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An Agricultural Law Research Article

Legal Liability Issues in Agricultural Biotechnology

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Legal liability in tort law should be contrasted with regulatory approval. Regulatory approval focuses on whether a particular transgenic crop, microorganism, or animal is safe to humans and the environment. Regulatory approval deals with whether and under what conditions agricultural biotechnology crops and animals may be produced, marketed, and used. By contrast, before or after regulatory approval, a particular transgenic plant, microorganism or animal could possibly cause damage to property, persons, markets, the environment, or to social structures. Legal liability in tort addresses the kinds of liability that may exist for these possible damages. Those who produce or use agricultural biotechnology products need to know about the legal standards by which they may be held accountable for damages. In addition, those who might potentially be damaged by agricultural biotechnology need to be aware of the kinds of claims that they might assert to establish legal liability against producers and users of this technology.

This article provides an overview of the tort legal liability issues in agricultural biotechnology.[1] The article does not aim to provide legal advocacy for or against a particular legal claim or legal defense. The article aims to be descriptive of the issues relating to legal liability so that the reader may learn about the issues. As a consequence of this descriptive orientation, this article is a beginning point for those interested in the legal liability issues in agricultural biotechnology.

A Special Regime of Legal Liability for Agricultural Biotechnology?

Whether a special regime of legal liability is needed or will be adopted depends upon a particular society answering a fundamental policy question: Is agricultural biotechnology different in essence – different per se in its technology – from other agricultural breeding technologies? If a particular society answers that question "yes," that society is more likely to adopt a special legal liability regime for agricultural biotechnology. If a particular society answers that question "no," the society is

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1. As this article focuses solely on legal liability in tort, this article does not address regulatory sanctions that may apply to applicants for regulatory approval when these applicants violate the conditions of regulatory laws. The focus of this article also excludes discussion of legal liability that may arise from anti-trust law, from consumer fraud statutes, or intellectual property law (primarily patents).

For another recent overview on these same tort legal liability issues, see Margaret Rosso Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 227-39 (2002).

more likely to rely upon legal liability regimes commonly used for other agricultural endeavors as the legal liability regime for agricultural biotechnology.

New Zealand is a society that has taken a careful look at this question. New Zealand created a Royal Commission on Genetic Modification and, as part of its warrant, called for information on the liability issues involved, or likely to be involved now or in the future, in relation to the use of genetic modification, genetically modified organisms, and products.[2]

The Royal Commission received submissions[3] that argued that agricultural biotechnology was so different in terms of the kinds of risks and magnitude of risks that agricultural biotechnology should be considered inherently dangerous. Those submitting these "different-in-kind" arguments requested a legal liability regime specific to agricultural biotechnology with, among others, the following attributes:

- strict liability for any and all damages caused;
- exposure to legal liability for damages for lengthy periods (e.g. 30 years or in perpetuity); and
- a requirement that those applying for regulatory approval, as a condition for approval, provide proof of financial responsibility either through insurance, a bond, or payments into a public compensation fund.[4]

The Royal Commission also received submissions[5] that argued that agricultural biotechnology was not different in essence from other breeding technologies. As a consequence, those who viewed agricultural biotechnology as similar to other breeding technologies contended that the existing tort and regulatory laws of New Zealand were sufficient in scope and flexibility to address any damages that might occur through the use of agricultural biotechnology. They argued that a special legal regime (as described above) served only to create a disincentive to scientific inquiry and to impose extra, unnecessary costs upon a beneficial emerging technology.

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2. ROYAL COMMISSION ON GENETIC MODIFICATION, REPORT, Ch.12 *Liability Issues* (2001) available at http://www.gmcommission.govt.nz/RCGM. [RCGM REPORT]. In Chapter 12, the Royal Commission explains the issues and discusses the options before making its recommendation. The mandate to address legal liability – Item (e) of the Warrant – is set forth several times, e.g., Appendix 2 at 173 and Appendix 3 at 80.

3. The submissions by Interested Persons and from the Public, both for and against a special legal regime for legal liability, may be found in RGCM REPORT, Appendix 2, *Outcomes of Consultation: Submissions from Interested Persons*, Sec. 3.10 Liability Issues and Appendix 3, *Outcomes of Consultation: Submissions from the Public*, Sec. 3.8 Liability.

4. Although only in the information-gathering stage, well before any specific decisions are made, an outline of a legal liability regime that treats agricultural biotechnology as fundamentally different from other agricultural technologies can be found in Note by the Executive Secretary, *Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms*, UNEP/CBD/ICCP/3/3, Mar. 2002. The Intergovernmental Committee for the Cartagena Protocol on Biosafety discussed this document relating to Article 27 (Liability and Redress) of the Cartagena Protocol at The Hague in April 2002.

5. RGCM REPORT, *Supra* note 2.

After studying these opposing submissions,[6] the Royal Commission gave the following Recommendation 12.2: "that for the time being there be no change in the liability system."[7] The Royal Commission explained its recommendation by stating:

> The Commission considers it is unnecessary to recommend legislation providing special remedies for third parties, where they may have been affected by the release of a genetically modified organism. As technology advanced with ever-increasing pace throughout the 20th century, the common law (that is, law based on court decisions, as distinct from statute law) showed it was well able to mould new remedies for novel situations. Parliamentary intervention has rarely been needed in this area. From a legal liability perspective we have not been persuaded there is anything radically different in genetic modification as to require new or special remedies.[8]

As of August 2002, the United States has a legal liability position that is in agreement with the conclusion reached by the New Zealand Royal Commission.[9] The United States has decided thus far

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6. The Royal Commission also obtained a legal analysis of liability issues to assist the Commission in its work. Stephen Todd, LIABILITY ISSUES INVOLVED, OR LIKELY TO BE INVOLVED NOW OR IN THE FUTURE, IN RELATION TO THE USE, IN NEW ZEALAND, OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS at http://www.gmcommission.govt.nz/inquiry/responses/Professor%20Stephen%20Todd.pdf . Stephen Todd is the Dean and Professor of Law of the University of Canterbury, Faculty of Law, New Zealand.

7. RCGM REPORT, *supra* note 2, at 329.

8. *Id.* ¶ 80 at p. 328. After the RCGM REPORT, its legal liability recommendation stirred debate. In response the New Zealand Government requested the New Zealand Law Commission to prepare a report on legal liability. In its report, after reviewing the options about legal liability, the Law Commission concluded that: "At the heart of this inquiry are substantial policy choices from which varying legal consequences would flow." The first policy choice is "the extent to which GMOs are different from other human activities or technologies from a scientific or ethical perspective." LAW COMMISSION REPORT, LIABILITY FOR LOSS RESULTING FROM THE DEVELOPMENT, SUPPLY OR USE OF GENETICALLY MODIFIED ORGANISMS ¶¶ 8, 146 (May 2002) . In addition, the New Zealand Ministry of Research, Science & Technology commissioned a legal liability study, CHARLES RIVER ASSOCIATES (ASIA PACIFIC) LTD., REVIEW OF CHEN, PALMER & PARTNERS AND SIMON TERRY ASSOCIATES, *Who Bears the Risk?* (Oct. 2001), available at http://www.morst.govt.nz/hot/biotechRCGM.html . Finally, the Ministry for the Environment of New Zealand has issued a public discussion paper that includes a chapter on legal liability. MINISTRY FOR THE ENVIRONMENT (NZ), IMPROVING THE OPERATION OF THE HSNO ACT FOR NEW ORGANISMS, Ch. 8 *Liability Issues* (Sept. 2002), available at http://www.mfe.govt.nz .

9. Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23302 (June 26, 1986) in General Recommendation 2 states:

> There is no scientific basis for specific legislation for the implementation of rDNA technology and applications. Member countries should examine their existing oversight and review mechanisms to ensure that adequate review and control may be applied while avoiding any undue burdens that may hamper technological developments in this field. *Id.* at 23308.

The Coordinated Framework focused on regulatory regimes for biotechnology but its conclusion that agricultural biotechnology does not differ in essence from other agricultural breeding techniques has meant that the United States does not have a special legal liability regime for transgenic crops and animals.

Commentators on U.S. regulatory policy, as enunciated in the OST 1986 document, differ as to whether the policy of "no-difference" is more theory than regulatory practice. *Compare, e.g.*, Henry Miller, *Nescience, Not Science, from the Academy*, 16 THE SCIENTIST No. 19 (Sept. 30, 2002) *with* Fred Gould & Jennifer Kuzma, *The Academy Responds*, 16 THE SCIENTIST No. 20 (Oct. 14, 2002), both available at http://www.the-

that agricultural biotechnology is not fundamentally different as a technology from other agricultural technologies. Hence, the United States leaves the issue of legal liability for agricultural biotechnology products – as products – to the laws applicable generally to agricultural products. Those generally applicable laws are primarily the common law of torts, as will be discussed more fully in this article.[10]

In contrast to New Zealand and the United States, the European Union has proposed classifying agricultural biotechnology as an inherently dangerous technology.[11] Consequently, the EU has proposed that agricultural biotechnology, along with other listed activities, be subject to a special legal liability regime.[12] The proposed EU regime provides for strict liability[13] for a wide-range of environmental damages[14] that is in addition to civil liability for damages to persons, property, or economic relations.[15] For these environmental damages, no statute of limitations exists.[16] Member

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scientist.com.

10. Obviously with an issue as contentious as agricultural biotechnology, there are those who disagree with the United States policy and who desire to create a special legal liability regime for agricultural biotechnology. *E.g.* H.R. 4816, 107th Cong., 2d Sess. (introduced May 22, 2002) to enact the "Genetically Engineered Organism Liability Act of 2002." *See also*, Note, *Designer Genes that Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products*, 100 HARV. L. REV. 1086 (1987).

11. Commission of the European Communities, *Proposal for a Directive of the European Parliament and of the Council ON ENVIRONMENTAL LIABILITY WITH REGARD TO THE PREVENTION AND RESTORATION OF ENVIRONMENTAL DAMAGE*, 17 Final, COM (2002) (presented week of January 21, 2002). As of August 2002, this proposal is undergoing the legislative process of the EU and a final directive is expected in 2002 or 2003. [EU Env. Liab. Proposal]. The EU Proposal creates an administrative liability regime, as contrasted with a legal liability regime through common law torts.

Two articles written prior to the Commission's January 2002 Proposal provide a pro and con European perspective on whether a special legal regime should exist for agricultural biotechnology. *Compare,* Mark Wilde, *The Law of Tort and the 'Precautionary Principle': Civil Liability Issues Arising from Trial Plantings of Genetically Modified Crops*, 6 ENV. LIAB. 163 (1998) (pro) *with* Lucas Bergkamp, *Allocating Unknown Risk: Liability for Environmental Damages Caused by Deliberately Released Genetically Modified Organisms*, 14 ENV. LIAB. L. REV. [Tijdschrift voor Milieuaansprakelijkheid] 61 (Part 1, June 2000) and 104 (Part II, Aug. 2000) (con).

12. The activities subject to the special legal liability regime are listed in EU Env. Liab. Proposal Annex I. Agricultural biotechnology is in the last two paragraphs of the Annex. Other activities listed include, among others, manufacture, use, storage, or transport of hazardous wastes, dangerous chemical substances, and plant protection products (pesticides).

13. *Compare* EU Env. Liab. Proposal, Article 3(1) [strict liability for Annex I activities] *with* Articles 3(2) and 8 [liability based on fault or negligence for non-Annex I activities].

14. EU Env. Liab. Proposal Article 2.1.5 defines "damages" as "a directly or indirectly occurring measurable adverse change in a natural resource and/or impairment of a natural resource service caused by any of the activity covered by this Directive." Article 2.1.19 defines "environmental damages" as including biodiversity damage, water damage, and land damage.

15. The Commission explained civil liability for personal injury, property, and economic loss in the Explanatory Memorandum that accompanied the Proposal. EU Env. Liab. Proposal at 15-16.

16. *Id.* at 28.

states should encourage those subject to the special legal liability to have insurance or other forms of financial security but these means of assuring financial accountability are not made compulsory.[17]

Civil Liability

In Europe, New Zealand, and the United States, producers and users of agricultural biotechnology are subject to the usual rules of civil (legal) liability that apply to all persons and products. More specifically, if a producer or user of transgenic crops or animals causes damage to the property, person, or markets (economic interests) of another person, the producer or user may be liable for those damages.[18] In this segment of the article, the text addresses these damage claims by category of damages – i.e., property, person, and markets. While the legal doctrines through which the claims are asserted are the ordinary claims of legal liability, the text focuses on unique issues that arise when applying these ordinary claims to agricultural biotechnology. Moreover, the text addresses these legal claims within the framework of the United States legal system with only brief reference to the civil liability issues in other nations.

Damage to Property

Property damage may occur most likely in two contexts – seed production and organic production. In both contexts, the source of the alleged damage will originate with pollen flow from the transgenic crop to non-transgenic crops. Organic producers may claim that transgenic pollen flow has damaged their organic production, rendering it no longer "organic." Seed producers may claim that transgenic pollen flow has damaged the purity of their seeds, rendering them no longer certifiable for specified purity as required by law.

Trespass

If seed producers or organic producers believe that they have suffered damages from transgenic pollen flow, they may bring a common law cause of action based in trespass.[19] Trespass involves the physical invasion of the possessory interests of the property (land) of the person claiming damages with the damages being caused by the farmer of the transgenic crops. The physical spread of transgenic pollen to neighboring fields may be enough by itself to establish the physical invasion element of trespass.

Pollen flow between varieties of the same crop or between related plant species is a biological fact. Hence, if pollen flow by itself gave rise to legal liability for trespass upon a neighbor's crops, all

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17. EU Env. Liab. Proposal Article 16. The Commission explained its decision that insurance or other forms of financial security need not be compulsory in the Explanatory Memorandum. *Id.* at p. 16.

