defendants ordinarily suffer punishment through fines and imprisonment. To our knowledge, there are no Canadian or American criminal statutes, independent of administrative statutes already described,<sup>98</sup> that are

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<sup>96</sup> D. Uchtman, *supra* note 91 provides a detailed history.

<sup>97</sup> In the United States, there have been lawsuits seeking to reverse administrative decisions authorizing the commercial release of transgenic crops. But these lawsuits are against the administrative agencies challenging the decision to allow commercial release. *E.g.* Geertson Farms Inc. v. Johanns, Case No. \_\_\_\_\_ (N.D. Calif. 2006) (lawsuit seeking to overturn the USDA decision deregulating transgenic alfalfa). These lawsuits are not against the developers or users of the transgenic crop. After administrative approval, there are no administrative liability provisions that apply against the users of the approved transgenic crops on environmental or biodiversity grounds.

<sup>98</sup> Regulatory statutes ordinarily contain provisions authorizing the competent administrative agency to impose sanctions upon regulated parties when those regulated parties fail to abide by regulatory obligations. However, these administrative sanctions are for administrative non-compliance and are not sanctions about the regulated parties' conduct *per se*. For example, administrative agencies can seek sanctions for discharge of a pollutant without a regulatory permit. The sanction is for the non-compliance with the regulatory obligation to obtain a permit; the sanction is not for the discharge *per se* because the discharge itself may be legally and socially proper if the regulated party had obtained the appropriate permit. By

uniquely applicable to those who create, sell, or use transgenic crops. Moreover, to our knowledge, the federal and provincial governments of Canada and the federal and state governments of the United States have shown no significant inclination to utilize criminal liability as a form of legal liability with respect to agricultural biotechnology.<sup>99</sup> Persons (individual or corporate) who are engaged in agricultural biotechnology have no greater or lesser risk of criminal liability for their agricultural activities than corporate or individual persons engaged in conventional and organic agriculture are at risk of criminal liability for their agricultural activities.

### **Legal Liability: Denmark**

Beginning in 2002, the Danish Ministry of Food, Agriculture and Fisheries (DFAF) established a working group to address issues of coexistence between conventional, organic, and

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contrast, criminal liability is a sanction against the conduct *per se*. This distinction between administrative sanctions and criminal liability is nicely made in the Report of the Working Group for the Government of Ireland *supra* note 26 at 123.

<sup>99</sup> One American and one British commentator have proposed enhanced use of criminal liability against those engaged in transgenic agriculture. M. DeGreer (Comment), *Can Round-Ready™ Seeds Ever Be Corralled?: Restraining Genetic Drift Through Criminal Sanctions*, 29 N.E. J. CRIM. & CIV. CONFINEMENT 255 (2003); Reece Walters, *Crime, Bio-Agriculture and the Exploitation of Hunger*, 46 BRIT. J. CRIMINOL. 26 (2006); Reece Walters, *Criminology and Genetically Modified Food*, 44 BRIT. J. CRIMINOL. 151 (2004). For a general discussion, N. Kubasek, M. Browne, & C Williamson, *The Role of Criminal Enforcement in Attaining Environmental Compliance in the United States and Abroad*, 7 U. BALT. J. ENVT'L L. 122 (2000); K. Gaynor & T. Bartman, *Criminal Enforcement of Environmental Laws*, 10 COLO. J. INT'L ENVT'L L. & POL'Y 39 (1999). *See also*, Mark Halsey, *Against "Green" Criminology*, 44 BRIT. J. CRIMINOL. 833 (2004).

transgenic agriculture.<sup>100</sup> As a consequence, Denmark published a major report<sup>101</sup> and held a major conference,<sup>102</sup> focusing on coexistence in Danish agriculture.<sup>103</sup> Using the information gathered from the DIAS Report and the 1<sup>st</sup> European Conference, the Danish government presented legislation to the Danish Parliament relating to coexistence and liability arising from the introduction of transgenic crops into Danish agriculture.<sup>104</sup>

### Civil Liability

On 9 June, 2004, Queen Margrethe II of Denmark gave Royal Assent to Act No. 436 of the Danish Parliament entitled *Act on the Growing etc. of Genetically Modified Crops*.<sup>105</sup> With this Royal Assent, Denmark became the first European country to enact legislation regulating the coexistence of conventional, organic, and transgenic agriculture.<sup>106</sup> The Act applies to the

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<sup>100</sup> Ministry of Food, Agriculture and Fisheries, Strategy for co-existence – genetically modified, conventional and organic crops (June 2003), [www.agrsci.dk/gmcc-03/background.htm](http://www.agrsci.dk/gmcc-03/background.htm).

<sup>101</sup> Danish Institute of Agricultural Sciences, Report from the Danish Working Group on the Co-existence of Genetically Modified Crops with Conventional and Organic Crops (Nov. 2003) [commonly known as the DIAS Report].

<sup>102</sup> B. Boelt (ed.), GMCC-03: GM Crops and Co-existence, Proc. 1<sup>st</sup> Euro. Conf. on the Co-existence of Genetically Modified Crops with Conventional and Organic Crops (Snekkersten, Denmark, Nov. 2003).

<sup>103</sup> For another report on coexistence in Denmark, read J. Toft, National Report – Denmark: Precautionary Expertise for GM Crops; Co-existence Bypassing Risk Issues, Project No. QLRT-2001-00034 Roskilde University (June 2004) (extensively detailed, descriptive history of the Danish reaction socially and politically to transgenic crops, with particular emphasis on the years 1998 to 2004).

<sup>104</sup> Ministry FAF, Strategy for co-existence, *supra* note 100.

<sup>105</sup> Government of Denmark, 2004: *Act on the Growing etc. of Genetically Modified Crops*, Ministry of Food, Agriculture and Fisheries File No. 2004-64. [Lov om dyrkning m.v. af genetisk modificerede afgrøder].

<sup>106</sup> Anon, Danish law on GMOs, AGRA INFORMA (June 21, 2004).

commercial growing, handling, sale and transport of genetically modified crops and has five divisions: Scope and Definitions;<sup>107</sup> Growing, Handling, Sale, Transport, etc.;<sup>108</sup> Compensation Scheme and Obligation to Contribute;<sup>109</sup> Administration of the Act;<sup>110</sup> and Provisions regarding Penalty and Coming into Force.<sup>111</sup>

In the regulatory sections of the Act,<sup>112</sup> the Minister of Food, Agriculture and Fisheries is given significant discretion to promulgate administrative rules fleshing out the statutory provisions relating to the growing, handling, sale, transportation of transgenic crops, and to the administration of the Act. To ensure that any GM crop production is tightly regulated by the State, the Minister may require that any Danish producer wishing to grow a GM crop must obtain a license prior to doing so.<sup>113</sup> The specifications of the licenses may entail that the intending producer, at the producer's own cost, has to participate in and pass an education course on co-existence between GM crops, conventional crops and organic crops.<sup>114</sup> The intent of this licensing scheme is to ensure that the Ministry has a known record of all transgenic producers

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<sup>107</sup> Act on the Growing etc., *supra* note 105 at §§ 1-2.

<sup>108</sup> *Id.* at §§ 3-8.

<sup>109</sup> *Id.* at §§ 9-12.

<sup>110</sup> *Id.* at §§ 13-18;

<sup>111</sup> *Id.* at §§ 19-22.

<sup>112</sup> *Id.* at §§ 3-8 and 13-18. The Minister of FAF implemented the regulatory provisions of the Act on 10 Nov 2004 with the issuance of an Executive Order on the Growing etc. of Genetically Modified Crops.

<sup>113</sup> Act on the Growing etc., *supra* note 105 at § 3(1).

<sup>114</sup> *Id.* at § 3(2),(3),(4).

within Denmark. The Danish regulatory system does not allow the unlicensed production of GM crops.

In addition to a production license, the Minister may require any Danish producer intending to grow a GM crop to notify the owners and users of neighbouring fields of this intent.<sup>115</sup> The transgenic producer also may be required to notify owners of the vehicles, machines, equipment, and storage the transgenic producer has or will use in growing, transporting, and storing the crop.<sup>116</sup>

As part of this notification, the Minister may require the transgenic producer to report all fields that will contain transgenic crops so that information about the fields may be made publically accessible.<sup>117</sup> The Act states,

Anybody shall have access to obtain information from the information system which either has been published or which is to be published. This access shall comprise individual pieces of information as well as mass information."<sup>118</sup>

The Minister may make all transgenic producer and crop location information available publicly via the Internet.<sup>119</sup> These provisions allow any member of the public to access the information system and determine where the transgenic crop is growing.

Turning specifically to civil legal liability, the Act provides compensation and a funding

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<sup>115</sup> *Id.* at § 6(1)(ii)(a).

<sup>116</sup> *Id.* at § 6(1)(ii)(b)&(c).

<sup>117</sup> *Id.* at §§ 6(1)(iii) & 7(4).

<sup>118</sup> *Id.* at § 7(4).

<sup>119</sup> *Id.* at § 7(2).



mechanism in sections 9 through 12. Without clearly stating the legal standard, the Act apparently adopts a fault liability regime whereby transgenic growers will bear the statutorily stated damages to conventional and organic producers only if they fail to comply with regulations governing the growing of transgenic crops.

The transgenic growers bear the liability by first paying a per hectare fee into a compensation fund. Second, a transgenic grower bears liability individually to reimburse the compensation fund if the grower failed to comply with regulations governing the growing of transgenic crops. The Danish liability system works as follows.

The Minister

shall pay compensation to any farmer who suffers a loss due to the occurrence of genetically modified material in his crops if:

- (i) in the same growing season within a specified area, a genetically modified crop of the same or a related variety has been grown which may be crossbred into the crop of the farmer suffering the loss and
- (ii) the genetically modified crop can be identified in the crop of the farmer suffering the loss.<sup>120</sup>

In addition to the compensation for pollen flow just quoted, the Minister also shall pay compensation “if an authorized organic farmer suffers a loss due to the occurrence of genetically modified seed in his seed for sowing.”<sup>121</sup>

In defining the compensation to which the farmer suffering the loss is entitled, the Act states that the amount to be paid for either pollen flow or organic seed

shall not exceed:

- (i) the reduction in the sales price of the crop caused by the

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<sup>120</sup> *Id.* at § 9(1).

<sup>121</sup> *Id.* at § 9(4).

occurrence of genetically modified material,  
(ii) the costs for sampling and analysis and  
(iii) any losses as a consequence of requirements for  
conversion of organic areas or animals due to the occurrence of  
genetically modified material.<sup>122</sup>

While the just-quoted section 9 subsections (1), (4), and (3) appear to create a very broad legal liability risk for the transgenic grower, the Act has several limitations which are likely to reduce greatly that legal liability risk. These several limitations are worthy of explicit discussion.

As probably the most important compensation limitation, the Act states,

Compensation cannot be paid for any loss suffered by such farmer as a consequence of the occurrence of genetically modified material in the crops of the farmer suffering the loss if the occurrence of genetically modified material does not exceed a specific threshold value fixed by the Minister.<sup>123</sup>

In the proposed Draft Executive Order to implement the Act with regulations, the Minister has set the specific threshold value as identical to that mandated by EU regulations for labelling of crops or seed as genetically modified.<sup>124</sup> The Danish Plant Directorate is tasked with sampling and testing to determine if the presences of transgenic material in the crop or seed of a neighbouring farmer is above the labelling threshold.<sup>125</sup> If the neighboring farmer's crop or seed

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<sup>122</sup> *Id.* at § 9(3).

<sup>123</sup> *Id.* at § 9(6).

<sup>124</sup> Draft Executive Order on Compensation for Losses due to Certain Occurrences of Genetically Modified Material at § 2(1) (10 Nov. 2004). [hereafter Draft Executive Order on Compensation].

The Minister likely set the threshold levels for compensation at the EU legal thresholds in order to gain approval of the Danish compensation scheme by the EU. European Commission, Secretariat General, State Aides – Denmark – Compensation for losses due to the presence of certain GMO material, No. 568/2004 (23 Nov 2005) (approval of the Danish Act).

<sup>125</sup> Draft Executive Order on Compensation at §§ 2(2), 7 & 8.

is below the threshold, the neighbouring farmer bears the cost of sampling and testing and does not receive compensation.<sup>126</sup>

As a second compensation limitation, the Minister is to promulgate administrative rules delimiting the geographic area within which a farmer can be considered a neighbour for purposes of compensation.<sup>127</sup> In the Draft Executive Order, the Minister attached an Annex 1 with a chart distinguishing between distances for seed and distances for crop production. The distances vary by the crop species: for maize the distance for production is 300 meters; for sugar beet, seed (3000 meters) and production (75 meters); for potato, seed (30 meters) and production (30 meter). The Minister set no distance for maize seed production because Denmark produces no seed for sowing of maize. Only farmers within these distances from a transgenic field are eligible to file claims for compensation under the Danish Act.

As a third compensation limitation, the farmer making the claim may forfeit the claim or have the claim reduced if the claiming farmer

... has deliberately or inadvertently contributed to the occurrence of the loss or due to his behaviour has reduced his opportunities of making a recourse claim.<sup>128</sup>

By statutory provision, a farmer forfeits a claim if the farmer fails to file a claim “without undue delay”<sup>129</sup> – a requirement obviously meant to facilitate the Danish Plant Directorate in sampling

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<sup>126</sup> Draft Executive Order on Compensation §§ 2(1) & 9.

<sup>127</sup> Act on the Growing etc., *supra* note 105 at § 9(2).

<sup>128</sup> Act on the Growing etc., *supra* note 105 at § 9(5).

<sup>129</sup> *Id.* at § 10. For the procedures for filing a compensation claim and appealing a compensation decision, Draft Executive Order on Compensation at §§ 4, 5, 6, & 13.

and testing the level of transgenic material present in the claiming farmer's field. Moreover, the farmer suffering loss either files a compensation claim or pursues a private civil liability remedy.<sup>130</sup> After paying a compensation claim, the Minister has subrogation rights to any civil liability remedy<sup>131</sup> and can also recover from the claiming farmer if the claiming farmer has obtained a double recovery (such as a settlement from the transgenic farmer or an insurance payment).<sup>132</sup>

In an attempt to recover part of, or all, of the costs related to this compensation scheme, the Act stipulates that all producers planting a transgenic crop are required to pay 100 Danish kroner<sup>133</sup> per hectare every year of transgenic crop seeded.<sup>134</sup> This per hectare fee is in addition to any cost that the transgenic producer would have to pay to have access to the technology from the seed companies.

In light of the compensation scheme set forth in the Act, it is unclear how the scheme will affect the behaviour of Danish farmers and the Danish government. Some possible behavioral responses to this new and untested law include the following:

- While non-transgenic farmers retain the right to pursue civil legal liability against transgenic farmers, non-transgenic farmers may well prefer to file a claim for

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<sup>130</sup> Act on Growing etc., *supra* note 105 at § 11.

<sup>131</sup> Draft Executive Order on Compensation at § 12.

<sup>132</sup> Draft Executive Order on Compensation at § 11(2).

<sup>133</sup> As of September 25, 2005, Internet websites showed an exchange rate of 100 Danish kroner equaling C\$19 or US\$16 per hectare. With one hectare being equivalent to 2.47 acres, the fee is C\$ 8.50 or US\$ 8.00 per acre.

<sup>134</sup> Act on Growing etc., *supra* note 105 at § 12.

compensation as a quicker, easier way of recovering compensation for losses. Hence, there may be few farmer versus farmer civil lawsuits.

- After paying compensation, the Danish government has subrogation rights against transgenic farmers but it is unclear whether the Danish government would pursue subrogation through civil legal liability. The transgenic farmers have already paid a per hectare fee that funded the compensation scheme. In effect, the transgenic farmers have already paid the Danish government. The Danish government may have little incentive, economic or political, to engage in civil litigation against these farmers because litigation would consume time and money of the Danish Ministry of Food, Agriculture, and Forestry.<sup>135</sup>

- In light of the per hectare fee per year that transgenic farmers must pay to grow transgenic crops and fund the compensation scheme, it is not clear how many hectares of approved transgenic crops Danish farmers would plant. The European Commission has approved this compensation scheme for the limited period of five years as a way of contributing to the successful introduction of transgenic agriculture to Denmark.<sup>136</sup> However, the fee is functionally a tax on producing transgenic crops. From the farmers' perspective, the tax – 100 Danish kroner per hectare per year – may make it not worthwhile or uneconomical to plant transgenic crops. Thus, it is unclear whether Danish farmers will actually plant transgenic crops

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<sup>135</sup> Of course, the Ministry FAF may well decide to pursue administrative sanctions against a farmer who caused a compensable loss – *e.g.* the revocation of the farmer's license to grow transgenic crops. Moreover, if the farmer who caused a compensable loss engaged in "gross or willful violations" of the provisions of the Act, MFAF can seek to apply the applicable sections of the Danish Criminal Code to the farmer's conduct. *Id.* at § 14.

<sup>136</sup> EU Commission, Secretariat General, State Aides – Denmark, *supra* note 124.

during the next five years of the tax.<sup>137</sup>

With the Danish Act described, it is now beneficial to make a comparison with the previous scenarios that were discussed within the Canadian and American legal contexts. Of course, the application of the Danish Act to the five scenarios will be a discussion in the abstract because, as no transgenic crops have been grown commercially in Denmark, no compensation fund exists and no claims for compensation have yet been possible.

Scenario One: Claim for damages arising from an unapproved transgenic crop mixing with commercial agricultural crops.

Section 9(6) speaks indirectly to liability for growing unapproved transgenic crops. Section 9(6) gives compensation if the presence of the genetic material exceeds a specific threshold set by the Minister of DFAF. In the Draft Executive Order on Compensation implementing section 9(6) the Minister did not specifically address the threshold for unapproved transgenic crops. However, it is easy to speculate with a high degree of confidence that the Minister would adopt the EU threshold for unapproved transgenic crops just as the Minister

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<sup>137</sup> Anon, Denmark to tax farmers of GM crops, NEW SCIENTIST (Dec. 2, 2005), [www.newscientist.com/channel/opinion/mg18825283.300](http://www.newscientist.com/channel/opinion/mg18825283.300). This article states, “Depending on your point of view, it’s either a neat ruse to help keep genetically modified crops out of Europe, or an unfair barrier to farmers who want to benefit from GM technology. ... Don’t expect the Danish fund to be bursting with cash though: like all European countries except Spain, it has no GM farmers yet.”

Under the 2004 amendments to its Act to Regulate Genetic Engineering, Germany too is considering a compensation scheme that would require farmers of transgenic crops to pay a fixed amount per hectare into a fund administered by the government. However, as of the January 2006, the German government and agricultural organizations (those representing farmers, seed companies, and seed developers) have been unable to agree on the specific details of such fund. This is another future development to watch as the German law evolves. Mark Hucko, GM crops in Germany stalled, CHECKBIOTECH (Jan. 20, 2006).

adopted the EU thresholds for seed production and crop production.<sup>138</sup> The EU threshold for unapproved transgenic crops is zero. Consequently, if a Danish court faced a claim for compensation due to the presence of unapproved transgenic material, the Danish court assuredly could and would interpret section 9(6) to allow compensation. By so doing, the Danish statutory scheme and the Danish court would impose civil legal liability for commingling of unapproved transgenic crops with conventional and organic crops just as happens in Canadian and American jurisprudence.

Scenario Two: Claim for damages arising from an approved transgenic crop mixing with non-transgenic crops resulting in a loss of a premium for a person or company who intended to sell a non-transgenic commodity or food product.

Scenario Three: Claim for damages arising from an approved transgenic crop mixing with organic crops resulting in a loss of the organic label for the specific organic crop or of organic certification for the organic farmer's farm.

The Danish Act<sup>139</sup> and the Draft Executive Order on Compensation<sup>140</sup> specifically address compensation for Scenarios Two and Three. If the non-transgenic farmer (conventional or organic) has the presence of transgenic material in his seed or crop above the EU legal thresholds, that non-transgenic farmer has a valid claim for compensation in Denmark. Because the laws and regulations of Denmark have specific thresholds related to labeling, Danish jurisprudence in theory will impose civil legal liability upon transgenic farmers more often than do Canadian and American cases and statutes.

In practice, however, it is likely that Danish jurisprudence will mirror Canadian and

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<sup>138</sup> For discussion of the section 9(6) thresholds for approved transgenic crops, read text and accompanying notes 123-126 *supra*.

<sup>139</sup> Act on Growing *supra* note 105 at § 9(1),(4),(6).

<sup>140</sup> Draft Executive Order on Compensation §§ 1 & 2.

American jurisprudence because the Danish Act will likely give rise infrequently to any compensable claims above the specified thresholds within the geographical boundaries that the Minister has established.<sup>141</sup> By adopting neighborly coexistence practices, Danish transgenic farmers can control the adventitious spread of their transgenic crops with fairly easy and familiar agronomic practices. Hence, transgenic farmers must pay attention to the potential for civil legal liability under the Danish Act and the DFAF Executive Order implementing it. But if transgenic farmers pay attention agronomically, they run minimal risk that civil legal liability will actually become reality.<sup>142</sup>

Making civil legal liability available in theory but rare in reality is the paradigm of coexistence in Denmark and at the Secretariat General level of the EU.<sup>143</sup>

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<sup>141</sup> Draft Executive Order on Compensation § 2 and Annex 1.

<sup>142</sup> Danish transgenic farmers can gain a sense for the relative ease of avoiding adventitious presence by reading DIAS Report *supra* note 101 at Ch. 6 Seed Production and Threshold Values, Ch. 7 Monitoring and analytical methods, and Ch. 10 Review of crops. See *also*, citations to coexistence studies in notes 176 & 181 *infra*.

<sup>143</sup> The Danish and EU Secretariat General paradigm of coexistence about civil liability explains why Friends of the Earth Europe complained about the Danish Act after its legislative enactment. Friends of the Earth Europe [FOEE], Danish co-existence law is full of weaknesses, BIOTECH MAILOUT 10 (July 2004).

It is interesting to note that when the Ministry for Food, Agriculture and Fisheries first presented its proposal for coexistence, the Ministry made the following comment:

“The rules governing co-existence will be based on the legal opinion of the Attorney to the Danish Government of 16 January 2003. Against this background, the rules governing co-existence will not contain separate provisions on liability. The point of departure is that the GM farmer may be held liable for any mistakes and violations whereby the organic or GM-free farmer has incurred a financial loss. Assessment of the question of liability will, subsequently, be left to the courts of law in accordance with the fundamental principles of liability in tort.”  
Ministry of FAF, Strategy for co-existence, *supra* note 100.



Scenario Four: Claim for damages arising from the loss of market access. For example, where a buyer decides against buying a farmer's crop even though there was no evidence of transgenic material or the evidence of transgenic material was below legally-set thresholds.

Scenario Five: Claim for damages arising from a decision by a farmer to forgo planting a particular crop because of concern about proximity to transgenic crops or market perception about transgenic crops.

Although the Danish Act was passed by a Parliament that has been described as a “GMO-cautious majority,”<sup>144</sup> neither the Act nor the Executive Orders (final and draft) of November 2004 use the word “precautionary.” By excluding this word from the statute and regulations relating to the laws about coexistence of conventional, organic, and transgenic crops in Danish agriculture, the Danish Parliament is signaling to the acceptance of transgenic crops within the Danish agricultural sector.<sup>145</sup>

This acceptance is also apparent in the fact that the Danish Act does not authorize compensation for loss of markets or farmer’s concern with consumer perceptions about transgenic crops. The Danish Act confines the compensation scheme only to transgenic pollen flow in seed and crop production to neighboring non-transgenic farms. Even regarding pollen flow, the neighboring farmer only has a compensable claim when experiencing transgenic presence above the EU legal threshold levels for labelling as genetically modified. Hence, the

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The Ministry’s proposal to rely solely on the “fundamental principles of liability in tort” was obviously rejected by the Danish Parliament, which opted for a fault liability and funded compensation scheme.

<sup>144</sup> The “GMO-cautious majority” terminology to describe the Danish Parliament is used numerous times by J. Toft, National Report, *supra* note 103.

<sup>145</sup> Anon, Soc Dem shift opens door on GMO, Denmark.dk The Official Window (16 Sept 2005) (“The opposition Social Democrats have announced that they plan to give up their blanket rejection of genetically modified organisms (GMO), reported national daily Politiken on Friday. ... With the Social Democrat’s change of course, the parliament’s long-standing majority opposition to GMO has dried up.”)

Danish Act does not create civil legal liability for Scenarios Four and Five.

By excluding Scenarios Four and Five from the compensation scheme, the Danish Parliament is rejecting civil legal liability claims for pure economic loss. By so doing, Danish jurisprudence will be substantially identical to the Canadian and American jurisprudence relating to pure economic loss.<sup>146</sup>

### Administrative Liability

The Danish Act on the Growing etc. of Genetically Modified Crops (June 2004) contains provisions creating administrative sanctions for those who violate the Act.<sup>147</sup> However, these administrative sanctions are common place in statutes that create a regulatory scheme. Therefore, the Danish Act does not create any unique or unusual administrative liability for Danish farmers who decide to grow transgenic crops.

The Danish Act does not create either civil liability or administrative liability for generalized environmental harms.<sup>148</sup> If transgenic crops cause environmental damage in Denmark, the Danish legal system will deal with these environmental harms through the ordinary and usual environmental liability instruments – e.g. Environmental Protection Act of 1998 (as amended) and the Act on Compensation for Environmental Damage of 1994 (as amended).<sup>149</sup>

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<sup>146</sup> For discussion of Scenarios Four and Five and the pure economic loss doctrine in Canada and the United States, read text and accompanying notes 36 to 68 *supra*.

<sup>147</sup> Act on the Growing etc., *supra* 105 at §§ 19 & 20.

<sup>148</sup> FOEE, Danish co-existence law, *supra* 143 at 12 (“Another major weakness of the compensation scheme is that it only covers economic and not environmental damage, as may occur as a result of the escape of GMOs to wild plants.”)

<sup>149</sup> For fuller discussion of these ordinary and usual Danish environmental liability instruments, P. Truelsen, *Environmental Liability as an Instrument in Danish Environmental*

Danish law does not impose unique or unusual administrative liability upon transgenic farmers and transgenic agriculture. In this regard, Danish jurisprudence is similar to the national jurisprudence of Canada and the United States.<sup>150</sup>

### Criminal Liability

The Danish Act on the Growing etc of Genetically Modified Crops (June 2004) does have criminal penalties for both individual farmers and for corporations that violate the regulatory scheme created in the Act.<sup>151</sup> However, these criminal penalties relate to violating the administrative obligations related to growing transgenic crops. Like Canada and the United States, Denmark has not created criminal statutes that are uniquely applicable to those who create, sell, use, or grow transgenic crops. Hence, assuming administrative compliance, a transgenic farmer in Denmark has no need to fear criminal liability for engaging in transgenic agriculture. The transgenic farmer is accountable to Danish criminal laws no differently than conventional and organic farmers are accountable to Danish criminal laws.<sup>152</sup>

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Law?, Workshop on Liability, Economics, and Insurance (Odense, Denmark, Oct. 1998), [www.akf.dk/som/pdf/som32](http://www.akf.dk/som/pdf/som32).

Of course, Denmark will also have the European Union Environmental Liability Directive as part of its law. The EU Environmental Liability Directive does not appear to have any unique implications for transgenic agriculture in Denmark. The Directive is more fully discussed under **Legal Liability: Germany Administrative Liability *infra*** where the Directive does have unique implications for transgenic agriculture in Germany.

<sup>150</sup> For discussion of administrative liability in Canada and the United States, read text and accompanying notes 69 to 97 *supra*.

<sup>151</sup> Act on the Growing etc., *supra* note 154 at §§ 14(1), 19 & 20.

<sup>152</sup> A recent commentator on the use of criminal law in Denmark for protecting the environment has concluded that Danish criminal law “plays a minor role compared to administrative enforcement.” P. Pagh, *Administrative Criminal Law Systems in Europe: An Asset for the Environment?*, Ch. 15 at 172 in F. Comte & L. Krämer (eds), ENVIRONMENTAL

## Legal Liability: Germany

In 1993, to conform German law to European Community laws,<sup>153</sup> Germany passed an Act to Regulate Genetic Engineering (GenTG).<sup>154</sup> In 2004, in response to more recent European Union laws relating to agricultural biotechnology,<sup>155</sup> Germany amended its GenTG by adding new provisions regarding legal liability that are of especial relevance for this article.<sup>156</sup>

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CRIME IN EUROPE (Europa Law Pub., Groningen 2004). Despite the title of Pagh's chapter, the substantive content of the chapter is almost entirely about Danish criminal law as an enforcement technique for protecting the Danish environment.

<sup>153</sup> Council Directive 90/220/EEC (23 Apr 1990) On the Deliberate Release into the Environment of Genetically Modified Organisms.

<sup>154</sup> Gentechnikgesetz (GenTG), Bundesgesetzblatt 1993 I, p. 2066 (published on 16 Dec 1993). The German legislature adopted amendments – that are not of significance for this article – to the 1993 law in 1994 and 1997.

<sup>155</sup> Directive 2001/18/EC (12 Mar 2001) On the Deliberate Release into the Environment of Genetically Modified Organisms (repealing Council Directive 90/220/EEC).

<sup>156</sup> Gesetz zur Neuordnung des Gentechnikrechts, Bundesgesetzblatt 2005 I, p. 186 (passed by the Bundestag on 26 Nov 2004; published on 21 Dec 2004; effective on 04 Feb 2005). The law may be found at [http://www.bmely.de/cln\\_045/nn\\_750598/SharedDocs/Gesetzestexte/G/GesetzNeuordnungGentechnikrechts.html](http://www.bmely.de/cln_045/nn_750598/SharedDocs/Gesetzestexte/G/GesetzNeuordnungGentechnikrechts.html)

For a good summary, Federal Ministry of Consumer Protection, Food and Agriculture, Information on the Amendment to Germany's Genetic Modification Act, <http://www.verbraucherministerium.de>.

(hereafter BMVEL Information). The German initials for the Federal Ministry of Consumer Protection, Food and Agriculture are "BMVEL." The German legislature delegated primary administrative responsibility for the GenTG to BMVEL.

In the fall 2005, while this article was being written, Germany held national elections. As a result of those elections, BMVEL Minister Renate Kuenast lost her portfolio. Timm Kragenow, The end of Kuenast's estates, FINANCIAL TIMES DEUTSCHLAND (Nov. 10, 2005). In December 2005, the new German government indicated that there would be substantial changes in the genetic engineering law, particularly relating to the 2004 amendments. Anon, Change in genetic engineering law, 4 (# 11-12) EURO. BIOTECH. 20 (Dec. 2005). As of the completion date of this article, the precise substantive changes to the German GenTG are not known. However, this article purposefully focuses on the 2004 German amendments because these amendments set

## Civil Liability

In the 1993 version of the GenTG, Part Five of the Law had five sections on “Provisions for Liability.”<sup>157</sup> These five 1993 sections were left unchanged by the 2004 amendments and, therefore, are still part of the present German law on genetic engineering.

Section 32(1) *Liability* imposes civil liability upon operators for the death, injury, impairment of health, or property damage of other persons resulting from the properties of a genetically engineering organism. Section 32(2) adopts joint and several liability for several operators if each is obliged to compensate for the same damage. Section 32(3) adds that Civil Code section 254 applies if the party suffering the damage contributed to the occurrence of the damage. Section 32(7) provides that liability for damage to property extends to impairment of nature or landscape for which the party damaged expends funds in restoration of the prior natural or landscaped state.<sup>158</sup>

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forth a distinct model for legal liability that is worth analyzing thoroughly even if that model does not survive, in light of the new (2005) German government’s policies, as the actual law in Germany.

One change in Germany should be noted. The new Minister, Horst Seehofer, changed the name of the ministry to Federal Ministry of Food, Agriculture and Consumer Protection. The German initials of the ministry have consequently changed to BMELV, as opposed to BMVEL under the previous government. The authors purposefully chose to use the initials BMVEL from the previous government in order to emphasize the 2004 law that is the comparative focus in this article. The 2004 amendments came at the initiative of the previous government under former Minister Renate Kuenast, a Green Party member.

<sup>157</sup> Those five sections are as follows: § 32 Liability (Haftung); § 33 Maximum amount of liability (Haftungshöchstbetrag); § 34 Presumption of cause (Ursachenvermutung); § 35 Right to information of the party having suffered damage (Auskunftsansprüche des Geschädigten); § 36 Provision of sufficient cover (Deckungsvorsorge); § 37 Liability according to other legal regulations (Haftung nach anderen Rechtsvorschriften).

<sup>158</sup> Section 32(4),(5),(6) specify compensable costs to include medical costs incurred for the injury, burial costs if the person is killed, and lost earning capacity to the person injured and

Section 3(9) *Definitions* defines “Operator” to include those who establish a genetic engineering installation,<sup>159</sup> perform genetic engineering operations,<sup>160</sup> or release<sup>161</sup> or place on the market genetically modified organisms without authorization under the GenTG.

When the Section 3(9) definition of “operator” is taken into account, it becomes clear that Section 32 *Liability* exists only for those involved with transgenic organisms through laboratory or confined experiments, field testing, or deliberate introduction into the environment (by release or placing on the market) without authorization. Moreover, the damage for which compensation exists under Section 32 is direct, physical damage to the life, health, or property (including nature and landscape) of another person. Finally, even when an operator is found liable for the direct, physical damage under Section 32, Section 33 *Maximum amount of liability* places an exposure cap of 160 million German marks<sup>162</sup> for this liability.

Taking into account the scope of Section 32 (liability against operators for direct, physical damages for transgenic organisms that are experimental or have not been authorized for placing on the market) and the maximum amount of liability of Section 33, the 1993 GenTG did not

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to those dependent upon the person injured or killed.

<sup>159</sup> Section 3(4) defines “genetic engineering installation.”

<sup>160</sup> Section 3(2) defines “genetic engineering operations.”

<sup>161</sup> Section 3(7) defines “release.”

<sup>162</sup> As of September 1, 2005, Internet websites showed an exchange rate of 160 million German marks equaling € 120,000,000 or \$US 100,800,000. The authors are aware that the European Union euro has replaced the German mark as the German currency.

create significant risks of civil liability for agricultural biotechnology.<sup>163</sup> As for transgenic crops authorized for placing on the market for introduction into the environment, the 1993 GenTG did not create any unique or special liability for developers of authorized transgenic seeds or for farmers who grew them.<sup>164</sup>

By its emphasis on direct, physical injury and the absence of authorization for commercial release of the transgenic organism, Section 32 of the 1993 GenTG creates civil liability that is quite similar to the civil liability that United States courts recognized for Aventis CropScience in the *StarLink*<sup>TM</sup> litigation.<sup>165</sup> Indeed, taking into account the Section 33 cap on damages for a Section 32 violation, the 1993 GenTG would have imposed lesser monetary damages upon Aventis CropScience than Aventis actually paid in the settlements resulting from

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<sup>163</sup> With respect to liability issues, the German Parliament adopted a civil liability law for harmful environmental effects in 1990. Federal Environmental Liability Act (Umwelthaftungsgezet), Bundesgesetzblatt 1990 I, p. 2634. Private parties who are injured in their life, body, health, or property by certain specified activities, listed in an annex to the statute, that have harmful effects on the environment are entitled to sue. Operators of the specified activities are strictly liable to those parties who are injured by harmful effects on the environment caused by the listed activities. Agricultural biotechnology is not a listed activity in the statutory annex. Moreover, the Environmental Liability Law does not allow for liability for purely environmental harms – i.e. harms that are not interrelated with an injury to life, body, health, or property of private persons. J. Taupitz, *The German Environmental Liability Law of 1990: Continuing Problems and the Impact of European Regulation*, 19 SYR. J. INT’L L. & COMM. 13 (1993).

When one reads the Environmental Liability Act, the striking similarity in content between its statutory provisions and the statutory provisions of the GenTG of 1993 is clearly obvious.

<sup>164</sup> While Germany itself has not approved any transgenic crops for German farmers, German farmers have had access to limited amounts of transgenic maize approved by Spain, a fellow member of the European Union. German farmers planted about 500 hectares in 2004. USDA-FAS GAIN Report #GM4014, *German Farmers’ Interest in Planting Bt-Corn 2004* (March 25, 2004).

<sup>165</sup> The *StarLink*<sup>TM</sup> litigation is discussed in the text accompanying notes 18-24 *supra*.

the *StarLink*<sup>TM</sup> litigation in the United States under Common Law tort claims.<sup>166</sup>

In 2004, the German legislature added a new section, section 36a,<sup>167</sup> to the Part V Provisions on Liability of the GenTG. To understand section 36a and its ramifications, it is worthwhile to quote section 36a(1), which sets forth the statutory language about civil liability, in full.