18. For a broad, non-legal overview of the issues, see Stuart Smyth et al., *Liabilities and Economics of Transgenic Crops*, 20 NAT. BIOTECH. 537 (2002).

19. For a discussion of the trespass claim relating to transgenic crops, see Richard Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDA. L. REV. 585 (2000); Grossman, *supra* note 1 at 235-36. Aside from the two class action lawsuits identified in note 72 *infra*, as of August 2002, there are no reported cases that have discussed the trespass claim in the context of transgenic pollen flow.

farmers would be exposed to legal liability for trespass for almost every crop they grow.[20] To differentiate between pollen flow that constitutes trespass and pollen flow that is accepted as a biological fact of farming, the law requires that the physical invasion cause damages.

In the United States, the Association of Official Seed Certifying Agencies (AOSCA) sets "the minimum standards for genetic purity and identity and recommended minimum standards for seed quality for the classes of certified seed."[21] In the United States, the AOSCA works through forty-two affiliated entities in the various states of the United States.

The Nebraska Crop Improvement Association (NCIA) is a state affiliate of AOSCA[22] and its seed standards are typical of those used in the United States. In Nebraska, in order to gain seed certification, seed producers must comply with requirements related to land use (such as isolation distances from fields of the same crop and the use of buffer rows),[23] agronomic practices (such as roguing of undesired plants, weed control, and detasseling),[24] and produce a seed crop that meets the tolerance levels for genetic purity.[25]

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20. This biological fact of pollen flow means that if trespass through pollen flow becomes a widely-adopted source of legal liability, organic and conventional farmers too will be subject to legal liability for pollen flow from their crops to transgenic crops, if the pollen flow from the organic or conventional crop causes damages to the transgenic crop. For example, if a transgenic farmer is growing a high-value pharmaceutical crop, the transgenic farmer might use the trespass claim for pollen flow against organic or conventional farmers. For similar issues between neighbors relating to straying cattle, see Robert Ellickson, *Of Coase and Cattle: Dispute Resolution Among Neighbors in Shasta County*, 38 STAN. L. REV. 623 (1986).

21. Quotation from the homepage of the AOSCA at http://aosca.org. The AOSCA and similar seed certifying agencies throughout the world have been setting purity standards for decades and are recognized as the expert bodies in the field of seed purity standards.

22. For information on NCIA and its certification standards, see http://www.unl.edu/ncia.

23. *Id.* Certification Standards, Hybrid Corn, Standards 2 (Land Requirements), 3 (Field Inspection), and 4(B) (Isolation from contaminating pollen).

24. *Id.* General Seed Certification Standards, Standard 13 (Field Inspection Roguing and Weed Control) and Certification Standards, Hybrid Corn, Standards 4(C) (Roguing Off-type and Volunteer Plants) and 4(D) (Detasseling and pollen control).

25. *Id.* Certification Standards, Hybrid Corn, Standard 6 (Seed Quality Standards). For genetic purity, depending upon the hybrid corn, the corn must be 99% to 99.5 % genetically pure. Standard 6 also sets tolerance levels for quality factors of the certified seed relating to other crop seeds (0.5%), weed seed (0%), inert matter (1.0%).

Scientists involved in two recent studies of pollen flow in canola, one transgenic and one non-transgenic, have concluded that isolation distances – such as those in the seed certification standards for canola – are sufficient to produce certified seed to the 99.75% level of genetic purity. Adrian Ewins, *Study Raises Questions about GM Buffer Zone*, WESTERN PRODUCER (July 4, 2002) (Canadian study), available at http://www.producer.com/articles/20020704/news/20020704news06.html; *Gene Flow is Low*, NATIONAL POST (Australia), July 22, 2002, at FP15 (Australian study). For a general overview of pollen flow, see Katie Eastham & Jeremy Sweet, European Environment Agency, *Genetically Modified Organisms (Gmos): the Significance of Gene Flow Through Pollen Transfer*, ENVIRONMENTAL ISSUE REPORT No. 28 (2002).

In the United States, federal law sets organic standards through the National Organic Program (NOP) of the United States Department of Agriculture (USDA).[26] NOP Section 205.2 specifically states that among the excluded methods of production are "methods used to genetically modify organisms."[27] However in the comments accompanying the official rule, the USDA wrote with specific reference to pollen flow,

> When we are considering drift issues, it is particularly important to remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act and the regulations. This regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes responsible steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.[28]

In a similar vein, USDA declined to set a tolerance threshold for the presence of transgenic crops in organic production and stated that the regulations do not establish a "zero tolerance" standard.[29] The presence of transgenic crops in organic production does not constitute a violation of USDA organic production standards so long as the organic producer follows the producer's own approved organic system plan.[30]

By reviewing the seed production standards and the organic production standards, two unique issues emerge regarding a trespass claim for damages for transgenic pollen drift. First, both sets of standards place the burden upon the person engaged in the production operation to comply with the required production standards. Failure to follow the production standards causes the producer to lose the certification, not the pollen flow from neighbor's crops. Second, neither set of standards makes the presence of transgenic crops per se a violation of the standards. Seed crops and organic crops may have the presence of transgenic crops without losing certification. Hence, seed producers and organic producers may face significant difficulties in proving that the farmer growing transgenic crops caused damage.

Strict Liability

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26. USDA, *National Organic Program*, 65 Fed. Reg. 80548 (Dec. 21, 2000) to be codified at 7 C.F.R. Part 205.

27. *Id.* at 80,639.

28. *Id.* at 80,556.

29. *Id.* at 80,632.

30. This text addresses the USDA NOP standards. Private, non-governmental organic organizations may set standards that do not allow the presence of transgenic crops in organic production. The article will address these stricter, private organic standards later in this article.

Persons who believe that their land or crops has been damaged by a neighbor's transgenic crops may bring a tort claim in strict liability – i.e. liability without fault and despite the exercise of utmost care – if the activity of growing transgenic crops is abnormally dangerous.[31]

As is obvious, a crucial question for the application of strict liability to transgenic crops is whether transgenic crops are abnormally dangerous. Restatement (Second) Torts Section 520 sets forth the relevant factors as follows:

> In determining whether an activity is abnormally dangerous, the following factors are to be considered:
>
> (a) existence of a high degree of risk of some harm to the person, land or chattels of others;
> (b) likelihood that the harm that results from it will be great;
> (c) inability to eliminate the risk by the exercise of reasonable care;
> (d) extent to which the activity is not a matter of common usage;
> (e) inappropriateness of the activity to the place where it is carried on; and
> (f) extent to which its value to the community is outweighed by its dangerous attributes.[32]

In the United States where the basic policy decision is that agricultural biotechnology is not different in kind from other agricultural breeding technologies, those alleging a strict liability claim may have difficulty establishing the existence and likelihood of factors (a) and (b).[33] Moreover, as American farmers have planted significant acreage to transgenic crops, those alleging strict liability may also have difficulty in establishing factors (d) and (e).[34]

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31. The Restatement of the Law (Second) Torts sets forth the common law principles for strict liability in §§ 519-524. AMERICAN LAW INSTITUTE, 3 RESTATEMENT OF THE LAW (SECOND) TORTS 34-52 (1977) (hereafter 3 Rstmt 2d Torts). For discussion of strict liability as applied to transgenic crops, see A. Bryan Enders, *"GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453, 488-91 (2000); Richard Repp, Comment, *supra* note 19, at 616-20; Grossman, *supra* note 1, at 237-39. Aside from the two class action lawsuits identified in note 72 *infra*, as of August 2002, there are no reported cases involving an allegation of strict liability for property damage against transgenic crops.