#### Section 36a Claims in Case of Impairment of Usage

(1) The transfer of characteristics of an organism that are based on genetic engineering work or other introductions of GMOs represent a significant impairment within the meaning of Section 906 of the German Civil Code if, contrary to what the party entitled to use [non-transgenic organisms] intended, and due to the transfer or other introduction, products may, in particular,

1. not be placed on the market or
2. according to the stipulations of the present Act or according to other regulations [the non-transgenic products may] only be placed on the market with a label indicating the genetic modification or
3. not be placed on the market with such label that would have been possible to be used according to the respective guidelines legally applicable for the production method.<sup>168</sup>

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<sup>166</sup> As indicated in note 24 *supra*, Aventis CropScience paid \$US 110 million as settlement in the United States. Using the exchange rates set forth in note 162 *supra*, the maximum liability that Aventis CropScience could have faced under the 1993 GenTG § 33 was \$US 100,800,000.

<sup>167</sup> Gesetz zur Neuordnung des Gentechnikrechts, Bundesgesetzblatt 2005 I, p. 186 §36a Claims in the Case of Impairment of Usage (Ansprüche bei Nutzungsbeeinträchtigungen).

<sup>168</sup> Translation from Hollander van der Mey/MS&L Public Relations/Public Affairs Netherlands, Amendments to the German Law of Genetic Engineering (November 2004). The German text is as follows:

#### Section 36a Ansprüche bei Nutzungsbeeinträchtigungen

(1) Die Übertragung von Eigenschaften eines Organismus, die auf gentechnischen Arbeiten beruhen, oder sonstige Einträge von gentechnisch veränderten Organismen stellen eine wesentliche Beeinträchtigung im Sinne von § 906 des Bürgerlichen Gesetzbuches dar, wenn entgegen der Absicht des Nutzungsberechtigten wegen der Übertragung oder des sonstigen Eintrags Erzeugnisse insbesondere



Section 36a(1) provides that civil liability attaches to any person growing transgenic crops when the “characteristics” of the transgenic crop transfer to other farm products or when the “other introduction” of transgenic crops impacts other farm products, which acts of transfer or other introduction are statutorily determined to “represent a significant impairment within the meaning of Section 906 of the German Civil Code.”<sup>169</sup> Section 36a(1) further provides that the “significant impairment” exists “in particular” in three instances:

- when another farm product cannot be placed on the market;<sup>170</sup>
- when another farm product can only be placed on the market with a label

indicating that it is genetically modified,<sup>171</sup> and

- when another farm product cannot be placed on the market with a label legally applicable to the production method used to produce that farm product.<sup>172</sup>

Several procedural rules from the GenTG strengthen the civil liability standard of section 36a(1). First, section 34, originating in the 1993 law, provides that if damage has resulted from a transgenic organism, the damages are presumed to come from the transgenic properties of the

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1. nicht in Verkehr gebracht werden dürfen oder
  2. nach den Vorschriften dieses Gesetzes oder nach anderen Vorschriften nur unter Hinweis auf die gentechnische Veränderung gekennzeichnet in den Verkehr gebracht werden dürfen oder
  3. nicht mit einer Kennzeichnung in den Verkehr gebracht werden dürfen, die nach den für die Produktionsweise jeweils geltenden Rechtsvorschriften möglich gewesen wäre.

<sup>169</sup> BMVEL translates this phrase as “represent a material negative effect within the meaning of Section 906 of the German Civil Code.” BMVEL Information *supra* at note 156.

<sup>170</sup> Section 36a(1).1

<sup>171</sup> Section 36a(1).2.

<sup>172</sup> Section 36a(1).3

crop unless it is probable that the damages came from non-transgenic properties of the plant. Second, section 36a(4) establishes joint and several liability for those neighbors of the person claiming damages. If several neighbors could be considered the cause of the significant impairment and if the person claiming damages from the transfer or other introduction of transgenic characteristics finds it not possible to establish which of the neighbors caused the impairment, then all neighbors growing transgenic crops bear the section 36a(1) liability. The several neighbors can avoid joint and several liability when one or all can establish who caused what portion of the significant impairment so that the court can properly allocate damages to individual neighbors. Third, section 33, the 1993 section setting a cap of damages, does not apply to liability under section 36a because by its statutory language the section 33 cap applies only to section 32 liability. The consequences of these three procedural statutes is that a person can plead minimal facts supporting the damage claim under section 36a(1) liability against several neighboring farmers growing transgenic crops and win the lawsuit based on the presumptions created by sections 34 and 36a(4) for uncapped damages.<sup>173</sup>

The contrast between the civil liability under Section 32 of the 1993 law and Section 36a of the 2004 law is exceedingly important. Section 36a creates liability for any person who grows transgenic crops. Obviously, section 36a applies to operators – those liable under Section 32 – but also transgenic farmers. Section 36a purposefully focuses on transgenic farmers as being

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<sup>173</sup> Section 35, originating in the 1993 law, also creates a procedural advantage for those claiming damages but this procedural advantage, by explicit statutory language, only applies to a claim under section 32 liability.

subject to civil liability and explicitly allows farmer versus farmer lawsuits.<sup>174</sup> In addition, Section 36a creates liability for authorized transgenic crops (i.e. those transgenic crops fully approved for placing on the market) whereas Section 32 liability only applies to those transgenic organisms that are not authorized for placing on the market. Section 36a(2) highlights liability for authorized transgenic crops by imposing the obligation of compliance with good agricultural practices, as specified in section 16b<sup>175</sup> and implemented by BMVEL regulations.<sup>176</sup> However, compliance with good farming practices is not a defense to imposition of civil liability under Section 36a(1).<sup>177</sup>

Section 36a(1) civil liability can be best understood by applying it to the five factual

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<sup>174</sup> BMVEL Information *supra* note 156 at “II.3. Defensive and compensatory claims under civil law, Section 36a.” *See also*, Friends of the Earth Europe [FOEE], German law on co-existence – improved, BIOTECH MAILOUT 6, 8 (July 2004).

<sup>175</sup> Section 16b Handling of product placed on the market (Umgang mit in Verkehr gebrachten Produkten). Section 16b was added to the GenTG by the 2004 amendments. Section 16b also incorporates the precautionary principle from § 1 Purpose of the Act (Zweck des Gesetzes). The explicit reference to the precautionary principle was added to § 1 by the 2004 amendments. BMVEL Information *supra* note 156 at “II.1. Obligation to take precautionary action and comply with “good farming practice”, Section 16b” and “III.1, Precautionary Principle, Section 1”.

<sup>176</sup> For example, BMVEL has proposed that good farming practices should require a 1,000 meter buffer zone between transgenic maize crops and surrounding crops. USDA-FAS GAIN Report #GM4051, German Genetech Law and GMO Test Plantings in 2004 (Dec. 2, 2004). By contrast, a scientific study by Martin Luther University (Germany) concluded that a 20 meter buffer zone would protect surrounding non-transgenic crops from adventitious presence in excess of the 0.9% level that triggers labeling as genetically modified under EU regulations. W. Weber & T. Bringezu, *supra* note 25. The difference between the BMVEL 1000 meter separation distance and the University 20 meter separation distance is an obvious application of the precautionary principle from § 1 of the Act into the good farm practices regulations of § 16b of the Act.

<sup>177</sup> BMVEL Information *supra* note 156 at “II.3 Defensive and compensatory claims under civil law, Section 36a..”

scenarios previously discussed under Canadian and American law.

Scenario One: Claim for damages arising from an unapproved transgenic crop mixing with commercial agricultural crops.

Section 36a(1).1 explicitly imposes civil liability when transgenic traits that are not fully authorized for placing on the market commingle with a neighbor's commercial crops. Under section 36a, the presence of any unauthorized-for-full-commercial-release transgenic traits in a commercial crop results in civil liability for economic damage because the commercial crop must be withheld or recalled from the market.

Section 36a(1).1 clearly creates civil liability in the same circumstances as existed in the United States in the *StarLink*<sup>TM</sup> litigation.<sup>178</sup> However, section 36a(1).1 also emphasizes broader civil liability beyond the *StarLink*<sup>TM</sup> litigation because the commentary on section 36a(1).1 focuses on authorized field trials as the most likely fact pattern to which section 36a(1).1 applies.<sup>179</sup> The *StarLink*<sup>TM</sup> litigation did not involve field trials. *StarLink*<sup>TM</sup> involved the intermingling of a transgenic crop approved for commercial release only for animal feed that became intermingled with the food supply. The *StarLink*<sup>TM</sup> litigation issued no ruling about civil liability, if any, arising from properly authorized and properly conducted field trials.<sup>180</sup> By

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<sup>178</sup> The *StarLink*<sup>TM</sup> litigation is discussed in the text accompanying notes 18-24 *supra*.

<sup>179</sup> BMVEL Information *supra* note 156 (specific discussion of liability for field trials) at II. Provisions to ensure the protection of GM-free farming (coexistence provisions).

<sup>180</sup> In the United States, the *Prodigene* incident may be most similar to the field trial focus of section 36a(1).1. Prodigene is a biopharmaceutical company that conducted field trials of corn genetically modified to produce a swine vaccine. Prodigene failed to comply with permit protocols and its transgenic corn became commingled with 500,000 bushels of commercial soybeans. As a consequence, Prodigene paid an administrative fine of \$US 250,000 and spent approximately \$US 3 million for disposal and cleanup costs. Aziz Elbehri, Biopharming and the Food System: Examining the Potential Benefits and Risks, 8(1) AGBIOFORUM 18, 23 (2005).

contrast, section 36a(1).1 imposes civil liability on any commingling from a field trial with a commercial agricultural crop even when the operator conducting the field trial has fully complied with required field trial protocols.

Scenario Two. Claim for damages arising from an approved transgenic crop mixing with non-transgenic crops resulting in a loss of a premium for a person or company who intended to sell a non-transgenic commodity or food product.

Section 36a(1).2 explicitly imposes civil liability when “according to the stipulations of the present Act or according to other regulations, [the non-transgenic farmer’s products may] only be placed on the market with a label indicating the genetic modification.”

In light of the statutory language of section 36a(1).2, German law clearly establishes civil liability for the economic loss of a premium when the person who lost the premium intended to produce a non-transgenic crop. Consequently, if a non-transgenic farmer produced a crop that had to be labeled under EU law, because it had above 0.9% adventitious presence of transgenic content, the non-transgenic farmer has a civil liability claim against neighboring transgenic farmers.

If section 36a(1).2 only applies to premiums lost when a non-transgenic farmer is required to label a product as “genetically modified” in accordance with EU legislation, the German civil liability law would likely produce very few, if any, law suits. In light of studies conducted in the European Union about coexistence, the risk of liability for adventitious presence above the 0.9% level is very small so long as farmers follow reasonable agronomic practices.<sup>181</sup>

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The *Prodigene* incident involved a violation of administrative permit conditions for conducting the field trial.

<sup>181</sup> G. Brookes & P. Barfoot, Co-existence of GM and non GM arable crops: the non GM and organic context in the EU (May 2004). Brookes and Barfoot write, “The evidence to date

If section 36a(1).2 only applies to labeling above the EU 0.9% limit for adventitious presences, German jurisprudence would mirror Canadian and American jurisprudence about civil liability for Scenario Two.<sup>182</sup>

However, section 36a(1).2 reads to apply to situations other than premiums lost because of EU labeling requirements. Section 36a(1).2 also applies when “according to other regulations” the product may only be placed on the market “with a label indicating the genetic modification.” While section 36a(1).2 is not clear, one environmental organization reads its language to also apply to factual situations in which a conventional farmer has contractually agreed to produce a crop with adventitious presence below the EU 0.9% labeling standard.<sup>183</sup> If the farmer fails to meet the contractually agreed standard and, therefore, must apply a label as “genetically modified,” this environmental organization argues that the farmer has suffered an economic loss for which section 36a(1).2 provides civil liability against neighboring transgenic

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shows that GM crops growing commercially in the EU and in North America have co-existed with conventional and organic crops without economic and commercial problems – only isolated instances have been reported of adventitious presence of GMOs occurring in organic crops, even in North America where GM crops dominate production of soybeans, maize and canola.” *Id.* at 3. *See also*, W. Weber & T. Bringezu, *supra* note 25 (20 meter separation distance) and European Commission Joint Research Centre Institute for Prospective Technological Studies, Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture (2002).

<sup>182</sup> For the discussion of Scenario Two under Canadian and American law, read text and accompanying notes 25-27 *supra*.

<sup>183</sup> For example, a conventional farmer signs a contract to produce a conventional crop with no transgenic presence; the farmer also agrees that the crop can be labeled as “genetically modified” if it tests for any transgenic presence. The farmer delivers the crop to the contract buyer who tests it and finds 0.1% transgenic material. The contract buyer says the crop with the 0.1% transgenic content, under the contract, must be labeled as “genetically modified.”

farmers.<sup>184</sup> If section 36a(1).2 imposes civil liability for voluntarily assumed contractual obligations, German civil liability would be much broader for authorized transgenic crops than is true for authorized transgenic crops in Canada and the United States.

Scenario Three. Claim for damages arising from an approved transgenic crop mixing with organic crops resulting in a loss of the organic label for the specific organic crop or of organic certification for the organic farmer's farm.<sup>185</sup>

Section 36a(1).3 explicitly imposes civil liability upon transgenic farmers if an organic farmer cannot place a crop on the market with an organic label "that would have been possible to be used according to the respective guidelines legally applicable for the production method."

If the section 36a(1).3 language – "the respective guidelines legally applicable" – referred solely to EU regulations about organic production, German transgenic farmers should have little concern about civil liability. EU organic regulations prohibit the use of transgenic seeds or transgenic materials because the regulations focus on production standards.<sup>186</sup> However, the EU organic regulations set no specific *de minimis* level for adventitious presence of transgenic material. Although not without dispute about the correct legal interpretation of the organic regulations, the EU Commission has advised that organic farmers do not lose the organic label for products unless the farmer intentionally uses transgenic seeds or materials or unless the

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<sup>184</sup> FOEE, German law, *supra* note 174.

<sup>185</sup> M. Migus, *supra* note 28.

<sup>186</sup> Council Regulation (EC) No 1804/1999 of 19 July 1999 supplemented by Regulation (EEC) No 2092/91 on organic production of agricultural products. *See especially*, Art. 4 Definitions (14) "use of GMOs and GMO derivatives" and Art. 5 Labelling *passim* "the product has been produced without the use of genetically modified organisms and/or any products derived from such organisms."

product is above the 0.9% labeling requirement generally applicable to agricultural products.<sup>187</sup>

The EU Commission has given this interpretation because, in the absence of a specific threshold for transgenic content being set forth in the organic regulations, the general thresholds apply.<sup>188</sup>

Hence, the EU organic regulations, like Canadian and American organic regulations, would not impose civil liability on transgenic farmers for solely adventitious presence (i.e. less than 0.9% in the EU) of transgenic material commingled with an organic crop.<sup>189</sup>

However, the statutory language of section 36a(1).3 – “the respective guidelines legally

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<sup>187</sup> This advice from the EU Commission is clearly seen in the coexistence documents prepared by the governments of the UK and Ireland. UK REPORT: GM Crops?, *supra* note 35 at 113 (Nov. 2003); Report of the Working Group (Ireland) *supra* note 26 at 96 (6.1.1 EU Regulations pertaining to GMOs and organic production). *But see*, A. Bock et al, Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture, EU/Joint Research Center/Inst. for Prospective. Tech. Studies (May 2002) (Bock et al simply assert, “The possibility of changing practices to meet very low thresholds for all crops, near the analytical limit of quantification (~0.1%) is also considered in the report. This reflects the situation in organic farming where the use of GM varieties is not permitted (Council Regulation (EC) 1804/1999), setting a de facto threshold.”)

<sup>188</sup> Although not a binding regulation, the EU Commission in its Guidelines for the Development of National Strategies and Best Practices to Ensure the Coexistence of Genetically Modified Crops with Conventional and Organic Farming (2003/556/EC) wrote,

“2.2.3 Labelling threshold values.

“National strategies and best practices for coexistence should refer to the legal labelling thresholds and applicable purity standards for GM food, feed and seed.

“... These labelling thresholds would apply to conventional and organic farming alike. No legal thresholds exist for the adventitious presence of non-GMOs in GMOs. For seed of GM varieties, the general crop-specific requirements for purity standards in seed production apply.

“The organic farming regulation [1804/1999] establishes that no GMOs shall be used in production. Thus, materials, including seeds, which are labelled as containing GMOs cannot be used. However, seed lots containing GM seeds below the seed thresholds (which would not need to be labelled for this GMO presence) could be used. The organic farming regulation does allow for the setting of a specific threshold for unavoidable presence of GMOs, but no threshold has been set. In the absence of such a specific threshold, the general thresholds apply.”

<sup>189</sup> For discussion of Scenario Three in Canadian and American law, read text and accompanying notes 28-34 *supra*.



applicable” – is a clear reference to 1998 German legislation which authorizes (but does not require) organic producers voluntarily to label their products as “without genetic engineering.”<sup>190</sup>

While the 1998 German law does not establish a *de minimis* standard, German organic trade organizations have selected 0.1% as the maximum amount of transgenic material allowed before a German organic farmer loses the voluntary “without genetic engineering” label.<sup>191</sup>

Consequently, section 36a(1).3 also imposes civil liability upon transgenic farmers for standards and labels voluntarily adopted by organic organizations in Germany. Under section 36a(1).3, transgenic farmers in Germany have acquired the legal obligation to insure that organic farmers meet organic standards and labels that the organic farmers voluntarily created for their own marketing niche. As a result, the German 2004 law imposes civil liability upon transgenic agriculture under Scenario Three that is much broader than Canadian and American law allows.

The EU Commission challenged the legality of § 36a(1).3 for imposing civil legal liability upon transgenic farmers as applied to the “without genetic engineering” label. The EU argued that Germany was attempting to establish quantitative thresholds for adventitious presence that contradicted the legal thresholds set forth in EU regulations.<sup>192</sup> In a reply the German government argued that § 36a did not contradict the quantitative thresholds of EU

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<sup>190</sup> BMVEL Information, *supra* note 156 at II. Provisions to ensure the protection of GM-free farming (coexistence provisions). For brief discussion of the 1998 German law, USDA-FAS GAIN Report #GM5027, Germany Biotechnology Annual 2005 at 6 & 7 (July 15, 2005).

<sup>191</sup> Institute of Science in Society, Europe Holding Firm Against GMOs p. 2 of 4 (Nov. 1, 2005) available at [www.i-sis.org.uk/EHFAG.php](http://www.i-sis.org.uk/EHFAG.php).

<sup>192</sup> Letter (Notification 2004/133/D) from Olli Rehn, Commission Member to His Excellency Mr. Joschka Fischer in 1.C Special Remarks on Article 1 Number 34 – (new § 36a concerning liability).

regulations but rather implemented the 1998 German law that gave the possibility for a label – “without genetic engineering”– that is fundamentally different from the EU label – “genetically modified”– to which, and only to which, the EU legal thresholds were legally relevant.<sup>193</sup> There has been no resolution of this disagreement between the EU Commission and the German government about the legality of section 36a(1).3.

Scenario Four. Claim for damages arising from the loss of market access. For example, where a buyer decides against buying a farmer’s crop even though there was no evidence of transgenic material or the evidence of transgenic material was below legally-set thresholds.

Scenario Five. Claim for damages arising from a decision by a farmer to forgo planting a particular crop because of concern about proximity to transgenic crops or market perception about transgenic crops.<sup>194</sup>

The key to understanding how section 36a(1) applies to Scenarios Four and Five are the two statutory words “in particular.” These two words mean that the three listed obligations of civil liability – section 36a(1).1 through .3 discussed respectively under Scenarios One, Two and Three – are examples of liability but do not exhaust the factual situations in which section 36a imposes civil liability. Hence, if non-transgenic farmers (conventional or organic) were to suffer economic losses because of the factual situations of Scenarios Four and Five, these non-transgenic farmers have a claim for liability against neighboring transgenic farmers. As Professor Matthias Herdegen, Director of the Institute for Public Law and Institute for International Law at the University of Bonn, has written:

“The purpose of this addition [of the words “in particular”] was to extend the conditions triggering liability to other types of

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<sup>193</sup> Response 2004/133/D from the Federal Republic of Germany to the EU Commission on Article 1 Number 34 (§36a). The authors have the Letter (cited in note 192 *supra*) and the Response (cited in this footnote) in German in their files.

<sup>194</sup> UK REPORT: GM Crops?, *supra* note 35 at p. 4 suggesting Scenarios Four and Five.

interference which qualify as essential from the rightful user's [non-transgenic farmer's] perspective. This modification of the initial wording injects a high dose of legal uncertainty into the liability regime. In consequence, liability risks appear incalculable and unpredictable."<sup>195</sup>

In light of the words “in particular” in section 36a, it is highly likely that German courts would impose civil liability upon transgenic farmers in factual situations of Scenarios Four and Five. Indeed, Professor Herdegen raised the question of whether section 36a would even impose civil liability upon transgenic farmers when non-transgenic farmers claim damages for significant impairment of their ethical values.<sup>196</sup> Professor Herdegen apparently was referring to the fact that the 2004 amendments to the GenTG added the words “giving due regard to ethical values” to section 1 Purposes of the Act, giving rise to the possibility that ethical values are among the claims in case of impairment of usage for which section 36a establishes civil liability.<sup>197</sup>

By imposing civil liability in Scenarios Four and Five, German jurisprudence is much broader than Canadian and American civil liability. More importantly, in light of the broad imposition of civil liability under section 36a(1), the German GenTG has specifically rejected an important limitation on the reach of civil liability under Canadian and American law – i.e. the pure economic loss doctrine. Scenarios Four and Five do not involve any allegation of physical harm or inability to market a particular crop; rather Scenarios Four and Five involve solely

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<sup>195</sup> M. Herdegen, *The Coexistence of Genetically Modified Crops with Other Forms of Farming: The Regulation by EU Member States in Light of EC Law*, 2 J. INT'L. BIOTECH. L. 89, 96 (2005).

<sup>196</sup> *Id.* at 94.

<sup>197</sup> Greenpeace, *Germany decides on new GE law*, Press Release (Nov. 2004) which states, “Ethical values and the precautionary principle have in [§ 1] paragraph 1 been included as criteria for the first time.” *Id.* at additional note to § 1 at 5.

market and consumer perceptions. Therefore, it is no surprise that Professor Herdegen describes the civil liability under section 36a as “incalculable and unpredictable.” The fact that the civil liability for pure economic loss is often “incalculable and unpredictable” substantially explains why Canadian and American courts have used the pure economic loss doctrine to exclude liability for Scenarios Four and Five.<sup>198</sup>

Under the 1993 GenTG, Section 32 only created civil liability for invasions of the life, health, or property of the injured person, but there was no liability for pure economic loss.<sup>199</sup> Moreover, as a general rule, German law does not widely recognize recovery for pure economic loss. As one German commentator wrote,

The fact the primary pure economic losses are compensable only subject to particular preconditions is probably due to the fact that one has to put up with the general risks of life. Our law is based on the principle that the person entitled to a legal interest is the person to sue for damage to it. If the interest in question is the most general of all, namely economic well-being, some special reason is required for transferring the loss to someone else. ... But primary economic loss calls for a special relationship of the party causing the harm to the “economic” interest infringed. This is met in cases of contract and some special torts. In other cases, however, negative economic effects are part of the risk of life which the person has to bear.<sup>200</sup>

In light of the general rule that German law does not widely recognize recovery for pure

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<sup>198</sup> For discussion of Scenarios Four and Five and the pure economic loss doctrine in Canada and the United States, read text and accompanying notes 36 to 68 *supra*.

<sup>199</sup> E. Deutsch, Compensation for Pure Economic Loss in German Law, Ch. 3 at 85 in E. BANAKAS *supra* note 36 (“There are several different bases for product liability in Germany. Objective, perhaps even strict, liability is imposed by ... § 31 ff of the Law on Genetic Engineering. A common feature is that only damage to person or property is covered, so there is no liability under these statutes for pure economic loss.”)

<sup>200</sup> E. Deutsch *supra* note 199 at 87.

economic loss, the significance of section 36a becomes even clearer. Section 36a specifically created claims in cases of impairment of usage – protections for impairments arising from consumer perception, market perception, and ethical values – so as to give a statutory basis in German law for a greatly expanded recovery for pure economic loss. Section 36a singled out transgenic agriculture to create “special torts” for which transgenic operators and farmers would be liable and for which pure economic loss would be recoverable. By singling out transgenic agriculture for special torts, German law presents a stark contrast with Canadian, American, and Danish jurisprudence about civil liability for transgenic crops.

What have been the reactions to the broad civil liability for agricultural biotechnology under section 36a of the German GenTG? The German Research Foundation predicted that German universities and research organizations will greatly reduce their transgenic crop research, particularly field trials, because these entities cannot bear the risks of civil liability flowing from section 36a.<sup>201</sup> German organizations representing farmers advised their members not to plant transgenic crops because the liability risks are too severe.<sup>202</sup> The German state of Saxony-Anhalt

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<sup>201</sup> *E.g.* I. Klöpfer, Off to Canada, FRANKFURTER ALLGEMEINE (June 14, 2005); Anon., German Scientists Predict Death on GM Industry, AGRA EUROPE (17 Sep 2004); N. Stafford, Law ‘may stifle German science,’ THE SCIENTIST (June 28, 2004) available at [www.the-scientist.com/news/20040628/02](http://www.the-scientist.com/news/20040628/02); German Research Foundation, Press Release No. 29 Gone with the Wind? The Amendment to the Law on “Green Genetic Engineering” Inhibits Innovation and Research in Germany (9 June 2004).

In addition to the impact of section 36 upon the liability risk of research, the German government that supported that 2004 amendments also generally withdrew support and financing for agricultural biotechnology science projects. *E.g.*, S. Hoffman, Seven years lost for genetic engineering, HANDELSBLATT (Sept. 14, 2005); USDA-FAS GAIN Report #GM5011, GMO Situation in Germany – 2005 at 4 (Feb. 24, 2005). N. Stafford, In the wake of a law seen as a major blow for science, a major project’s funding dries up, THE SCIENTIST (Jan. 13, 2005).

<sup>202</sup> *E.g.* N. Stafford, GM law “a blow to science,” THE SCIENTIST (Dec. 1, 2004); Anon., German liability law impedes GM, AGRA INFORMA (JULY 8, 2004); Anon., New German genetic

sued the German government challenging the GenTG 2004 amendments as violating German constitutional provisions on occupational freedom, property rights, and the principle of equality.<sup>203</sup> The European Commission (EC) told the German government that the 2004 amendments to the GenTG conflict with EU regulations governing agricultural biotechnology.<sup>204</sup> Specifically, the EC claimed that the 2004 amendments cannot impose liability for adventitious presence below the EU standard of 0.9%, cannot hold neighboring farmers legally responsible for damages unless the individual farmer caused the damage, and cannot impose legal obligations that make it impractical or impossible for farmers to choose to plant approved transgenic

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engineering law and reactions, Bio-Markt.info (July 2, 2004).

Despite the advice not to plant transgenic crops, German farmers have begun to plant transgenic crops. Fifty-eight farmers planted 342 ha in 2005 of Bt maize and one hundred forty-five registered to plant approximately 1900 ha. in 2006. For data, see the website for the German cultivation register, [http://194.95.226.237/stareg\\_web/showflaechen.do](http://194.95.226.237/stareg_web/showflaechen.do). For a report about the German cultivation register, A. Gathmann & D. Bartsch, Public GMO location registers for supporting national coexistence measures in PROC. OF THE 2<sup>nd</sup> INT'L CONF. ON CO-EXISTENCE BETWEEN GM AND NON-GM BASED SUPPLY CHAINS (Montpellier, Nov. 2005). *See also*, David Evans, Are Europe's farmers warming to GMO maize? REUTERS (Sept. 23, 2005).

<sup>203</sup> *E.g.* Saxony-Anhalt: Constitutional review of the GenTG: Essential constitutional arguments (April 2005) (document in possession of author); C. Sargent, German state to sue Federal Government over GM laws, BLOOMBERG (April 11, 2005). *See also*, Anon, Baden-Württemberg Underlines its Opposition to the German Genetech Law, BIOTECH/LIFESCIENCES PORTAL BADEN-WÜRTTENBERG (March 17, 2005) available at [www.bio-pro.de/en/life/meldungen/01206](http://www.bio-pro.de/en/life/meldungen/01206); Joint declaration of the representatives of the BioRegions on the amendment of the Genetic Engineering Law (GenGT) and the use of plant biotechnology in Germany, BIOTECH/LIFESCIENCES PORTAL BADEN-WÜRTTENBERG (Nov. 2004) available at [www.bio-pro.de/en/life/meldungen/00790](http://www.bio-pro.de/en/life/meldungen/00790).

<sup>204</sup> Letter (Notification 2004/133/D) from Olli Rehn, Commission Member *supra* note 192. *See also*, Anon, European Commission Unhappy with German Biotech Bill, FOOD CHEMICAL NEWS (Aug. 23, 2004); USDA-FAS GAIN Report #GM4029, European Commission not Happy with Germany Genetech Law (Aug. 9, 2004)..

crops.<sup>205</sup> Supporters and opponents of the GenTG amendments are in agreement that these amendments create a *de facto* ban on agricultural biotechnology in Germany.<sup>206</sup> Similarly, the EU Commission ended its review of section 36 by informing the German government,

The proposed liability regulations are generally not allowed to lead to a high and unpredictable economic risk for GMO-farmers. The Commission would therefore approve this bill only on the condition that these regulations will not in actuality inhibit within Germany the cultivation of genetically modified organisms.<sup>207</sup>

### Administrative Liability

The European Union and the German Federal Republic have adopted a specialized regulatory system that focuses on agricultural biotechnology and the process by which agricultural biotechnology is created.<sup>208</sup> However, the European and German regulatory laws referred to in the preceding sentence do not address liability issues related to agricultural biotechnology. This European and German regulatory approach to agricultural biotechnology –

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<sup>205</sup> For a thorough discussion of the asserted conflicts between the EU regulations and the GenTG 2004 amendments, M. Herdegen, *supra* note 195.

<sup>206</sup> *E.g.* K. Merkner, New law on gene crops a “de-facto ban,” FRANKFRUTER ALLGEMEINE (Dec. 3, 2004); FOEE, German law, *supra* note 174 at 9.

<sup>207</sup> Letter (Notification 2004/133/D) from Olli Rehn, Commission Member *supra* note 138.

<sup>208</sup> The EU legislation is as follows: Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms; Regulation (EC) No. 1829/2003 of 22 Sept. 2003 on genetically modified food and feed; Regulation (EC) No. 1830/2003 of 22 Sept. 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. The German GenTG transposes the EU legislation into domestic law. The German transposition of these EU laws is not yet complete and it is expected that additional amendments to the GenTG will be presented to the German parliament in 2006 to finish the task of full transposition.

the specialized, process-oriented system – contrasts starkly with the Canadian and American regulatory systems which do not use a specialized administrative system and which focus on the products, not the process, of agricultural biotechnology.<sup>209</sup>

With respect to liability for environmental harms, the European Union has adopted an Environmental Liability Directive<sup>210</sup> that creates administrative (public law) liability for harms related to natural resources<sup>211</sup> and to biodiversity.<sup>212</sup> Operators of certain occupational activities,

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<sup>209</sup> For a comparison of the European regulatory system with the Canadian and American regulatory systems, read D. Uchtman & W. Nelson, U.S. Regulatory Oversight of Agricultural and Food-related Biotechnology, 44 AMER. BEHAVIORAL SCIENTIST 350 (2000) and M. Grossman & B. Endres, Regulation of Genetically Modified Organisms in the European Union, 44 AMER. BEHAVIORAL SCIENTIST 378 (2000).

<sup>210</sup> Directive 2004/35/CE of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage. EU members have until 30 April 2007 to transpose this directive into domestic law. *Id.* Art. 19.1.

Article 2.2 of the Directive defines damage to mean “a measurable adverse change in natural resource or measurable impairment of a natural resource service which may occur directly or indirectly.”

For general discussion of the Directive on environmental liability, L. Krämer, Directive 2004/35/EC on Environmental Liability, 16 ENV'T'L L. & MNGT. 5 (2003); V. Fogleman, The Environmental Liability Directive, 12 ENV'T'L LIAB. 101 (2004); C. Clarke, The Proposed EC Liability Directive: Half-way through Co-decision, 12 REV. EURO. COMM. & INT'L ENV'T'L L. 254 (2003).

<sup>211</sup> The natural resources protected are water and land. Water is protected from “any damage that significantly adversely affects the ecological, chemical and/or quantitative status and/or ecological potential.” *Id.* Art. 2.1(b). Land is protected from “contamination that creates a significant risk of human health being adversely affected as a result of the direct or indirect introduction, in, on or under land, of substances, preparations, organisms or micro-organisms.” *Id.* Art. 2.1(c).

<sup>212</sup> Biodiversity refers to protected species and natural habitats that are protected from “significant adverse effects on reaching or maintaining the favourable conservation status of such habitats or species.” *Id.* Art. 2.1(a). Art. 2.3 further defines “protected species and natural habitats” as limited to those species listed in Directive 79/409/EEC Art. 4(2) & Annex I or Directive 92/43/EEC Annex II & IV; as those habitats listed in Directive 79/409/EEC Art. 4(2) & Annex I, Directive 92/43/EEC Annex I, II, & IV; or those species or habitats not listed in



specially listed in Annex III of the directive, have strict liability for environmental damage.<sup>213</sup>

Among the listed occupational activities are contained use of genetically modified micro-organisms<sup>214</sup> and any deliberate release into the environment or placing on the market of genetically modified organisms.<sup>215</sup> Operators who are liable for environmental harms from transgenic occupational activities include transgenic farmers, research institutes and transgenic seed developers if they have “decisive economic power over the technical functioning of” the occupational activity that caused the environmental damage.<sup>216</sup> Competent authorities<sup>217</sup> are entitled to pursue environmental liability focused on preventive actions,<sup>218</sup> remedial actions,<sup>219</sup> and the imposition of costs for taking preventive and remedial action upon the responsible operator.<sup>220</sup>

Private causes of action (civil liability) for environmental damages are not authorized by

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Directive 79/409/EEC and Directive 92/43/EEC that Member states designate for equivalent purposes as those set forth in those two Directives.

<sup>213</sup> *Id.* Art. 1 and Art. 3.1(a).

<sup>214</sup> *Id.* Annex III ¶ 10.

<sup>215</sup> *Id.* Annex III ¶ 11.

<sup>216</sup> *Id.* Art. 2.6. Transgenic seed developers will be liable only if their liability is “provided in national legislation.” Greenpeace complained that the 2004 amendments to the GenTG did not take advantage of this opportunity in the EU Environmental Liability Directive. As Greenpeace reads the German 2004 GenTG, transgenic seed developers, in contrast to farmers, are not liable for environmental damage. Greenpeace Press Release *supra* note 197 at 2.

<sup>217</sup> *Id.* Art. 11.

<sup>218</sup> *Id.* Art. 5.

<sup>219</sup> *Id.* Art. 6.

<sup>220</sup> *Id.* Art. 8.

the Directive on Environmental Liability.<sup>221</sup> However, the Directive does empower private citizens, including non-governmental organizations, to present information about environmental harms to the competent authorities and request that the authorities take appropriate action.<sup>222</sup> Competent authorities must promptly inform the person or entity making the request of its decision about appropriate action.<sup>223</sup> If the person or entity making the request is dissatisfied with the decision, the person or entity is entitled to an independent and impartial review of the decision.<sup>224</sup> An independent review means a review independent of the competent authority and, therefore, strongly implies a judicial review.<sup>225</sup>

Article 4 of the Directive sets forth seven exceptions to the scope of liability of which three likely have relevant implications for agricultural biotechnology.

- Article 4.1(a) creates an exception to liability for “an act of armed conflict, hostilities, civil war or insurrection.” Article 8.3(a) reinforces the Article 4.1(a) exception by relieving operators of liability for environmental damage “caused by a third party ... despite the

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<sup>221</sup> *Id.* Art. 3.3. Article 3.3 is “without prejudice to relevant national legislation” that allows private causes of action. The German GenTG section 32 gives a private cause of action to a person whose life, body, health has been impaired because of genetically modified organisms and section 36a gives a private cause of action to persons whose interests are significantly impaired by genetically modified organisms. Read the discussion of sections 32 and 36a *supra* **Legal Liability: Germany Civil Liability**.

<sup>222</sup> Directive 2004/35/CE at Art. 12.1. Article 12.1 also sets forth who qualifies (or who has standing) to make the request of competent authorities.