32. 3 Restatement 2d Torts at 36.

33. 3 Restatement 2d Torts, Comment g (Risk of harm) states: "An activity that is abnormally dangerous ordinarily involves a high degree of risk of serious harm to the person, land or chattels of others. The harm threatened must be major in degree, and sufficiently serious in its possible consequences to justify holding the defendant strictly responsible for subjecting others to an unusual risk. It is not enough that there is a recognizable risk of some relatively slight harm, even though that risk might be sufficient to make the actor's conduct negligent if the utility of his conduct did not outweigh it, or if he did not exercise reasonable care in conducting it. If the potential harm is sufficiently great, however, as in the case of nuclear explosion, the likelihood that it will take place may be comparatively slight and yet the activity be regarded as abnormally dangerous." *Id.* at 38. Read also the cited document and opinions *supra* note 9.

34. In the United States, the USDA reported that transgenic crops accounted for 75% of the soybeans, 34% of the corn, and 71% of the upland cotton in 2002. Transgenic crops constituted 13% more acres in 2002 as compared to 2001. *Biotech Popularity Grows in US*, AGBIOTECH REPORTER, Aug. 2002, at 12. In Canada too transgenic crops are commonplace in farming country: 40-50% of soybeans, 45-50% corn, 90-

In addition, organic farmers may face an additional hurdle to establishing strict liability against transgenic crops. Section 524A of the Restatement (Second) Torts states:

> There is no strict liability for harm caused by an abnormally dangerous activity if the harm would not have resulted but for the abnormally sensitive character of the plaintiff's activity.[35]

Organic farmers do not lose their organic certification under USDA-NOP standards for the presence of transgenic crops. However, some private, non-governmental organic organizations may impose stricter standards that deny the private certification for even the presence of transgenic crops.[36] These stricter standards may show "an abnormally sensitive character" for those organic growers who adhere to these private, non-governmental organic organizations.[37]

It is important to differentiate between transgenic commodity crops (such as canola, corn, cotton and soybeans) and transgenic crops that produce a non-food product, e.g., a transgenic pharmaceutical crop.[38] If damage occurs, biotechnology companies and farmers are likely at greater risk (when compared to commodity transgenics) that a court, using the factors of section 520, will rule that a pharmaceutical transgenic crop is abnormally dangerous. However, section 520(f) allows courts to engage in social-utility balancing in making an abnormally dangerous classification which means that a court could decide against strict liability and in favor of a negligence liability standard even for transgenic pharmaceutical crops.[39]

Negligence

95% canola in 2002. *Ontario Use of Biotech Crops on Increase Again*, CANADA NEWSWIRE (Aug. 21, 2002).

35. 3 Restatement 2d Torts at 51.

36. The Organic Crop Improvement Association International, Inc. (OCIA) has a standard that states: "The use of products made from organisms that have been modified by genetic engineering techniques (as defined in the Materials List) is prohibited and is in direct violation of the philosophy and organic intent of OCIA." OCIA, INTERNATIONAL CERTIFICATION STANDARDS, Standard 1.2 (March 2000). *See also*, OCIA Standards 9.2 and 9.3.

37. 3 Restatement 2d Torts § 524A Comment a states: "The plaintiff cannot, by himself resorting to an abnormally sensitive activity, impose upon the defendant an additional burden of liability, even though the defendant is aware of the fact." *Id.* at 51.

38. Press Release, American Corn Growers Association, Corn Growers Want Biotechs Held Liable for Pollen Drift from Pharmaceutical Corn, May 9, 2002. StarLink™ corn raises the same issue. Discussion of StarLink™ corn occurs later in this article.

39. For discussion of social-utility balancing and the court's power, read 3 Restatement 2d Torts Comments k and l at 42-43. Whether a court classifies a transgenic pharmaceutical crop as abnormally dangerous may also be influenced by whether the regulatory agency approving the production of the crop has established a tolerance for the presence of the pharmaceutical crop in commodity crops intended for food and feed.

Persons who believe their crops or property have been damaged because a neighbor growing transgenic crops failed to take adequate precautions may have a claim for negligence against the farmer and the agricultural biotechnology company that created the crop. Negligence is a fault-based claim with the fault arising from the fact that the negligent person failed to take adequate precautions. Using more technical legal language, section 282 of the Restatement (Second) of Torts defines negligence as ". . . conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm."[40] Plaintiffs have the burden to prove four traditional elements of a negligence: duty of care to the plaintiff, breach of that duty by unreasonable conduct, causation (both factual and proximate) of the damages claimed, and damages (a harm or injury valued in a monetary amount).[41]

If presence alone of transgenic crops (pollen or volunteer plants) on another person's land does not constitute a trespass or a strict liability claim, negligence liability for growing transgenic crops would not differ from negligence for growing non-transgenic crops. In other words, farmers in both instances would owe their neighbors the duty to exercise reasonable care so as to avoid causing injury or harm to the neighbor's land or crops. Farmers would have no new or additional negligence liability solely because they decided to grow transgenic crops.

With respect to certain transgenic crops, biotechnology companies and farmers growing transgenic crops may have the obligation to take additional reasonable precautions if, for example, the agronomic evidence showed that a particular transgenic crop(s) caused weediness, pollen flow, or volunteer plants to a greater degree than non-transgenic crops.[42] Moreover, the companies and farmers would likely have the duty to adopt additional reasonable precautions if the transgenic crop, such as a transgenic pharmaceutical crop, needed to be segregated from commodity crops destined for food or feed. As these possible, additional duties are presently foreseeable, biotechnology companies and farmers are developing techniques to prevent pollen flow and volunteer plants. By developing these preventive techniques, the companies and farmers may establish that they have taken adequate reasonable measures and thereby avoided negligence liability to a neighbor.

Biotechnology companies can engineer the transgenic crop to have biological barriers against pollen flow or volunteer survival. To mention several possible biological barriers, the transgenic crops may have male sterility to produce infertile pollen, seed sterility to prevent volunteer crops, or control of flowering time to prevent cross-pollination.[43] Indeed, if these biological barriers could reasonably be incorporated into the transgenic crop, a biotechnology company that failed to incorporate these

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40. 2 RESTATEMENT OF THE LAW (SECOND) TORTS 9 (1965) [2 Restatement 2d Torts].