<sup>223</sup> *Id.* Art. 12.4.

<sup>224</sup> *Id.* Art. 13.1.

<sup>225</sup> *Id.* Art. 13.2. Member States may make the independent, impartial review contingent upon the exhaustion of administrative review procedures.

fact that appropriate safety measures were in place.”<sup>226</sup> Third party vandalism of transgenic field trials or transgenic fields that causes environmental harm may come within these two clauses.<sup>227</sup>

- Article 4.1(b) creates an exception to liability for “a natural phenomenon of exceptional, inevitable and irresistible character.” The parameters of this exception are unclear and will likely remain so until such time as a terrible flood, snow storm, heat wave, or wild fire occurs. Even more pertinently, one could ask whether cross-pollination is a “natural phenomenon of exceptional, inevitable and irresistible character” and, therefore, whether cross-pollination is within the exception to liability.

- Article 4.5 states that the Directive only applies to environmental damage “caused by pollution of a diffuse character where it is possible to establish a causal link between the damage and the activities of individual operators.” By reading Article 4.5, one can instantly sense the potential conflict between this requirement of a causal connection to an individual operator and GenTG section 36a.4 imposing joint and several liability on transgenic farmers and GenTG section 34 creating a rebuttable presumption of causation from transgenic crops.

Germany may well have a proper answer to this potential conflict by pointing to Directive Article

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<sup>226</sup> Article 8.3(a) is a defense, not an exception, to the Directive on Environmental Liability because the operator must prove that a third party caused the damage despite the operator having taking appropriate safety measures.

<sup>227</sup> In 2003, a field trial of transgenic potatoes was destroyed by activists opposed to agricultural biotechnology. N. Stafford, In the wake of a law seen as a major blow for science, a major project’s funding dries up, *THE SCIENTIST* (Jan. 13, 2005). V. Fogleman, *supra* note 210 at 110 (commenting that the European Council meant for terrorism to be within the meaning of Articles 4.1(a) and 8.3(a).) *See also*, Anon., Greenpeace on trial under Danish terror law after GMO protest, *AGENCE FRANCE PRESSE* (June 9, 2005). *But see*, Anon., More anti-GM activists acquitted by French court, *AGENCE FRANCE PRESSE* (Jan. 12, 2006) and Anon., Activists’ destruction of GM crops was justified: French court, *AGENCE FRANCE PRESSE* (Dec. 9, 2005).

16.1 that allows Member States to adopt “more stringent provisions” including “the identification of additional responsible parties.” Resolution of the issue of legal conflict between EU Environmental Liability Directive and the German Genetic Engineering Law is a concern for the future, if the issue ever arises.<sup>228</sup>

Article 8.4 sets forth a discretionary defense to operator liability under the Directive.

Article 8.4 reads as follows:

The Member States may allow the operator not to bear the cost of remedial actions taken pursuant to this Directive where he demonstrates that he was not at fault or negligent and that the environmental damage was caused by:

(a) an emission or event expressly authorised by, and fully in accordance with the conditions of, an authorisation conferred by or given under applicable national laws and regulations which implement those legislative measures adopted by the Community specified in Annex III, as applied at the date of the emission or event;

(b) an emission or activity or any manner of using a product in the course of an activity which the operator demonstrates was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when the emission was released or the activity took place.

The defense in Article 8.4(a) is known as the “compliance-with-permit-conditions” defense.<sup>229</sup> However, in the 2004 amendments to the GenTG, Germany exercised its discretion in section 36a.1 to impose liability for any adventitious presence of transgenic material. Section 36a.1 makes clear that Germany has not “expressly authorised” an emission or event of

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<sup>228</sup> See text accompanying and authorities cited in notes 192 & 204-207 *supra*. See also, C. Clarke *supra* note 210 at 266-268 (discussing potential conflicts between the EU Directive on Environmental Liability and national laws in the various Member States.)

<sup>229</sup> L. Krämer *supra* note 210 at 11; V. Fogleman, *supra* note 210 at 110. Both authors discuss the scope and meaning of the Art. 8.4(a) defense.

adventitious presence even for approved transgenic crops. Consequently, Directive Article 8.4(a) likely has no legal meaning as a defense for German farmers or research institutes growing transgenic crops.

The defense of Article 8.4(b) is known as the “state-of-the-art” defense.<sup>230</sup> However, in the 2004 amendments to the GenTG, Germany exercised its discretion in section 36a.2 to state that “compliance with good agricultural practices ... can be reasonably expected.” Section 36a.2 makes clear that the rules and regulations, no matter how stringent, promulgated by the Federal Ministry of Consumer Protection, Food and Agriculture (BMVEL) constitute the state-of-the-art for the purposes of liability for agricultural biotechnology. Consequently, whether the Article 8.4(b) defense has any practical meaning in Germany will depend upon the “good agricultural practices” promulgated by BMVEL.

In summary, the German Parliament used its discretion under Directive Article 8.4 to draft statutory language in section 36a of the GenTG that almost assuredly nullifies both defenses of Article 8.4.

In light of the broad civil liability created by Section 36a of the GenTG, it is reasonable to expect that non-governmental organizations will use the request-for-action provision of Directive Article 12 quite often to seek protective actions and remedial actions related to water, land, protected species, and natural habitats<sup>231</sup> from adventitious presence of transgenic crops and transgenic field trials. If the competent authority in German (BMVEL) is kindly receptive to

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<sup>230</sup> V. Fogleman, *supra* note 210 at 110-111.

<sup>231</sup> For the definition of protected species and natural habitats in the EU Directive on Environmental Liability, read note 212 *supra*.

these requests, farmers and research institutions of transgenic organisms likely face substantial administrative liability, in addition to civil liability, for engaging in agricultural biotechnology.

Neither Canada nor the United States – at the federal level – have an environmental liability statute applicable to transgenic crops and transgenic field trials that is comparable to the European Union Directive on Environmental Liability. Due to the interrelationship between the EU Directive and the German GenTG, the potential administrative liability for agricultural biotechnology is, therefore, significantly greater in Germany than in Canada and the United States. However, as previously discussed, the Canadian Province of Saskatchewan has three environmental statutes that allow civil liability (private law) lawsuits for environmental harms.<sup>232</sup> The Saskatchewan statutes provide a contrasting model to the EU Directive which allows only administrative liability (public law) for environmental harms. Yet, the Saskatchewan statutes, like the EU Directive, may impose substantial liability upon agricultural biotechnology.

### Criminal Liability

Sections 38 & 39 of the German GenTG prescribe fines and penal sanctions for violations of the regulatory obligations contained in the prior sections of the Act. Fines and penal sanctions for violations of environmental regulatory statutes are common. Thus, these two sections should not be particularly threatening to transgenic farmers and research institutes. However, section 39.3 does establish a term of imprisonment of three months (implied as a minimum) but not exceeding five years for any of a list of regulatory violations that “endangers the body or life of another person, other property of considerable value or elements of the ecosystem of

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<sup>232</sup> For discussion of the Saskatchewan environmental statutes, read text and accompanying notes 76-90 *supra*.

considerable ecological importance.” Criminal liability for endangerment of “elements of the ecosystem of considerable ecological importance” appears to introduce a new criminal liability that may create significant concerns for those engaged in agricultural biotechnology.

It is unclear whether criminal liability extends to legal persons (e.g. corporations) because German penal law has traditionally not applied to legal persons because legal persons lack a conscience.<sup>233</sup> However, the EU Directive on Environmental Liability specifically imposes liability upon both natural and legal persons.<sup>234</sup> Therefore, Germany could adopt the EU approach, including criminal liability for legal persons, when Germany transposes the EU Directive into domestic law before 30 April 2007.

Germany has a special chapter of its penal code entitled “Crimes Against the Environment.” However, this special chapter does not impose any new or unique criminal liability upon those engaged in agricultural biotechnology.<sup>235</sup>

#### **Legal Liability: Article 27 of The Cartagena Protocol on Biosafety**

When the Cartagena Protocol on Biosafety (BSP) was finalized in January 2000, Article 27 addressed liability and redress.<sup>236</sup> However, due to the contentious nature of the negotiations

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<sup>233</sup> K. Gaynor & T. Bartman, *supra* note 99 at 91.

<sup>234</sup> Directive Art. 2.6 (definition of “operator”).

<sup>235</sup> For a general discussion of environmental crimes in Germany, R. Hüper, Application of Criminal Environmental Law in Germany, Ch. 6 in F. Comte & L. Krämer (eds), *supra* note 152.

<sup>236</sup> For a brief history of the negotiations relating to Article 27, Secretariat of the Convention on Biological Diversity (CBD), The Cartagena Protocol on Biosafety: A Record of the Negotiations 82-84 (2003). [hereinafter Record of the Negotiations]

about liability and redress,<sup>237</sup> Article 27 did not provide any substantive resolution of the issues. Rather, Article 27 created a process for further discussion of the issues after the BSP became effective as an international agreement. Article 27 reads as follows:

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years."<sup>238</sup>

By its terms, the BSP would become effective ninety days after the fiftieth country had ratified the BSP. This occurred in September 2003.

The Article 27 process began in October 2004, when the Secretariat CBD convened a meeting of technical experts on liability and redress. The technical experts had the task of preparing the background material necessary for the first full meeting of the Open-ended Ad-Hoc Working Group of Legal and Technical Experts on Liability and Redress meeting in May 2005<sup>239</sup>.

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<sup>237</sup> While the official history of the negotiations is the document cited in the preceding footnote, the better feel for the contentiousness is found in C. Bail, R. Falkner & Helen Marquard, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?* (2002). With respect to Article 27 specifically, read W. Damena, *Liability and Redress*, Ch. 40 at 366-370 in C. Bail et al, *id.*; and, K. Cooke, *Liability: "No Liability, No Protocol,"* Ch. 41 at 371-384 in C. Bail et al, *id.*

<sup>238</sup> Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes, Art. 27 at 20 (Secretariat CBD, 2000), available at <http://www.bio-div.org>. [hereafter BSP]

<sup>239</sup> Report of the Technical Group of Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, UNEP/CBD/BS/TEG-L&R/1/3 (18-20 Oct 2004), available at <http://www.biodiv.org/doc/meeting.aspx?mtg=BSTELR-01>. [hereafter Technical Group]

The discussions at the October 2004 meeting addressed many distinct issues. For



At the October 2004 meeting, the Technical Group focused on three broad areas: first, potential damage scenarios; second, the application of international rules and procedures; and third, the elaboration of options for rules and procedures.<sup>240</sup>

Regarding damage scenarios, the Technical Group built upon damage scenarios developed by a Workshop on Liability and Redress in the Context of the Cartagena Protocol on Biosafety, that occurred in December 2002.<sup>241</sup> The Technical Group discussion highlighted three types of damage: damage to property; damage to human health; and damage to the environment (with damage to biodiversity as a sub-category of damage to the environment).<sup>242</sup>

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example, the Technical Group discussed the scope of the BSP Article 27 – whether it should be read broadly to apply to all international shipments, transit through countries, handling and use within specific countries, or narrowly to apply only to international shipments of genetically modified organisms. *Id.* at ¶ 27 and Annex II. Scope of “Damage Resulting from Transboundary Movements of LMOs.” For the purposes of this article, the authors desire to keep the focus on scenarios of liability and the types of damage. Hence, the authors of this article purposefully do not discuss many issues discussed at the Technical Group or at the Open-Ended Ad-Hoc Working Group [hereafter Working Group]. The report of the Working Group is fully cited *infra* note 253.

<sup>240</sup> Agenda Item 4 of the October 2004 meeting reads as follows:

4. Consideration of issues on liability and redress pursuant to Article 27 of the Protocol:
  - 4.1. Analysis of general issues relating to:
    - (a) The potential and/or actual damage scenarios of concern that may be covered under the Protocol in order to identify the situations for which international rules and procedures referred to in Article 27 of the Protocol may be needed;
    - (b) The application of international rules and procedures on liability and redress to the damage scenarios of concern that may be covered under Article 27 of the Protocol;
  - 4.2. Elaboration of options for elements of rules and procedures referred to in Article 27 of the Protocol. *Id.* at ¶ 10.

<sup>241</sup> *Id.* at ¶ 20.

<sup>242</sup> *Id.* at ¶¶ 23-24.

However, the discussion also emphasized socio-economic damages, including spiritual and cultural aspects of socio-economic damages.<sup>243</sup>

Regarding the application of existing international and/or regional agreements to transgenic organisms as covered under Article 27, the Technical Group identified numerous international and regional agreements that might serve as models or sources of provisions for Article 27.<sup>244</sup> However, the Co-Chair noted that none of these agreements specifically addressed liability and redress for damage that could result from transboundary movements of genetically modified organisms.<sup>245</sup>

Interestingly the Technical Group did not identify two other international agreements that appear relevant. No mention was made of the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization, where Article 2.3 states:

Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including

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<sup>243</sup> *Id.* at ¶¶ 25.

<sup>244</sup> International instruments identified included:

- the work of the International Law Commission on international liability for the injurious consequences arising out of acts not prohibited by international law;
- existing agreements on the transportation of hazardous goods such as nuclear waste and the Hague Conference on Private International Law.

Regional instruments included:

- The Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment;
- Directive 2004/35/EC of the European Parliament, the Council on Environmental Liability with regard to the Prevention and Remedying of Environmental Damage;
- the Nordic Environmental Protection Convention; and
- the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters. *Id.* at ¶¶ 32-36.

<sup>245</sup> *Id.* at ¶ 36.

between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."<sup>246</sup>

Nor did the Technical group mention of the International Plant Protection Convention Article 1.4

which reads:

Where appropriate, the provisions of this Convention may be deemed by contracting parties to extend, in addition to plants and plant products, to storage places, packaging, conveyances, containers, soil and any other organism, object or material capable of harbouring or spreading plant pests, particularly where international transportation is involved.<sup>247</sup>

While neither of these international agreements pertain directly to international liability, they deal with it indirectly through the ability to use the dispute settlement mechanism of the World Trade Organization (WTO).<sup>248</sup>

Regarding the options for elements of rules and procedures, the Technical Group compiled an extensive list of topics with multiple options under each topic: definition and nature of damage; scope of damages; valuation of damage; threshold of damage; causation; channelling

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<sup>246</sup> World Trade Organization (WTO), Agreement on the Application of Sanitary and Phytosanitary Measures.

<sup>247</sup> International Plant Protection Convention.

<sup>248</sup> Disagreement between two WTO parties (i.e. countries) regarding the Sanitary and Phytosanitary (SPS), the Technical Barriers to Trade (TBT), and GATT can be resolved through the use of the WTO dispute settlement mechanism. Thus, Argentina, Canada and the United States brought a complaint against the European Union about their legal regime for agricultural biotechnology and its products. The complaining countries sought a ruling against the EU for loss of export markets in violation of the SPS, the TBT, and GATT – international agreements governing international trade between parties. The WTO Panel ruled substantially in favor of Argentina, Canada and the United States. WTO Interim Report of the Panel, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, 1029-1031 WT/DS291/Interim (7 Feb 2006) (¶¶ 8.1 to 8.10 present the overview of the conclusions and recommendations).

of liability; mechanisms of financial security; standing or the right to bring claims; choice of instruments; settlement of claims; limitations on liability; and non-parties to the BSP.<sup>249</sup>

Specifically with respect to definition and nature of damage, the Technical Group identified the following optional components:

- damage to environment;
- damage to conservation and sustainable use of biological diversity;
- damage to human health;
- socio-economic damage, especially in relation to indigenous and local communities;
- traditional damage of loss of life or personal injury, loss of property or damage to property, and loss of income;
- cost of response measures.<sup>250</sup>

The Technical Group forwarded its report with annex of options to the first meeting of the Open-ended Ad-Hoc Working Group of Legal and Technical Experts on Liability and Redress for consideration.<sup>251</sup> But as the Technical Group forwarded the report, the Technical Group identified several areas where additional information regarding liability and redress of transboundary movements of genetically modified organisms would benefit the larger Working Group.<sup>252</sup> Reading these recommendations for additional information, two points are of

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<sup>249</sup> Technical Group, *supra* note 239 at ¶¶ 37-113 and Annex.

<sup>250</sup> *Id.* at Annex, III. Damage: A. Optional components for the definition of damage.

<sup>251</sup> *Id.* at ¶ 117.

<sup>252</sup> In the recommendations section of the Technical Group report, the following were identified as areas where additional information was needed:

- The scientific analysis and assessment of risks involved in the transboundary movement of living modified organisms in respect of which reference was made to the ongoing work under the Biosafety Protocol;
- The determination of damage to the conservation and sustainable use of biodiversity in respect of which reference was made to the definition of biodiversity loss in paragraph 2 of decision VII/30 of the Conference of Parties to the Convention on Biological Diversity as well as the on-going work on the framework of indicators under that Convention;

particular importance for this article: the need for additional information on the determination of damage to the conservation and sustainable use of biodiversity and the need for additional information on the determination of socio-economic damage. By commenting on the need for additional information on these two points, the Technical Group highlighted (purposefully or unintentionally) how vague and ill-defined these two types of damages are.

In the opening address to the meeting of the Working Group in May 2005, Dr. Hamdallah Zedan, Executive Secretary of the Convention on Biological Diversity (CBD), indicated that the Working Group's task was to "analyse relevant issues and elaborate options for elements of international rules and procedures on liability and redress with a view to building understanding and consensus on the nature and contents of those rules and procedures."<sup>253</sup>

The meeting agenda adopted by the Working Group had two items directly relating to an international liability and redress regime – Agenda Item 3 and Agenda Item 4.<sup>254</sup>

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- The determination of socio-economic damage in respect of which reference was made to the ongoing work under Article 26 of the Biosafety Protocol;
  - The availability of financial security to cover liability resulting from the transboundary movement of living modified organisms and the prices at which such financial security is available;
  - The status of treaties that provide for third-party liability, including the number of Parties and Signatories; relevant dates where possible; and an analysis of reasons why several of those treaties have not entered into force;
  - Recent developments in international law relating to liability and redress, including soft law;
  - The work under the International Law Commission with respect to State responsibility and State liability.

<sup>253</sup> Report of the Open-ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress under the Cartagena Protocol on Biosafety, UNEP/CBD/BS/COP-MOP/2/11 (May 2005), available at <http://www.biodiv.org/biosafety/issues/liability2.aspx#>. [hereafter Working Group]

<sup>254</sup> Agenda item 3 stated, "Review of information relating to liability and redress for damage resulting from transboundary movements of living modified organisms."

In addressing Agenda Item 3, two separate presentations were made to the Party representatives and other participants. The first was made by Ms. Muffy Koch and Mr. Piet van der Meer, experts on risk analysis and assessment of transgenic organisms, explaining the scientific analysis and assessment of risk involved in the transboundary movement of genetically modified organism.<sup>255</sup> Mr. Dan Ogolla, of the CBD Secretariat, made the second presentation on state responsibility and state liability.<sup>256</sup> Mr. Ogolla clarified that in international law the words “state responsibility” refer to a breach of an international duty (i.e. an internationally wrongful act) arising from an international legal obligation.<sup>257</sup> By contrast, Mr. Ogolla explained that in international law the words “state liability” refers to reparation or compensation for a harm arising from acts not prohibited by international law.<sup>258</sup> In accordance with its terms, the BSP creates a system for the international transboundary movement of genetically modified organisms. Hence, if states were made liable under Article 27 Liability and Redress, the term

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Agenda item 4 was identical to agenda item 4 from the meeting of the Technical Group. Read agenda item 4 *supra* note 239.

<sup>255</sup> Working Group, *supra* note 253 at ¶¶ 22-23. The presentation by Ms. Koch and Mr. van der Meer responded to the Technical Group’s recommendation that the Working Group have additional information on scientific analysis and risk assessment. See the first bullet point set forth *supra* note 252.

<sup>256</sup> Working Group, *supra* note 253 at ¶ 27.

<sup>257</sup> *Id.*

<sup>258</sup> *Id.* The report of Mr. Ogolla responded to the Technical Group’s recommendation that the Working Group have additional information on state responsibility and state liability. See the last bullet point set forth *supra* note 252.

“state

liability” is the terminology to apply to any responsibility that may accrue from this lawful transboundary movement.<sup>259</sup>

The Working Group used four sessions over three days to address Agenda Item 4. As a result of its deliberations, the Working Group adopted an annex that expanded the options related to liability and redress that would be on the table for discussion at the second meeting of the Working Group in February 2006.<sup>260</sup> In the Annex to the Report of the first meeting, the Working Group identified the options related to components of damage as follows:

- damage to conservation and sustainable use of biological diversity or its components;
- damage to environment, including damage to conservation and sustainable use of biological diversity or its components, impairment of soil quality, impairment of water quality, impairment of air quality;
- damage to human health, including loss of life or personal injury, loss of income, public health measures, impairment of health;
- socio-economic damage, especially in relation to indigenous and local communities, including loss of income, loss of cultural, social and spiritual values, loss of food security, loss of competitiveness;
- traditional damage, including loss of life or personal injury, loss of or damage to property, economic loss;
- cost of restorative measures.<sup>261</sup>

In addition, the Working Group added an Option 6 to the choice of instruments: No instrument.

Option 6 would allow the Working Group to conclude, in accordance with the language of

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<sup>259</sup> For additional discussion of the distinction between state responsibility and state liability, read Note of the Executive Secretary, Liability and Redress in the Context of Paragraph 2 of Article 14 of the Convention on Biological Diversity: An Analysis of Pertinent Issues, UNEP/CBD/EG-L&R/1/2 (12-14 Oct. 2005) ¶¶ 7-15. [hereafter Note of the Executive Secretary].

<sup>260</sup> Working Group, *supra* note 253 Annex and ¶ 45.

<sup>261</sup> *Id.* at Annex: II. Damage: A. Optional components for the definition of damage.

Article 27, that no international liability and redress regime was the “appropriate elaboration” of Article 27.<sup>262</sup>

While the parties to the BSP are discussing Article 27 liability and redress, the parties to the Convention on Biological Diversity (CBD) are discussing a separate, but parallel and cross-fertilizing, liability and redress regime under CBD Article 14 paragraph 2.<sup>263</sup> Article 14 paragraph 2 states:

The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is purely an internal matter.”<sup>264</sup>

Although the text of the CBD emerged from Rio de Janeiro in 1992 and the Conference of the Parties of the CBD meet for the first time in 1994, little progress has been made regarding the issue of liability and redress under Article 14 paragraph 2. As the Report of the Group of Legal and Technical Experts from the October 2005 meeting makes clear, the experts have significant disagreements about many issues related to Article 14 paragraph 2. Specifically relevant to this article, the Legal and Technical Experts evidenced significant disagreement about

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<sup>262</sup> *Id.* at Annex: XII. Choice of Instrument, Option 6. Several delegates objected to the inclusion of Option 6 in the Working Group. *Id.* at ¶ 52.

<sup>263</sup> Report of the Group of Legal and Technical Experts on Liability and Redress in the Context of Paragraph 2 of Article 14 of the Conventions on Biological Diversity, UNEP/CBD/COP/8/27/Add.3 (18 October 2005) at ¶ 14. [hereafter Legal and Technical Experts]. The COP-CBD will consider this Report at its eighth meeting in Curitiba, Brazil in March 2006.

At the October 2005 meeting of the Legal and Technical Experts, the Co-Chair of the Working Group on BSP Article 27 made a report about the discussions related to liability and redress under the BSP. *Id.* at ¶¶ 11-14.

<sup>264</sup> Convention on Biological Diversity, Art. 14.2, available at <http://www.biodiv.org>.



environment,<sup>265</sup>

- the definition of damage to biological diversity or damage to the environment;<sup>265</sup>
- the threshold of damage that should exist before liability can arise;<sup>266</sup>
- the appropriateness of developing a liability and redress regime for the CBD;<sup>267</sup>

and

- the scope of a liability and redress regime for the CBD in light of exclusion in Article 14 paragraph 2 of “purely internal matters.”<sup>268</sup>

Moreover, some experts pointed out that the background document<sup>269</sup> prepared by the CBD Secretariat for the Legal and Technical Experts relied on literature that “lacked an authoritative scientific basis.”<sup>270</sup> The Legal and Technical Experts regarding Article 14 paragraph 2 ended

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<sup>265</sup> *Id.* at ¶¶ 19-22 and 29.

<sup>266</sup> *Id.* at ¶¶ 30-32.

<sup>267</sup> *Id.* at ¶¶ 43-51. In ¶ 44, the document reports that “a number of experts suggested that a general liability regime might not be appropriate, given the complexity of the issues, the broad range of activities and the difficulty in defining damage to biological diversity.”

<sup>268</sup> *Id.* at ¶ 33.

<sup>269</sup> Note of the Executive Secretary, *supra* note 263.

<sup>270</sup> Legal and Technical Experts, *supra* note 261 at ¶ 17.

In the background Note, the Executive Secretary referred to a Friends of the Earth International statement and David Quist & Ignacio H. Chapela, 2001. Transgenic DNA introgressed into Traditional Maize Landraces in Oaxaca, Mexico, *NATURE* vol.414, p. 541. Note of the Executive Secretary, *supra* note 263 at ¶ 34. However, the Secretariat failed to inform the delegates that the editors of *Nature*, in a subsequent edition, had written, “In light of these discussions [about the Quist/Chapela article] and the diverse advice received, *Nature* has concluded that the evidence available is not sufficient to justify the publication of the original paper. As the authors nevertheless wish to stand by the available evidence for their conclusions, we feel it best simply to make these circumstances clear, to publish the criticisms, the author’s response and new data, and to allow our readers to judge the science for themselves.” 416 *NATURE* 600-601 (2003).

Moreover, in a scientific study published after the Executive Secretary had prepared the Note for the Legal and Technical Experts, scientists found no evidence in 2003 and 2004 that Mexican maize had any introgression of transgenic material. S. Ortiz-García et al., Absence of Detectable Transgenes in local landraces of maize in Oaxaca, Mexico (2003-2004), Proceedings of the National Academy of Sciences (2005). However, by October 2005 when the Legal and Technical Experts met, the S. Ortiz-García et al. study was widely known, giving further

their report with an Annex of Conclusions, without any setting forth of options for further consideration, that by what it says and what it does not say evidences how far the COP-CBD is from reaching any consensus about a liability and redress regime under Article 14 paragraph 2.

Having presented a review of the on-going discussions about liability and redress under BSP Article 27 and CBD Article 14 paragraph 2, this article now turns to the potential legal and economic implications of pursuing such an international regime. The article will first address the legal interpretation of an international liability and redress regime, using the components for the definition of damage presented by the Working Group on BSP Article 27,<sup>271</sup> as applied to the five scenarios presented in discussing the domestic legal regimes of Canada, Denmark, Germany, and the United States. Following the legal discussion of the scenarios, this article will present an economic perspective on the implementation of such a regime.

### Civil Liability

The Working Group specified the possible components of the definition of damage as follows:

- damage to conservation and sustainable use of biological diversity or its components;
- damage to environment, including damage to conservation and sustainable use of biological diversity or its components, impairment of soil quality, impairment of water quality, impairment of air quality;
- damage to human health, including loss of life or personal injury, loss of income, public health measures, impairment of health;

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credence to the *Nature* 2003 statement that the evidence in 2001 did not justify the publication of the original paper. Thus, experts referred to in ¶ 17 were correct to point out the lack of authoritative scientific basis for the literature cited by the Executive Secretary both before and after the Executive Secretary prepared the Note.

<sup>271</sup> Working Group, *supra* note 253 at Annex: II. Damage: A. Optional Components for the definition of damage

- socio-economic damage, especially in relation to indigenous and local communities, including loss of income, loss of cultural, social and spiritual values, loss of food security, loss of competitiveness;
- traditional damage, including loss of life or personal injury, loss of or damage to property, economic loss;
- cost of restorative measures.<sup>272</sup>

Scenario One: Claim for damages arising from an unapproved transgenic crop mixing with commercial agricultural crops.

Scenario Two: Claim for damages arising from an approved transgenic crop mixing with non-transgenic crops resulting in a loss of a premium for a person or company who intended to sell a non-transgenic commodity or food product.

Scenario Three: Claim for damages arising from an approved transgenic crop mixing with organic crops resulting in a loss of the organic label for the specific organic crop or of organic certification for the organic farmer's farm.<sup>273</sup>

Scenarios One, Two, and Three fit within the Working Group component of “traditional damage, including loss of life or personal injury, loss of or damage to property, economic loss.”

Thus, Scenarios One, Two, and Three would be covered by the international liability and redress regime of Article 27, if this traditional damage component were adopted as part of the regime.

But the question remains, should traditional damage become part of the international regime?

CBD Article 14 paragraph 2 explicitly states that its studies are about liability and redress for “damage to biological diversity, except where such liability is purely an internal matter.”

BSP Article 27 is explicitly about “liability and redress for damage resulting from transboundary movement” of genetically modified organisms. By the language of these two provisions, it seems unlikely that traditional damages should be part of any international liability regime for several reasons.

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<sup>272</sup> *Id.*

<sup>273</sup> M. Migus, *supra* note 28.

As previously shown in this article, Canada, Denmark, Germany and the United States all have statutes or case law dealing specifically with traditional damage – unapproved crops entering the market, personal injury, property damage, and economic loss (“pure economic loss”). Moreover, these countries do not deal with Scenarios One, Two and Three in the same manner. Wide disparities exist between the domestic law regimes of these four countries, particularly with respect to liability for adventitious presence and for “pure economic loss.” Hence, to include traditional damage within an international liability and redress regime would require a harmonization of domestic laws that is highly unlikely to occur. More to the point, if countries are unwilling to harmonize their domestic laws, these countries are unlikely to agree to a consensus for an international liability and redress regime.<sup>274</sup>

In addition, including traditional damage within an international liability and redress regime may significantly displace domestic liability and redress regimes that individual nations have developed from their own legal traditions and political history and compromises. While it is possible to imagine traditional damage occurring from transboundary movements, it is much more likely that pollen flow between fields or unapproved release will occur within a particular county – geographically internal to a particular country. Countries are more likely to consider these liability and redress concerns as purely internal matters related to that country’s particular rules about coexistence and product liability.

The legal systems of most countries, even if additional capacity building for development of legal systems would be helpful to some countries, are familiar with and competent to handle

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<sup>274</sup> For fuller discussion of the difficulties of harmonization and agreement, Katharina Kummer Peiry, Biosafety Protocol Process on Liability and Redress: Food for Thought on Key Issues – Paper No. 14, Why Have Existing Civil Liability Treaties Failed to Enter into Force? (21 Feb 2006), available at [www.econsult.ch](http://www.econsult.ch).

traditional damage such as set forth in Scenarios One, Two and Three. To include traditional damage such as Scenarios One, Two and Three in an international liability and redress regime seems unnecessarily duplicative of already functioning regimes, and complicating for reaching agreement under Article 27.

Furthermore, traditional damage such as set forth in Scenarios One, Two and Three has little if anything to do with damage to biological diversity. Claims for loss of premiums arising from labeling laws or organic production have nothing to do with biological diversity. These claims about premiums are purely claims arising from competing, alternative approaches to agriculture. Claims arising from unapproved crops mixing with commercial agriculture come from regulatory laws that are not focused on biological diversity but on risk assessment and risk management (in which environmental impacts are assessed and managed).

The best option for Scenarios One, Two and Three is the “no option,” – that is, to have no international liability and redress regime addressing traditional damage.<sup>275</sup>

Scenario Four. Claim for damages arising from the loss of market access. For example, where a buyer decides against buying a farmer’s crop even though there was no evidence of transgenic material or the evidence of transgenic material was below legally-set thresholds.

Scenario Five. Claim for damages arising from a decision by a farmer to forgo planting a particular crop because of concern about proximity to transgenic crops or market perception about transgenic crops.<sup>276</sup>

Scenarios Four and Five could fit within the Working Group component of “traditional damage, including ... economic loss.” Treating Scenarios Four and Five as traditional damage

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<sup>275</sup> For a conclusion on similar grounds that traditional damage should be excluded from any Article 27 liability and redress regime, K. Holtby, *International Liability and Trade in Genetically Modified Products – Possibility or Improbability?*, Ch. 3 Theoretical Model, 3.1 Background, especially pp. 86-87, Thesis for the Degree of Master of Science, University of Saskatchewan Library (2005). [hereinafter Holtby Thesis].

<sup>276</sup> UK REPORT: GM Crops?, *supra* note 35 at p. 4 suggesting Scenarios Four and Five.

(economic loss) would be treating Scenarios Four and Five under Article 27 as these two scenarios were treated in the discussions of the domestic legal regimes of Canada, Denmark, Germany, and the United States. In those domestic legal regimes, Scenarios Four and Five raised the issue of whether the legal system compensated for “pure economic loss.” As the discussion of those domestic legal regimes indicated, those legal regimes generally do not compensate for pure economic loss, except for the 2004 amendments to the GenTG of Germany. If Scenarios Four and Five were classified as traditional damage (economic loss) under the Working Group components for Article 27, the discussion presented about Scenarios One, Two, and Three under Article 27 would be equally applicable to Scenarios Four and Five. Moreover, for the same reasons as presented with regard to Scenarios One, Two and Three under Article 27, the same conclusion should also follow – that is, to have no international liability and redress regime addressing traditional damage.

However, Scenarios Four and Five may better fit within the Working Group component of “socio-economic damage, especially in relation to indigenous and local communities, including loss of income, loss of cultural, social and spiritual values, loss of food security, loss of competitiveness.” Thus, Scenarios Four and Five would be covered by the international liability and redress regime of Article 27, if this socio-economic component were adopted as part of the regime. But the question remains, should socio-economic damage become part of the international regime?

Including socio-economic damage within the Article 27 liability and redress regime (particularly when including loss of income, loss of cultural-social-spiritual values, and loss of competitiveness) is equivalent to making those who are engaged in production and export of

genetically modified organisms pay for the changes which inevitably will occur with the introduction of any new technology. In both the Report of the Technical Group and the Report of the Legal and Technical Experts, various delegates commented that the liability and redress regime should not make a legally responsible party (be that party a Nation State, a corporation, or an individual human being)<sup>277</sup> legally accountable for change alone.<sup>278</sup> Indeed, those countries and companies engaged in the development, production, and export of genetically modified organisms may well have pride in their innovativeness and perceive no reason why they should compensate those who have failed to remain competitive, who feel they have lost income, or who feel that their cultural-social-spiritual values have been affected.

It is not obvious why Brazil, China or India, each with exceptionally talented agricultural biotechnology scientists and exceptionally strong agricultural biotechnology research programs,<sup>279</sup> should compensate another nation claiming non-competitiveness (including loss of income) or cultural-social-spiritual change because of imported Brazilian, Chinese, or Indian

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<sup>277</sup> The Working Group identified the options for channelling of liability as follows:

- state responsibility for internationally wrongful acts;
- primary state liability for acts even if in full compliance with the obligations of the BSP;
- residual state liability in combination with primary liability of operator for acts even if in full compliance with the obligation of the BSP;
- no state liability but with civil liability for one or more of the following persons, including the developer, the producer, the notifier, the exporter, the importer, the carrier, or the supplier. Working Group, *supra* note 253 at IV. Channelling of Liability, Role of Parties of Import and Export, Standard of Liability.

<sup>278</sup> Technical Group, *supra* note 239 at ¶ 27; Legal and Technical Experts, *supra* note 263 at ¶ 19.

<sup>279</sup> Even if the BSP Article 27 negotiators choose not to make Nation states liable, Brazil, China and India could still be liable through the civil liability options as a developer, producer, notifier, or exporter of their transgenic crops created through public research.

transgenic plants or materials as crops for farmers to grow or as commodities for food or feed.<sup>280</sup>

More pertinently, it is not obvious why Brazil, China and India would agree to an international liability and redress regime that would expose their public research institutions to being held legally accountable for socio-economic damage.

In October 2004, Mr. René Lefeber, Co-Chair of the Technical Group, pointed out that third-party liability (e.g. developer, producer, etc.) had been contentious in prior negotiations and cautioned the negotiators “to learn from past experience with a view to preventing the adoption of rules and procedures on liability and redress under Article 27 of the Protocol that would not become operational.”<sup>281</sup> At the CBD Article 14 paragraph 2 negotiations, the Note of the Executive Secretary highlighted that a significant number of international liability and redress

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<sup>280</sup> Brazil: Embrapa (Brazilian Agricultural Research Company) has made a strategic decision to become a creator of transgenic crops. As of January 2006, Embrapa has created fourteen transgenic species that are ready for commercialization to farmers in Brazil and around the world. Eduardo Mamcasz, Brazil’s state firm Embrapa creates 14 transgenic species. Seeds are for sale, BRAZZIL MAGAZINE (Jan 2006), [www.brazzilmag.com](http://www.brazzilmag.com).