41. For discussion of negligence as applied to transgenic crops, see Enders, *supra* note 31 at 482-87 and Richard Repp, Comment, *supra* note 19, at 613-16; Grossman, *supra* note 1 at 236-37. Aside from the two class action lawsuits identified in note 72 *infra*, as of August 2002, there are no reported cases involving an allegation of negligence for property damage against transgenic crops.

42. The agronomic characteristic of transgenic crops in comparison to non-transgenic crops is outside the scope of this article focused on legal liability.

43. For discussion of biological barriers for transgenic crops, see Henry Daniell, *Molecular Strategies for Gene Containment in Transgenic Crops*, 20 NAT. BIOTECH. 581-86 (2002) and Eastham & Sweet *supra* note 25, at § 10.3.1 (biological gene flow barriers).

biological barriers thereby causing damage to property or person may be liable for a products liability claim for design defect.[44]

Biotechnology companies and farmers of transgenic crops can also adopt agronomic practices that they hope are best management practices to prevent pollen flow or volunteer plants. Examples of these best management practices could include isolation distances between fields, barrier crops, border rows,[45] refugia,[46] or agronomic zones for transgenic and non-transgenic crops.[47] Biotechnology companies would likely have the duty to educate farmers about these best management practices and, possibly, have the obligation to police their farmers through contractual and monitoring arrangements. Farmers would have the obligation to abide by these agronomic practices.[48] If biotechnology companies and farmers of transgenic crops that create additional risks fail to adopt best management practices and consequently cause damage, they may face legal liability through negligence claims.

Private Nuisance[49]

The common law claims of trespass, strict liability and negligence focus on the conduct or the activity that causes harm to the property of another. By contrast, the common law claim of private nuisance focuses not on conduct but on the interest to be protected, i.e., the private use and enjoyment

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44. RESTATEMENT OF LAW (THIRD) TORTS – PRODUCTS LIABILITY §§ 1 & 2 at 5,14 (1997) [Restatement 3d Prod. Liab.]. Section 2(b) categorizes a product as having a design defect when "foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe." *Id.* at 14.

45. For discussion of physical barriers by isolation distance, barrier crops, and border rows, see Eastham & Sweet, *supra* note 25, at 10.3.2 (physical gene flow barriers).

46. As part of the regulatory approval for Bt crops, the EPA has required that biotechnology companies and farmers implement a refuge policy for insects in non-transgenic fields of the same crop (non-transgenic cotton, non-transgenic corn, etc.) EPA has imposed this refugia obligation in order to reduce the emergence of insect resistance to the Bt toxin in the Bt crops. See EPA & USDA, *Position Paper on Insect Resistance Management in Bt Crops* (1999) available at http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_position_paper_618.htm.

47. Australian and New Zealand have addressed the issue of Genetic Modification-Free Zones fairly extensively. *See*, Avcare, Ltd. (Australia), *Genetic Engineering Free Zones: A Discussion Paper* (Nov. 2001) and Life Sciences Network (New Zealand), *Genetic Modification-Free Zones: a Discussion Paper for Public Consultation* (Feb. 2002), both papers available at http://www.lifesciencesnetwork.com. For discussion of agronomic zones in the United States, Grossman *supra* note 1, at 246-47.

48. For contrasting views of the relationship between biotechnology companies and farmers regarding best management practices, *compare* Stanley Abramson & Thomas Carrato, *Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L. J. 241, 259-65 (2001) *with* Nicole Nachtigal , Note, *A Modern David and Goliath, Farmer v. Monsanto: Advising a Grower on the Monsanto Technology Agreement*, 6 GREAT PLAINS NAT. RESOURCES. J. 50, 62-63 (2001).

49. Private nuisance must be distinguished from public nuisance. This article discusses public nuisance later under the heading of Damage to Economic Interests (Markets).

of land free from nontrespassory invasion by others.[50] By focusing on the use and enjoyment of land, nuisance may overlap with the other common law claims that focus on conduct, but nuisance is a distinct and independent basis for legal liability.

Fundamental to the nuisance claim is the idea that neighbors must not interfere with neighbors using and enjoying their own land and property. As each neighbor is entitled to the use and enjoyment of its own land, the legal claim of nuisance recognizes that neighbors must be accommodating to one another so as to allow a peaceable coexistence in use and enjoyment.[51] To ascertain the balance needed for peaceable coexistence, the courts have defined the elements of nuisance to include an invasion that is:

- either intentional and unreasonable or unintentional and otherwise actionable as a legal claim for trespass, strict liability, or negligence;[52] and
- causes significant harm.[53]

Persons bringing a legal claim for nuisance must provide proof that nearby fields of transgenic crops have unreasonably interfered with the use and enjoyment of their own land. In light of the wide-spread planting of transgenic crops under regulatory permission in the United States, persons bringing a nuisance claim are unlikely to establish that transgenic crops per se are unreasonable. Thus persons bringing a nuisance action are likely to have difficulty using private nuisance against biotechnology companies. However, the legal claim of nuisance is oriented to the specific facts and circumstances between neighbors and to a definition of "unreasonableness" in the context of those specific facts and circumstances.[54] While private nuisance may be a more viable legal claim against a neighbor growing transgenic crops, the courts are unlikely to endorse a private nuisance claim that insists on zero tolerance of pollen flow or volunteer plants.[55] Courts expect neighbors to have reasonable tolerances towards one another as the court engages in the balancing of gravity of the harm against the social utility of each neighbor's use and enjoyment of their own land.[56]

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50. 4 RESTATEMENT OF THE LAW (SECOND) TORTS § 821D at 100 (1979) [4 Restatement 2d Torts]. For discussion of private nuisance as applied to transgenic crops, see Enders, *supra* note 31, at 492-94; Richard Repp, Comment, *supra* note 19, at 605-13; Grossman, *supra* note 1, at 232-36. Aside from the two class action lawsuits identified in note 72 *infra*, as of August 2002, there are no reported cases involving an allegation of private nuisance for property damage against transgenic crops.

51. For a discussion of coexistence between neighbors regarding straying cattle, read Ellickson, *supra* note 20.

52. 4 Restatement 2d Torts § 822 at 108.

53. *Id.* at § 821F at 105.

54. *Id.* at § 822 Comment g (Intentional invasions – unreasonableness) at 112.

55. For discussion of tolerances, EUROPEAN COMM. SCIENTIFIC COMMITTEE ON PLANTS, OPINION CONCERNING THE ADVENTITIOUS PRESENCE OF GM SEEDS IN CONVENTIONAL SEEDS (Mar. 13, 2001), available at http://europa.eu.int/comm/food/fs/sc/scp/out93_gmo_en.pdf.

56. 4 Restatement 2d Torts §§ 826-828 and accompanying comments provide guidance to the courts about the balancing of interests between neighbors when considering whether or not a private nuisance exists.