China: At the 7<sup>th</sup> Asian-Pacific Economic Conference (APEC) in Beijing on December 2, 2003, Mr. Zhang Fengtong, Ministry of Agriculture-Department of Science and Education, explained that the Chinese governmental program in agricultural biotechnology involved more than 100 different genes and 130 different plant species. AgBioView Listserve (8 Dec. 2003). Moreover, it has been reported that the Chinese government has invested \$180 million dollars into biotechnology from 1996 to 2000 and has plans to invest another \$600 million between 2000 and 2005 in 300 publicly-funded laboratories employing 20,000 researchers. Anon, Chinese Biotechnology: Biotech’s Yin and Yang, THE ECONOMIST (Dec. 12, 2002).

India: In March 2004, India commercialized the first transgenic cotton developed by Indian researchers at the National Botanical Research Institute (NBRI). Simultaneously, NBRI stated its intentions to patent the transgenic cotton in other countries and to export the cotton and the technology. K. Jayaraman, India Produces Homegrown GM Cotton, 22 NAT. BIOTECH. 255 (2004). Also in March 2004, the Indian Council of Agricultural Research (ICAR) decided to develop transgenic varieties of 14 selected crops, specifically rohu, catfish, rice, sorghum, maize, pigeonpea, chickpea, cotton, tomato, brinjal, soybean, potato, banana, and papaya. Anon, ICAR to develop transgenic kind of 14 crops, INDIAN EXPRESS NEWS (10 Mar 2004).

<sup>281</sup> Technical Group, *supra* note 239 at ¶¶ 8 and 36.



regimes had not become effective despite the passage of many years since adoption in negotiations.<sup>282</sup> Including socio-economic damage within any Article 27 liability and redress regime may well doom the regime from every becoming operational. Or in the alternative, if an Article 27 liability and redress regime became operational, countries that become developers, producers and exporters of transgenic crops and animals would have an enormous incentive to withdraw from the BSP in order to terminate its consent to being held accountable for socio-economic damage.<sup>283</sup>

Leaving aside whether including socio-economic damage is wise, a more fundamental question may be whether the inclusion of socio-economic damages within the Article 27 liability and redress regime is legally permissible under the BSP.

The word “socio-economic” appears in only one article of the BSP. Article 26 **Socio-Economic Considerations** reads in full:

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol,

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<sup>282</sup> Note of the Executive Secretary, *supra* note 263 at ¶ 40. The Executive Secretary listed the 1977 Convention on Civil Liability for Oil Pollution Damage resulting from Exploration for and Exploitation of Seabed Mineral Resources; the 1996 International Convention on Liability and Compensation for Damage in connection with the Carriage of Hazardous and Noxious Substances by Sea; the 1999 Basel Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and Their Disposal; the 1989 Convention on Civil Liability for Damage caused during Carriage of Dangerous Goods By Road, Rail and Inland Navigation Vessels; and the 1993 Lugano Convention. *Id.*

<sup>283</sup> BSP, *supra* note 238 Article 39 Withdrawal. Parties can withdraw from the BSP by giving notice and the passage of one year from the date of receipt of the notice by the Secretariat.

Of course, a particular nation, even if it had developed, produced, or exported transgenic organisms, would have no incentive to withdraw if the nation were willing to abandon its agricultural biotechnology investments and innovations. At that point, such nation would probably be looking to make money from agricultural biotechnology by becoming a claimant for socio-economic damage.

may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.<sup>284</sup>

Reading the language of Article 26 clearly shows that socio-economic considerations may be taken into account in “reaching a decision on import” and “to cooperate on research and information exchange” about impacts of transgenic crops. Article 26 allows socio-economic considerations only for these two reasons. Nowhere does Article 26 indicate that socio-economic considerations are permissible for any other reason under the BSP. Nowhere does either the language of Article 26 or Article 27 authorize the consideration of socio-economic impacts as a form of damage for a liability and redress regime.<sup>285</sup>

In other words, under Article 26, countries may take into account socio-economic considerations in making the decision on import. But once the country has made the decision on import, the country has accepted the transgenic organism along with the change that the introduction of new technology brings. Countries should not be allowed to consent on import and then later claim that any resulting change arising from that consent should now result in liability and redress under Article 27. Under Article 26 countries may choose either to have

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<sup>284</sup> BSP, *supra* note 238 at Article 26.

<sup>285</sup> Similarly one expert at the CBD Article 14 paragraph 2 discussions stated that socio-economic damage fell outside the mandate of the Group because socio-economic damage was not within the scope of Article 14 paragraph 2. Legal and Technical Experts, *supra* note 263 at ¶ 25.

agricultural biotechnology or to decline agricultural biotechnology but they cannot later attempt to recover for socio-economic damage resulting from the decision that the country has made.<sup>286</sup>

In addition to the very limited, explicitly-stated reasons for which socio-economic considerations are relevant by the language of BSP Articles 26 & 27, the history of the negotiations of Article 26 also indicates that socio-economic considerations are not permissibly a type of damage for liability and redress. At one point in the BSP negotiations, proponents of socio-economic considerations were able to get an option included for negotiation which option would have allowed socio-economic considerations “to be taken into consideration at all levels of this Protocol.”<sup>287</sup> When no agreement could be reached on that option, the Chair proposed a text which circumscribed socio-economic considerations to language quite similar to the present Article 26. As the Record of the Negotiations then reports,

Although many delegations, especially developing countries, were initially unhappy with the Chair’s proposed text, the wording on

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<sup>286</sup> For example, if a country denied import of agricultural biotechnology from Brazil, China or India under Article 26, the authors think it would seem surprisingly strange for that country to be allowed under Article 27 to claim liability and redress against Brazil, China or India for loss of competitiveness because Brazil, China or India proceeded ahead with agricultural biotechnology while the country denying import decided not to utilize agricultural biotechnology.

However, proponents of socio-economic damages have consistently attacked agricultural biotechnology on the ground, among others, that agricultural biotechnology could lead to substitution products – i.e. agricultural products produced from transgenic agriculture more cheaply – and that the substitution product could replace export products grown by conventional and organic agriculture. The argument for socio-economic damage by the country denying import is now clear. Transboundary movement of transgenic crops – i.e. the substitute products being purchased in international trade – has caused socio-economic damage to the countries without the technology. Therefore, the developer, producer, exporter should bear the market loss (loss of competitiveness) of the country that does not have the transgenic crop. Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* ¶ 4.31 (1999).

<sup>287</sup> Record of the Negotiations, *supra* note 236 at 80.

socio-economic consideration was ultimately accepted with little discussion.<sup>288</sup>

As it appears unwise to declare change itself to be a type of damage, and as it appears that socio-economic considerations are not permissibly a type of damage within the remit of Article 27, the best option for Scenarios Four and Five is the “no option,” – that is, to have no international liability and redress regime addressing socio-economic considerations.<sup>289</sup>

Scenario Six: (Option one) Damage to conservation and sustainable use of biological diversity and its components; (Option two) Damage to environment, including damage to conservation and sustainable use of biological diversity or its components, impairment of soil quality, impairment of water quality, impairment of air quality.

Scenario Seven: Damage to human health, including loss of life or personal injury, loss of income public health measures, impairment of health.<sup>290</sup>

Scenarios Six and Seven were not explicitly discussed previously with respect to civil legal liability within the domestic legal regimes of Canada, Denmark, Germany, and the United States. However, these two scenarios were indirectly addressed under the heading of Administrative Liability for each of the domestic legal regimes analyzed in this article.<sup>291</sup> What is distinctive about Scenarios Six and Seven within the context of Article 27 liability and redress is that the Article 27 negotiations are considering Scenarios Six and Seven as types of damage for

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<sup>288</sup> *Id.* at 80-81.

<sup>289</sup> For a conclusion on similar grounds that socio-economic considerations should be excluded from any Article 27 liability and redress regime, Holtby Thesis, *supra* note 275, Ch. 3 Theoretical Model, 3.1 Background, especially pp. 86-88.

<sup>290</sup> Scenarios Six and Seven are taken from the Working Group options. Working Group, *supra* note 253 at Annex: II. Damage: A. Optional Components for the definition of damage.

<sup>291</sup> For discussion of Administrative Liability within the several domestic legal regimes analyzed in this article, read text and accompanying notes 69-96 *supra* (Canada and the United States), text and accompanying notes 147-150 *supra* (Denmark), and text and accompanying notes 208-232 *supra* (Germany).

civil legal liability. When this article earlier discussed, in an indirect fashion, Scenarios Six and Seven, the article did so as part of administrative liability (i.e. as part of public regulatory schemes) and not as part of a claim for damage as liability and redress.

Scenario Six has two options that need clarification – Option one solely on biological diversity; Option two on environmental damage that subsumes biological diversity as a subtype of environmental damage. Option one solely on biological diversity aims to focus on damage to the variability of species and habitats before and after the introduction of transgenic agriculture. Option two focuses on the damage to specific components of the environment (e.g. soil quality, water quality, air quality) and, by working to remedy soil, water, and air quality, to protect the habitats and their species, both of which are components of biological diversity.<sup>292</sup>

Scenario Seven also requires clarification. Scenario Seven aims to focus not on short-term human health reactions to transgenic crops, such as an immediate allergic reaction, because these short-term human health concerns would be covered by traditional damage as personal injury. Rather, Scenario Seven aims to focus on long-term human health reactions to transgenic crops, such as medical problems from long-term exposure resulting in death, health impairment, or loss of quality of life. Scenario Seven differs from traditional damage by the time-scale (the long-term) meant to be encompassed within Scenario Seven.<sup>293</sup>

Scenarios Six and Seven would be covered by the international liability and redress regime of Article 27, if biological diversity damage and/or environmental damage, and human

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<sup>292</sup> Biological diversity as compared to environmental damage is discussed in Technical Group, *supra* note 239 at ¶¶ 39 & 46, in Note of the Executive Secretary, *supra* note 259 at ¶¶ 16-17, 38 and in Legal and Technical Experts, *supra* note 263 at ¶¶ 20-22.

<sup>293</sup> Technical Group, *supra* note 239 at ¶ 43 & 56; Note of the Executive Secretary, *supra* note 259 at ¶ 16.

long-term health concerns were adopted as part of the regime. But the question remains, should these types of damage become part of the international regime?

Some delegates to the meetings about liability and redress under either BSP Article 27 or CBD Article 14 paragraph 2 have pointed out that damage to biological diversity and environmental damage (Scenarios Six), as general terms, are overly broad and difficult to define because lacking concrete references,<sup>294</sup> likely to impose liability for change alone,<sup>295</sup> likely to impose liability for beneficial changes or insignificant harms unless a significant threshold of adverse impact modifies these terms,<sup>296</sup> and difficult to measure unless careful, accurate baseline studies exist.<sup>297</sup>

As a consequence of the difficulties with the concepts of biological diversity (pointed out in the preceding paragraph), the European Union in its Environmental Liability Directive chose to exclude consideration of biological diversity, as defined in the CBD, as a type of damage and linked damage to identifiable environmental components (soil, water, protected species,

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<sup>294</sup> Technical Group, *supra* note 239 at ¶ 42; Legal and Technical Experts, *supra* note 263 at ¶¶ 20, 28 & 48.

<sup>295</sup> Technical Group, *supra* note 239 at ¶ 27; Note of the Executive Secretary, *supra* note 259 at ¶ 19; Legal and Technical Experts, *supra* note 263 at ¶¶ 17 & 19.

<sup>296</sup> Note of the Executive Secretary, *supra* note 259 at ¶ 19; Legal and Technical Experts, *supra* note 263 at ¶¶ 29 & 31.

As pointed out by the Canadian judge in *Hoffman v. Monsanto Canada*, if the environmental damage is not limited to an adverse impact, environmental damage could be interpreted to include even kindly, gentle, favorable, and beneficial environmental effects. Read note 82 *supra* and its accompanying text. Of course such a result would be the imposition of legal liability for change alone.

<sup>297</sup> Report of the Technical Group, *supra* note 239 at ¶ 45, 55 & 57; Legal and Technical Experts, *supra* note 263 at ¶¶ 22 & 32.

protected habitats).<sup>298</sup> While the European Environmental Liability Directive uses the term “biological diversity,” the usage within the Liability Directive refers only to protected species and protected habitats. Thus, the Liability Directive’s biological diversity is much narrower than the term “biological diversity” in the CBD.<sup>299</sup>

With respect to both damage to biological diversity and/or the environment, and long-term human health damage, the issue of causation will be a very difficult issue. With the passage of many years – ten, twenty, thirty – years before countries or others<sup>300</sup> possibly make claims alleging damage to biological diversity, the environment, or long-term human health, delegates to the BSP Article 27 negotiations pointed out that identifying when a harm occurred, the complexities of causal interactions, and the responsible party(ies) would be a very difficult task

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<sup>298</sup> Note of the Executive Secretary, *supra* note 259 at ¶¶ 16 & 19; Legal and Technical Experts, *supra* note 263 at ¶ 21.

<sup>299</sup> For a fuller discussion of the European Environmental Liability Directive, read **Legal Liability: Germany Administrative Liability**.

<sup>300</sup> The authors do not discuss the issue as to who – e.g. countries, individual, corporations, or NGOs – will gain standing to bring a claim. In the 2<sup>nd</sup> meeting of the Working Group on Liability and Redress, the issue of standing was presented for discussion but no participant chose to speak to the issue. Obviously, standing is an issue that awaits much fuller development and debate. WGLR-2 Final, 9 (#345) EARTH NEGOTIATIONS BULL. 11 (27 Feb. 2006). *See also*, Katharina Kummer Peiry, *supra* note 274 at Paper No. 10 Only Persons or Entities Directly Impacted Can Bring a Claim (26 Apr 2005).

Moreover, if individuals, corporations, or NGOs are given standing to bring a claim, the authors do not discuss whether they could sue their own governments, under an Article 27 Liability and Redress regime, for causing the particular alleged loss because their own country, as an example, gave consent on the import of a transgenic crop.

These issues of standing and responsible parties are particularly important with respect to socio-economic damage. For example, read note 286 *supra*.

Of course individuals can use their countries’ domestic laws on coexistence and legal liability to seek recovery for alleged harms, as discussed in the comparative law sections of this article about the legal regimes of Canada, Denmark, Germany, and the United States.

for the international negotiations.<sup>301</sup> Mr. René Lefeber, Co-Chair of the BSP Article 27 negotiations, commented specifically that the issue of causation had most often been left to judicial determination during adjudication, rather than addressed in international agreements.<sup>302</sup>

The time-scale contemplated by Scenarios Six and Seven and the difficulty of causation flowing from this lengthy time-scale should be of particular importance to international negotiators. Since the adoption of the CBD in 1992 and the BSP in 2000, the two most prominent claims for human health and environmental damage have been shown to be without an authoritative scientific basis.

■ In the United States, in the aftermath of the commingling of *StarLink*<sup>TM</sup> corn, approved only for feed, with the food supply, several persons claimed allergic reactions to food products containing some remnant of *StarLink*<sup>TM</sup>. The U.S. Centers for Disease Control and Prevention (CDC) subsequently conducted appropriate tests and concluded that “findings do not provide any evidence that the reactions that the affected people experiences were associated with hypersensitivity to the Cry9c protein [the *StarLink*<sup>TM</sup> transgenic protein].”<sup>303</sup>

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<sup>301</sup> Technical Group, *supra* note 239 at ¶¶ 64, 66, 67;

<sup>302</sup> Technical Group, *supra* note 239 at ¶ 64; Legal and Technical Experts, *supra* note 263 at ¶ 36. Working Group, *supra* note 253 listed the causation options for further consideration as follows:

- level of regulation (international/or domestic level);
- establishment of the causal link between damage and the activity, including what test (foreseeability, direct/indirect damage, proximate cause, vulnerability clause), cumulative effects, and complexity of interaction of genetically modified organisms with the receiving environment and time scales involved;
- burden of proof, including relaxation of the burden of proof, reversal of the burden or proof, burden of proof on the exporter and importer. *Id.* at Annex: III. Causation.

<sup>303</sup> Centers for Disease Control and Prevention, Investigation of Human Health Effects Associated with Potential Exposure to Genetically Modified Corn (2001) (quoted words from the Executive Summary).



■ In Mexico, statements were made that transgenic corn had “contaminated” indigenous landraces, causing loss of biological diversity. Later developments (scientific criticism of the initial statements and a subsequent study) established that no traces of cross-pollination could be found and that, if any cross-pollination had ever occurred, that the cross-pollination had been reversed within two years.<sup>304</sup>

If international negotiators do not pay careful attention to the issues of time-scale and causation, the negotiators may allow numerous claims lacking an authoritative scientific basis to be brought against those to whom liability and redress are channelled.

More fundamental in consideration of whether Scenarios Six and Seven should become part of the international regime than the difficulties of definition, threshold, baseline, time-scale, and causation is the question of the nature of agricultural biotechnology. As some delegates to the negotiations emphasized, agricultural biotechnology (in its ten years of performance within commercial agricultural systems) has not given rise to any verified claim of environmental damage, loss of biological diversity, or human health problems.<sup>305</sup> Hence, to include Scenarios Six and Seven within the types of damages for which claims could be brought in any Article 27 liability and redress regime would be to give legal recognition to speculative claims – i.e. claims that have no present factual basis and no determinable probability of becoming factual in the future.<sup>306</sup>

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<sup>304</sup> For fuller discussion of this Mexican corn episode, read note 270 *supra*.

<sup>305</sup> Legal and Technical Experts, *supra* 263 at ¶ 17.

<sup>306</sup> Ms. Kareen Holtby, in her University of Saskatchewan Master’s Thesis, explains speculative risks. She writes, “Speculative risks are the least predictable. Like hypothetical risks, they have not been observed. However, their cause and effect relationship is not understood either. Thus, the probability of their occurrence cannot be assigned.” Holtby Thesis,

Additionally, as one CBD Article 14 paragraph 2 delegate stated, agricultural biotechnology is not inherently dangerous.<sup>307</sup> Negotiations for the creation of previous international liability and redress regimes have focused on inherently dangerous activities.<sup>308</sup> Even with respect to the international negotiations about liability and redress for acknowledged inherently dangerous activities, the negotiations have been contentious, slow-moving, and (even when a text has been produced) very difficult to bring into force as binding international agreements.<sup>309</sup> Hence, to include speculative claims— related to long-term biological diversity, environmental, or human health damage within an Article 27 liability and redress regime – for a product not inherently dangerous may well mean that even if a text for the regime is ultimately adopted that the text will never become operational.<sup>310</sup>

It is not obvious why – to select three countries as examples – Cuba, Denmark, or Iran would agree to a text or ultimately ratify a text that would subject themselves, their public research institutions, and private companies to claims ten-twenty-thirty years in the future for

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*supra* note 275 at 4 Fn. 4.