Persons bringing a private nuisance claim must also establish that the invasion caused significant harm. The case law gives two components to the significant harm – its gravity[57] and its normality in a particular locality.[58] Persons claiming private nuisance will not be able to establish the significant harm element if their harm is primarily personal disgust or opposition to transgenic crops.

Damage to the Person

Persons claiming personal damage arising from transgenic crops might assert harm based on toxicity of the transgenic crop or its food product, an allergic response to these crops or their food products, or a claim that long-term exposure to transgenic crops or their foods caused ill-effects to health. In the United States, concerns about the health effects of transgenic crops and their food products explain why the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) exercise regulatory control over transgenic crops.[59]

In light of the regulatory approvals from the FDA and the EPA, if transgenic crops or their food products had toxic effects, the crop and food would probably be denied approval for the market. As for long-term health effects, monitoring for alleged effects is at present the most feasible response.[60] Consequently the most likely personal damage claim now or in the near future would involve a claim that the transgenic crop caused an allergic response in the person alleging damages.[61] Personal

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57. 4 Restatement 2d Torts § 821F Comment c states, "By significant harm is meant harm of importance, involving more than slight inconvenience or petty annoyance. . . . [T]here must be a real and appreciable interference with the plaintiff's use or enjoyment of his land before he can have a cause of action." *Id.* at 105.

58. 4 Restatement 2d Torts § 821F Comment d states, "The standard for the determination of significant character is the standard of normal persons or property in the particular locality. If normal persons living in the community would regard the invasion in question as definitely offensive, seriously annoying or intolerable, then the invasion is significant. If normal persons in that locality would not be substantially annoyed or disturbed by the situation, then the invasion is not a significant one, even though the idiosyncracies of the particular plaintiff may make it unendurable to him." *Id.* at 105-106. Read also text and notes 37-39 *supra* about the "abnormally sensitive" defense in strict liability.

59. The FDA regulates foods from transgenic crops under the authority of the Federal Food, Drug and Cosmetic Act (FFDCA). FDA, *Statement of Policy: Foods Derived from New Plant Varieties*, 57 Fed. Reg. 22,984 (May 29, 1992). While the 1992 Policy has been updated, the 1992 Policy explains the regulatory framework.

The EPA regulates transgenic crops and their food products if the transgenic crop has in-built pesticidal traits (e.g., Bt crops). The EPA regulates these plant-incorporated protectant crops under the Federal Insecticide, Fungicide and Rodenticide Act and the FFDCA for setting tolerances of pesticide residues for processed foods. EPA, *Regulation under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (formerly Plant-Pesticides)*, 66 Fed. Reg. 37,772 (July 19, 2001).

60. Monitoring can be done by regulatory agencies, the biotechnology companies, environmental or health organizations, or private litigation alleging a long-term ill-effect. As of August 2002, there are no reported cases against transgenic crops alleging long-term personal damage.

61. Once the EPA approves a transgenic crop, damage claims based on failure to warn, improper labeling, and related torts are preempted by federal law. In re StarLink Corn Products Liability Litigation, 212 F. Supp.2d 828, 830 (MDL N.D. Ill., 2002). *See generally*, Celeste Steen, Comment, *FIFRA's Preemption of Common Law Tort Actions Involving Genetically Engineered Pesticides*, 38 ARIZ. L. REV. 763 (1996).

damage claims for allergic responses could involve legal liability claims based on strict liability, products liability, nuisance, or negligence with the same elements and burdens of proof as discussed regarding property damage claims.

With regard to personal damage claims, the presently approved transgenic crops and their food products have created no new or additional legal liability risks for food safety than the risks that exist for non-transgenic crops and their foods.[62] Indeed, failure to use transgenic crops as food ingredients when these crops reduce food safety risks means that food companies could be exposed to legal liability for design defect in products liability law.[63]

In the one instance in the United States in which persons made adverse effects reports (AERs) from a transgenic crop and its food products (StarLink™ corn), the transgenic corn was not approved for human consumption as food. Regarding StarLink™ and allergic responses in consumers, the Center For Disease Control (CDC) concluded:

> "Although the study participants may have experienced allergic reactions, based upon the results of this study alone, we cannot confirm that a reported illness was a food-associated allergic reaction. Although our results do not provide any evidence that the allergic reactions experienced by the people who file AERs were associated with hypersensitivity to Cry9c [StarLink™] protein, we cannot completely rule out this possibility, in part because food allergies may occur without detectible serum IgE to the allergens."[64]

In light of the lack of approval for StarLink™ in human food and the CDC report, a class-action lawsuit on behalf of consumers alleging that they ate food not fit for human consumption was successfully

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62. A press release from the Australia-New Zealand Food Agency (ANZFA) contained the following comments: "'I [Ian Lindenmayer, Managing Director, ANZFA] don't pretend that we have all the answers about GM foods, but we have enough to know that those we approve are at least as safe as their non-GM counterparts.' Lindenmayer said GM foods had been in the world's food supply for more than a decade – without a single scientifically-documented case of causing harm to a person. The ANZFA safety assessment process ensured that . . . the toxicity and allergenicity of these foods is at levels no higher than in conventionally grown crops." ANZFA Release (Feb. 13, 2002). While urging continuing and enhanced regulatory oversight for food safety concerns, the American Medical Association and The Royal Society (UK) expressed similar conclusions about transgenic crops and their food products as ANZFA. American Medical Assoc., *Report on Biotechnology Press Release* (Dec. 2000) ("These foods are substantially equivalent to their conventional counterparts. Genetic engineering is capable of introducing allergens into recipient plants, but the overall risks of introducing an allergen into the food supply are believed to be similar to or less than that associated with conventional breeding methods."), available at http://www.ama-assn.org/ama/pub/article/2036-3604.html; The Royal Society, *Genetically Modified Plants for Food Use and Human Health: An Update* (Policy Doc. 4/02, Feb. 2002) ("There is at present no evidence that GM food cause allergic reactions. The allergenic risk posed by GM plants are in principle no greater than those posed by conventionally derived crops or by plants introduced from other areas of the world.") *Id.* at ¶ 7 p. 3.

63. Drew Kershen, *The Risks of Going Non-GMO*, 53 OKLA. L. REV. 631, 633-37 (2000) (discussion of possible food company legal liability for failure to use transgenic crops that have a lower risk of food harms to consumers than organic or conventional crops).

64. CDC, *Investigation of Human Health Effects Associated with Potential Exposure to Genetically Modified Corn*, June 2001, at 10.

concluded with a settlement against Aventis, the owner of StarLink.™[65] Transgenic crops that have not been approved for human consumption thus present the legal liability risk of claims from consumers even if the consumer has not suffered a toxic, allergic, or other health-related harm.