Ms. Holtby agrees that to include biological diversity, the environment, and long-term human health claims within the Article 27 liability and redress regime would be to recognize speculative risks as a legitimate basis for international claims. *Id.* at 4 fn. 4, 83-86, 89, 94 fn. 15, 100 fn. 19, and 108-109. For reasons to be explained in a few paragraphs, Ms. Holtby considers inclusion of speculative risks within the Article 27 liability and redress regime to be a proper and correct decision.

<sup>307</sup> Legal and Technical Experts, *supra* note 263 at ¶ 17.

<sup>308</sup> Note of the Executive Secretary, *supra* note 259 at ¶¶ 14-15 & 39.

<sup>309</sup> Note of the Executive Secretary, *supra* note 259 at ¶¶ 14-15 & 39-40.

<sup>310</sup> *See*, Technical Group, *supra* note 239 at ¶ 36. *See also*, Katharina Kummer Peiry, *supra* note 274 at Paper No. 8, Strict Liability for Environmental Damage is Normally Reserved for Hazardous Activities (12 Apr 2005).

speculative damages related to biological diversity, the environment, or human health.<sup>311</sup> It is not obvious why these three nations would be willing to consent to allow antagonistic countries, natural or legal persons, or NGOs to bring these types of claims for damage against their biotechnology sectors.<sup>312</sup> Cuba, Denmark, Iran approved the transgenic organisms (micro-organisms, crops, or animals) developed, produced, and exported in or from their countries. Moreover, the countries in which the damage to biological diversity, the environment, or human health will be alleged to have occurred ten-twenty-thirty years hence will have also consented to the import of the transgenic organisms after an approval process. With two approvals determining safety to biological diversity, the environment, and human health, it seems that nations and their developers, producers, and exporters of genetically modified organisms may

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<sup>311</sup> Cuba has a sophisticated biotechnology sector focused on pharmaceuticals and foods. In 2006 Cuba is field testing transgenic corn, rice, sweet potatoes, and sugar cane with the goal to commercialize these varieties by 2010 for use in Cuba and other nations around the world. Anon, Cuba goes it alone with new biotech crops, *AGBIOTECH REPORTER* 12-13 (Jan. 2006).

Denmark is home to Novo Nordisk, maybe the largest developer in the world of transgenic food-processing aids (bacteria and yeasts) and their enzyme products. Novo Nordisk has already felt the panic of speculative claims in Japan when bread made in New Zealand, using an imported Novo Nordisk enzyme produced by a genetically modified organism, was forced from the market shelves. Anon, Govt baffled by GE scare, questions of timing of revelation, *NZOOM* (27 Oct 2003).

Iran developed transgenic rice and is the first country in the world to release transgenic rice for commercial production by farmers. D. Aglay, Iran, First to Plant GMO Rice, Hopes to Cut Imports, *REUTERS NEWS SERVICE* (Nov. 21, 2005).

<sup>312</sup> Who will have standing to bring claims under the BSP Article 27 liability and redress regime is another legal issue still under discussion. The options listed for further discussion are

- damage to environment/conservation and sustainable use of biodiversity – affected state; groups acting in vindication of common interests;
- damage to human health – affected state; affected person or any other person entitled to act on behalf of that person;
- socio-economic damage – affected state; groups acting in vindication of common interests or communities. Working Group, *supra* note 253 at Annex: VIII. Standing/Right to Bring Claims.

well see no reason why they should subject themselves to speculative claims for damage awards based on alleged long-term impact on biological diversity, the environment, and human health.

In light of the difficulties in concepts, scientific knowledge, and operative adoption, the best option for Scenarios Six and Seven from a legal perspective appears to be the “no option,” – that is, to have no international liability and redress regime addressing biological diversity, environmental, and long-term human health damage.

However, the legal perspective may not adequately encompass relevant economic considerations that possibly provide solid policy reasons for the adoption of an Article 27 liability and redress regime. It has been carefully and thoughtfully argued that countries with concerns about these speculative risks (biological diversity, environmental harm, and long-term human health) will not participate in international trade in agricultural biotechnology unless their concerns can be adequately addressed by a liability and redress regime. It is argued that an Article 27 liability and redress regime will provide assurances to these risk-averse countries that if something, though presently speculative, does occur that the risk-averse countries will have prevention, restoration, and compensation remedies.<sup>313</sup> Hence, it is possible to argue that a social welfare maximizing BSP must create a liability and redress regime so as to entice the greatest

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<sup>313</sup> The authors of this article do not discuss the final option set forth by the Working Group in its damage options – i.e. costs of response measures. Costs of response measures seem more closely related to remedies (prevention, restoration, or monetary compensation) once liability for a legally-recognized damage has occurred. Hence, cost of response measures seems to be on the redress side, rather than the liability side, of the Article 27 regime. This article focuses on “liability” and not on “redress.” For discussion about options related to redress, Note of the Executive Secretary, *supra* note 259 at ¶¶ 20-26 and Legal and Technical Experts, *supra* note 263 at ¶¶ 23, 27 and Annex: Conclusions 7 and 8.

number of countries to participate in international trade in agricultural biotechnology.<sup>314</sup> It is to this economic argument that this article now turns.

As was stated previously, the Holtby Thesis posits that a liability and redress regime can be welfare enhancing. Her arguments are based on two assumptions that bear further analysis.

Assumption One: Holtby argues that speculative harms need to be included in an international liability and redress regime to ensure that any potentially adverse long-term environmental and health impacts within developing and less developed nations will be compensated. Without the possibility for compensation, developing and less developed countries will not adopt agricultural biotechnology.

Assumption Two: Holtby argues that a liability and redress regime is welfare enhancing when contrasted against the alternative of an importing nation imposing an import barrier against GMOs "... as the liability regime serves to reduce the expected costs of importing GMOs so that the benefits outweigh the costs."<sup>315</sup>

Speculative harms or risks are undoubtedly the most contentious of the risk categories given the lack of capability to substantiate this category of risks. In 1997, van den Daele *et al.* identified three categories of risk<sup>316</sup> based on research into consumer perceptions of genetic modification technologies. The first category of risks are probabilistic risks, defined as those that involve theoretically grounded and empirically demonstrated risks related to the product or its technology. The methods and much of the evidence about probabilistic risks is available in peer-

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<sup>314</sup> The social welfare maximizing analysis of the BSP as requiring an Article 27 redress and liability regime is the central point and argument of the Holtby Thesis, *supra* note 275.

<sup>315</sup> Holtby Thesis, *supra* note 275 at 161.

<sup>316</sup> van den Daele, W., Puhler, A., and Sukopp, H. 1997. Transgenic Herbicide- Resistant Crops: A Participatory Technology Assessment. Summary Report for the Federal Ministry for Research and Technology. Berlin: Wissenschaftszentrum Berlin für Sozialforschung.

reviewed journals or public records. The second category, hypothetical risks, in contrast involve those possibilities that are grounded in accepted theory but lack empirical experience or evidence that can establish probabilities. Most of these hypothetical risks can be identified in academic literature. The third category, speculative risks, in contrast to the other two identified risks, have neither established theory nor empirical experience to indicate their existence in the real world. Those speculative risks that have garnered attention can be found in working papers or other developing (popular) literature. Beyond these thought exercises, almost any correlation can be made to show the potential for risk, irrespective of whether there is any theoretical basis for the speculative possibility.<sup>317</sup>

Irrespective of the tendency in the BSP to be focused more on social rationality rather than scientific rationality, in contrast to the WTO agreements,<sup>318</sup> international consensus on a liability and redress regime will likely not be reached if it is principled on the abstract concept of speculative risks. While some countries may see inclusion of speculative risks as a necessary condition of a liability and redress regime, there is a very high probability that a regime including speculative risks would join the list of international liability and redress regimes that have been negotiated but never enacted.<sup>319</sup>

Developers of new agricultural biotechnology crops and animals – be they public or private; be they in industrialized or developing countries – would be hindered by the inclusion of

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<sup>317</sup> The sentences in this paragraph attempt to summarize succinctly the van den Daele, *et al.* study cited in the preceding footnote. *See also*, G. Issac, 2002 *Agricultural Biotechnology and Transatlantic Trade: Regulatory Barriers to GM Crops*. Oxford: CABI publishing, esp. Ch. 5.

<sup>318</sup> Professor Grant Issac in his comparison and contrast of the BSP with the WTO indicates that the BSP uses social rationality whereas the WTO uses scientific rationality. Issac, *supra* note 317 at 143 Table 5.5.

<sup>319</sup> For a list of inoperative international agreements that apparently foundered over liability and redress, read note 282 *supra* and the accompanying text.

speculative risks in a liability and redress regime, especially public researchers in developing countries (e. g. International Rice Research Institute in The Philippines). While it is conceivable that private developers in industrialized countries could absorb the cost of any out-year liability without having substantial adverse impacts on the development of new biotechnologies, the same cannot be said for public developers, especially in developing countries. Public research institutes simply do not have comparable rates of return or financial pools of capital capable of being utilized to fund future liability costs. In this case, the potential of a future liability cost could adversely affect both the direction of agricultural research and its effectiveness in addressing developmental needs.

Moreover, inclusion of speculative risks in an international liability and redress regime appears to contradict the objectives of the United Nation's Millennium Development Goals (MDGs). Goal Seven of this project is to ensure environmental sustainability. The authors of a recent report on achieving the goals have stated that decentralization of research capacity and increasing research self-determination will be crucial to achieving the MDGs.<sup>320</sup> The key focus of the MDGs is to work with developing countries to alleviate hunger and poverty by encouraging the integration of local interests and initiatives.<sup>321</sup>

The implementation of an Article 27 liability and redress regime could certainly be expected to have an adverse effect on achieving the MDGs in developing countries. Public

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<sup>320</sup> Gillis, N. and Southey, S. 2005. *New Strategies for Development: A Community Dialogue for Meeting the Millennium Development Goals*. New York: Fordham University Press.

<sup>321</sup> Gillis and Southey observe "... individuals living in poverty in rural areas are often reliant upon ecosystem services, with an estimated one-tenth of food-insecure people globally depending principally on agriculture.... Investment is thus urgently required to support community-driven approaches that enhance biodiversity and ecosystem services ... in ways that respect local communities and indigenous peoples as both environmental stewards and rural producers." *Id.* at 3.

research institutes, especially those within developing countries, work closely with the very populations most severely affected by hunger and poverty. There is a very real concern that an Article 27 liability and redress regime would have a negative effect on this relationship by impeding public research on behalf of the poor. It is likely that any maximization of trade in agricultural biotechnology for developing countries, by including speculative risks within an Article 27 liability and redress regime, would be more than offset by detrimental effects caused by such regime in reducing the amount and availability of agricultural biotechnology for the poor in developing nations.<sup>322</sup>

From this perspective, it would appear that an Article 27 liability and redress regime would have an adverse impact on biological diversity, the environment, and on human health within developing and less developed countries should such a regime proceed. Based on the MDGs, the choice that enhances social welfare most would appear to be the "no liability option" – i.e no international liability and redress regime addressing speculative risks for biological diversity, environmental harm, and long-term human health.

Turning now to examine welfare enhancement between the proposed Article 27 liability and redress regime and the use of an import barrier, it is important to understand that under the WTO agreements, such a barrier would likely not be allowable. If a developing or less developed country perceived that an import barrier was economically justifiable to prevent

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<sup>322</sup> For fuller discussion of agricultural biotechnology capacity in developing countries, *see e.g.*, Atanas Atanassov et al., *To Reach the Poor – Results from the ISNAR-IFPRI Next Harvest Study of Genetically Modified Crops, Public Research, and Policy Implications*, (IFPRI Mar 2004); Joel Cohen, John Komen, & José Falck Z., *National Agricultural Biotechnology Research Capacity in Developing Countries*, ESA Working Paper No. 04-14 (June 2004), [www.fao.org/es/esa](http://www.fao.org/es/esa).



speculative risks, there are no special provisions under either the Sanitary and Phyto-Sanitary (SPS) Agreement or the Technical Barriers to Trade (TBT) Agreement of the WTO that would allow such a barrier to be put in place. Any country intending to implement an import barrier against agricultural biotechnology would have to justify the reason for doing so, using either the SPS or TBT agreements. Import barriers that are implemented outside of the SPS and TBT agreements are trade distorting.

A country wishing to impose an import barrier has two main options, tariffs or quotas. A tariff is simply a tax that the importing government places on a specific good or the goods from a specific country. This makes the price of the good more expensive in the importing country, thus lowering demand for that good. The effect on the exporting country will be to lower the volume of that good available for export as the price to exporters will be lower, thus lowering production. If the tariff is high enough, it is capable of stopping trade.

When an importing country imposes an import quota, the country restricts the level of a particular good entering the country to a fixed amount. The economic effect in the importing country is that demand for the product is higher than the supply of the product, thereby raising the price of the product. In the exporting country, production will decline due to the lower level of total exports. Global prices tend to vary more widely under quotas than under tariffs.

A country seeking to avoid any speculative harm to biological diversity, the environment or human health by using an import barrier may well be in violation of the SPS and/or the TBT Agreements. Assuming that a country would choose to comply with the WTO Agreements, such compliance removes the option of using an import barrier, as the use of such a barrier would be a violation. Factors that distort trade – such as violations of WTO Agreements -- have been shown

to reduce social welfare.<sup>323</sup> A country that complies with the WTO Agreements will not distort trade and, thereby, will not diminish social welfare.

On the other hand, assuming the country would choose not to comply with the WTO Agreement, countries can use the BSP to inhibit trade even if an Article 27 liability and redress regime exists. Under the BSP, the importing country has relatively unfettered power to allow or disallow the import of transgenic crops and animals. And whatever the importing country decides has no effective challenge because the BSP has no enforcement mechanism.<sup>324</sup> Consequently, it is not at all clear that any incentive to engage in trade that an Article 27 liability and redress regime may have for certain countries will in fact result in increased trade. The Article 27 liability and redress regime is more likely to be a disincentive to engaging in agricultural research for the benefit of the poor without any offsetting advantage of welfare maximization through increased trade.<sup>325</sup> In light of this likely consequences, from a social

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<sup>323</sup> Stuart Smyth, W. Kerr, and K. Davey, *Closing Markets to Biotechnology: Does it Pose an Economic Risk if Markets are Globalized?*, (under publication review, 2006). The authors show that one country using a barrier against GM crops directly reduces the revenue for the exporting country and indirectly reduces the social welfare for the importing nation. The authors note that changes in revenue are not useful measures of economic change, which is why change is shown in terms of social welfare. *See also*, Guillaume Gruère, *An Analysis of Trade Related International Regulations of Genetically Modified Food and their Effects on Developing Countries*, INT'L FOOD POL'Y RES. INST. (EPT Discussion Paper # 147, Feb. 2006).

<sup>324</sup> Through BSP Art. 32 *supra* note 238, the dispute settlement provisions of the Convention on Biological Diversity (CBD) apply to disputes between parties under the BSP. *See*, CBD Art. 27 Settlement of Disputes and Annex II (Arbitration and Conciliation), [www.biodiv.org](http://www.biodiv.org). However, it is highly questionable that the CBD dispute settlement provisions would allow a challenge to a specific decision of a country to deny import of transgenic organisms. *See also*, Katharina Kummer Peiry, *supra* 274 at Paper No. 2 Effective Use of an International Civil Liability Treaty Depends on National Legislation and Judicial Institutions (7 Feb 2005) (“A civil liability treaty does not establish an international court or an international enforcement mechanism. Instead, the national courts of a given county will adjudicate claims brought by nationals of another country under the international treaty.”)

<sup>325</sup> Holtby Thesis, *supra* note 275 at sec. 2.5 Interpretation (of the BSP as a trade inhibitor, trade facilitator, or trade dispute weapon).

welfare maximization perspective, the best option appears to be the “no option,” – i.e. that is, to have no international liability and redress regime addressing biological diversity, environmental, and long-term human health damage.

Hence, both Holtby Thesis assumptions seem dubious. Including speculative risks within an Article 27 liability and redress regime is likely to reduce social welfare, even if trade occurs, because of its negative impact on public research. Moreover, an Article 27 liability and redress regime may well have this negative impact without any offsetting gain from increased trade because the BSP gives so much discretionary and unchallengeable power to the importing country. Rethinking two of the conditions within the Holtby Thesis would appear to indicate that an international liability and redress regime under Article 27 of the BSP would not be welfare enhancing. This would certainly be apparent when taken in context of the United Nation's Millennium Development Goals.

#### Administrative Liability

Although the BSP creates administrative processes for the transboundary movement of transgenic organisms,<sup>326</sup> the BSP does not create any administrative liabilities. The BSP does not create an international regulatory agency nor specify any penalties for disregarding the administrative processes created by the Protocol. The only liability encompassed within the BSP is the Article 27 liability and redress regime – a civil liability regime. Hence, the BSP has no administrative liability for this article to discuss.

#### Criminal Liability

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<sup>326</sup> BSP, *supra* note 238 at Articles 7-13, 15 & 16.

The BSP does not have any provisions authorizing criminal liability. Hence, the BSP has no criminal liability for this article to discuss.

### **Conclusion**

As the BSP negotiations regarding an international liability and redress regime continue to move forward, it appears that there is a very substantial downside of such an agreement for public researchers, particularly in developing and less developed countries. This article has shown that the domestic liability regimes in Denmark and Germany have created considerable concern about the development of the biotechnology industry in both countries. If liability regimes focused on agricultural biotechnology raise considerable concern in developed countries, the effects may well be magnified for developing and less developed countries should a liability and redress regime focused on agricultural biotechnology be implemented internationally.

Biotechnology has been identified as but one of the tools capable of assisting the developing world in moving away from extreme poverty. Given that two of the eight goals of the United Nation's MDGs are the eradication of extreme poverty and environmental sustainability, the implementation of an international liability and redress regime may be very counter-productive towards the achievement of these goals. Integration of those afflicted by poverty into innovative research technologies requires the availability of more tools and options, not fewer, as would likely be the case under a liability and redress regime.

Taking into account the legal and economic considerations of an Article 27 liability and redress regime, the “appropriate elaboration” for Article 27 is the “no option” – that is, there should be no international liability and redress regime for the Cartagena Biosafety Protocol.