As for legal claims for damages to the person, pharmaceutical transgenic crops most likely present the greatest legal risk to the biotechnology companies and their growers.[66] In many (if not most) instances, the pharmaceutical trait from the transgenic crop will need to be kept out of food and feed crops to protect against claims of toxic, allergic, and unfit food harms. In light of this fact, regulatory authorities in the United States have recently proposed new guidelines for the segregation of pharmaceutical transgenic crops from food and feed crops.[67] However, these regulatory measures should be viewed as minimum measures and biotechnology companies will assuredly need to develop contractual provisions with their growers for segregation measures, for control of volunteer plants, and for identity preservation of the pharmaceutical crop from the field to the pharmaceutical processing facilities.[68]

If biotechnology companies and their growers comply with regulatory requirements, if biotechnology companies develop effective stewardship contractual programs with their growers, the companies and their growers may be able to minimize the risk of legal liability. For approved pharmaceutical transgenic crops and approved field trials to develop these pharmaceutical crops, courts will have the power to choose between strict liability and negligence standards for legal liability if tort claims are asserted because the pharmaceutical trait got into a food product. In deciding whether to apply strict liability, courts would balance the social benefit (the creation of pharmaceutical products)

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65. A. Harris, *Danger Uncertain, But Suits Multiply – Billions Could Be at Stake in Farmers' Cases*, NATIONAL L.J., Sept. 9, 2002, at A12 (reporting a settlement valued at $9 million for the consumer class action.) [Harris.] In the settlement, the benefitted consumers get a discount coupon, not cash. In re StarLink Corn Products Liability Litigation, No. 1403,01C1181, 2002 WL 1291790 at *1 (N.D. Ill. June 11, 2002).

66. For an overview of this issue, Thomas Redick, *Biopharming, Biosafety, and Billion Dollar Debacles: Preventing Liability for Biotech Crops*, American Agricultural Law Association Annual Conference, Indianapolis, IN (Oct. 2002). [Redick *Biopharming*]

67. USDA-APHIS, *Information for Field Testing of Pharmaceutical Plants in 2002* ,May 21, 2002, at http://www.aphis.usda.gov/ppq/biotech/pdf/pharm-2002.pdf . The USDA-APHIS guidelines primarily stress three segregation techniques: geographical isolation (separation distances), temporal isolation (planting time differences), and field monitoring for control of volunteer plants. FDA, *Guidance for Industry: Drugs, Biologics, and Medical Devises Dervied from Bioengineered Plants for Use in Humans and Animals*, 67 Fed. Reg. 57,828 (Sept. 12, 2002). The FDA Guidance Document (Part III on environmental considerations) sets forth confinement measures meant to control pharmaceutical traits from transgenic crops from entering the food or feed chain. *Cf. also*, Office of Science & Technology (OSTP), *Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and to Establish Early Food Safety Assessments of New Proteins Produced by Such Plants*, 67 Fed. Reg. 50,578 (Aug. 2, 2002) (field test requirements for any transgenic crops). The biotechnology industry has responded to these governmental initiatives by proposing voluntary industry standards that are stricter than the suggestions in the government documents. Justin Gillis, *Biotech Industry Adopts Precaution*, WASHINGTON POST, Oct. 22, 2002 , at E01.

68. This sentence attempts to encapsulate the argument for identity preservation arrangements presented by Redick Biopharming, *supra* note 66. For an identity-preservation program that has been used successfully in Canada for transgenic canola, see Stuart Smyth & P.W.B. Phillips, *Competitors Co-operating: Establishing a Supply Chain to Manage Genetically Modified Canola*, 4 INT'L FOOD & AGRIBUS. MNGT. REV. 51 (2002).

against the likelihood of possible harm (the risks of toxicity or allergenicity) in the food supply.[69] If courts were to decide that the social benefit outweighs the risk, the court could decide against strict liability. Courts may be influenced in this decision by how effective and thorough the contractual stewardship programs[70] are and by any tolerance standards adopted by the regulatory authorities.[71] If courts decide against strict liability, courts would look to negligence as the source of legal recovery and to determine whether the company and the grower acted reasonably in their crop production, harvesting, volunteer control, and handling activities. If the company and grower acted reasonably, no liability would exist.

Damage to Economic Interests (Markets)

Several lawsuits have been filed against agricultural biotechnology companies by farmers who did not grow transgenic crops.[72] In these lawsuits, the farmers claiming damage emphasize the legal

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69. 3 Restatement 2d Torts § 520(f) and comment k at 36, 42. For example, farmers belonging to the Iowa Cooperative are growing a transgenic corn that contains an enzyme that helps cystic fibrosis patients digest food. Meristem Therapeutics, a French biotechnology company, developed the transgenic corn as a process that is 14 times cheaper than producing the same enzyme in the laboratory. Emily Gersema, *The Latest in Biotech: 'Pharmers'*, WICHITA EAGLE, Aug. 11, 2002, at 4.

70. In addition to the USDA-APHIS geographic and temporal isolation requirements, Meristem Therapeutics and their farmers also use male-sterile corn and detassling to prevent pollen flow from the pharmaceutical crop to other fields. *Id.* *See*, Gene Stevens, *Implications of Pollen Research to APHIS Pharmaceutical Corn Regulations*, INFORMATION SYSTEMS FOR BIOTECHNOLOGY NEWS REPORT, Sept. 2002, available at http://www.isb.vt.edu/news/2002/news02.sep.html .

71. In the OSTP document cited in note 66, the U.S. regulatory agencies agreed to regulate transgenic crops in accordance with the level of environmental, human, and animal health risk. On a case-by-case basis, some traits from transgenic crops being field tested would be prohibited in commercial seed, commodities, and processed food and feed as presenting an unacceptable risk. In other instances, intermittent, low levels of transgenic traits from these field tests could be acceptable. 67 Fed. Reg. 50579. Hence, the U.S. regulatory agencies have indicated that zero tolerance will not be the automatic or default result when transgenic traits from field trials or pharmaceutical crops enter the food and feed chain.

72. These several lawsuits have been consolidated into two separate multi-district, class action lawsuits in federal courts – one in the Northern District of Illinois and one in the Eastern District of Missouri.

The Northern District of Illinois class action: In re StarLink Corn Products Liability Litigation, 211 F. Supp.2d 1060 (N.D. Ill. 2002) and In re StarLink Corn Products Liability Litigation, 152 F. Supp. 1378 (J.P.M.L. 2001). These two cases created the multi-district, class-action lawsuit in the Northern District of Illinois. Farmers in this lawsuit did not plant the transgenic corn StarLink and do claim property damage through cross-pollination.

The Eastern District of Missouri class action: Blades v. Monsanto Company, 2001 WL 775980 (S.D. Ill., Jan. 3, 2001). This case upheld the forum selection clause in the Monsanto Technology Agreement that specifies the Eastern District of Missouri as the forum for lawsuits related to the technology agreement. After upholding the forum selection clause, the District Judge transferred the case to the United States District Court for the Eastern District of Missouri.

In the consolidated Missouri case, the farmers asserting tort claims (Class 2) did not plant transgenic crops and do claim damages through cross-pollination. These tort claims are asserted against Monsanto Company only. Sample v. Monsanto Company, Civil No. 4:01cv00065RWS (E.D. Mo. 2001), First Amended Class Action Complaint, Count VII (public nuisance) and Count VIII (negligence), available at http://www.cmht.com/casewatch/antitrust/biological.html . The other counts in the Missouri case are anti-trust

claim that the introduction of transgenic crops increased their production and equipment costs and depressed the price for their agricultural products. These farmers claim that, while their particular crops have suffered property damage through cross-pollination, their more significant damage claim is that the presence alone of the transgenic crops in the agricultural sector has affected market access and the market prices for their non-transgenic crops generally.

Damages for Economic Interests (Markets)

In discussing damages for economic interests (markets), the potential claims can be more easily understood if the fact patterns are distinguished between crops approved for limited uses in the United States, crops approved for all uses in the United States, and crops approved in the United States but unapproved in major export markets. Moreover, it is worthwhile to note that lawsuits arising from transgenic crops and claiming damage to economic interests will almost always be against the agricultural biotechnology companies. Only agricultural biotechnology companies place transgenic crops on the market and by so doing arguably impact market access and market prices for non-transgenic crops. Therefore, farmers who grow transgenic crops are at basically zero risk that economic-interests lawsuits will be brought against individual growers of transgenic crops.

Transgenic Crops Approved for Limited Use in the United States

Of the transgenic crops approved thus far for commercial sale in the United States, the only crop to have a been given a limited use approval was StarLink™. When the Cry9C gene was found in foods, the options open to the EPA were three: to grant an exemption from a tolerance, to set a tolerance level for the Cry9C gene in foods, or to deny a tolerance and have the foods considered adulterated. When the EPA decided against an exemption and against a tolerance, the EPA effectively created a zero tolerance for the Cry9C gene in the food supply.[73]

With zero tolerance as the regulatory standard, it is no surprise that the trial judge in the multi-district, class-action litigation in the Northern District of Illinois allowed the case to proceed to trial on the tort legal liability claims of negligence, negligence per se (statutory violations), strict liability, private nuisance, and public nuisance.[74] At trial, the plaintiffs (farmers alleging damages to economic interests) and defendant (Aventis Corporation) will present evidence establishing and rebutting, respectively, the elements of these torts that must be proven to create legal liability.

In March 2001, the EPA stated that it will no longer grant limited registrations for transgenic crops.[75] Consequently, the precise situation of StarLink™ should not recur. However, as transgenic crops come into field trials and commercial production for pharmaceutical products, the Food and Drug

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claims (Class 1) and consumer fraud claims (Class 1a) for farmers who purchased and grew transgenic crops. These claims are asserted against five agricultural biotechnology companies. These anti-trust and consumer fraud claims are outside the scope of this article.

73. For a detailed study of StarLink™, including the EPA decisions about exemption and tolerance, see Donald Uchtmann, *StarLink™ – A Case Study of Agricultural Biotechnology Regulation,* 7 DRAKE J. AGRI. L. 159, 196-202 (2002).

74. In re StarLink Corn Products Liability Litigation, 212 F. Supp.2d 828 (N.D. Ill. 2002).

75. Uchtmann *supra* note 73, at 205.

Administration will face the similar issue – a split approval for pharmaceutical use but not for food or feed use. If the Food and Drug Administration adopts a zero tolerance standard for the pharmaceutical traits in the food supply,[76] the biotechnology companies will have three options: grow the pharmaceutical crop in contained and confined structures only, grow the pharmaceutical crop in fields but subject to the tort claims identical to those being pursued in the StarLink™ Corn Products Liability Litigation, or abandon the transgenic crop as a production method for pharmaceutical products.

Transgenic Crops Approved for All Uses in the United States

The multi-district, class action lawsuit in the Eastern District of Missouri presents the questions of legal liability in tort for an agricultural biotechnology company for fully approved transgenic crops.[77] The plaintiff-farmers in the Missouri case allege that the presence of transgenic genes in the corn and soybean supply (that have either cross-pollinated with their own non-transgenic crops or been commingled with their crops during harvesting and storage) has increased the plaintiff's costs of production and depressed the prices for corn and soybeans.

The *Sample v. Monsanto Company* case in the Eastern District of Missouri only plead negligence and public nuisance as tort causes of action.[78] The *Sample* plaintiffs do not allege private nuisance nor strict liability. However, the fact that the *Sample* plaintiffs did not allege private nuisance or strict liability does not mean that other plaintiffs in other cases cannot use these two torts as alternative or additional claims for tort legal liability in similar fact patterns.

With respect to negligence, private nuisance, and strict liability, the farmers in *Sample* must prove the same elements of these torts as has been discussed previously in this article. But in addition, farmers who claim damages to economic interests may face an additional defense – the defense called the "economic loss" doctrine.

The economic loss doctrine has its origins in products liability law at the interface between tort law and contract law.[79] However, the doctrine now has grown beyond the torts-contracts interface to

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76. As indicated in note 71 *supra*, the FDA will make the determination about a tolerance on a case-by-case basis and will not adopt a zero tolerance standard as the automatic or default standard.

77. Sample v. Monsanto Company, Civil No. 4:01cv00065RWS (E.D. Mo. 2001), First Amended Class Action Complaint, Count VII (public nuisance) and Count VIII (negligence), available at http://www.cmht.com/casewatch/antitrust/biological.html .

In Canada, two farmers, as representatives of the 1000 certified organic farmers of Saskatchewan, have filed a lawsuit against Monsanto Company and Aventis Cropscience Canada alleging four common law claims and two claims under provincial environmental laws. The four common law claims are trespass, nuisance, strict liability, and negligence. On the pleadings, the four common law claims present legal liability issues that are similar to the pleadings in *Sample v. Monsanto Company*. Aaron Bouchie, *Organic Farmers Sue GMO Producers*, 20 NAT. BIOTECH. 210 (Mar. 2002). While Saskatchewan and the United States share the common law legal system, the article focuses on United States tort law and tort precedents and not Canadian law.

78. Sample v. Monsanto Counts VII & VIII *supra* note 79.

79. RESTATEMENT OF THE LAW THIRD – TORTS: PRODUCTS LIABILITY § 21 (1997). [Restatement 3rd Prod. Liab.]

be an analysis about which forms of economic loss are recoverable in tort, even in the absence of a contract law dimension to the legal dispute.[80]

In *In re Starlink*, the court ruled that the economic loss doctrine did not apply because, if proven, the unapproved crop cross-pollinated or was commingled with the non-transgenic crop of the farmer-plaintiffs, thereby damaging the property (non-transgenic corn) of the farmers who did not grow StarLink™ corn because it could not be sold for food.[81] In discussing the issue, the court wrote several paragraphs that may have particular significance when the fact pattern involves fully-approved transgenic crops that can be sold for all uses. The court wrote:

> What these [bridge or road closure – access] cases share in common with traditional economic loss doctrine jurisprudence is the lack of property damage. Moreover, because the only harms alleged were profits lost due to customer's inability to access the premises, these damages fit neatly within the rubric of 'disappointed commercial expectations.'[82]
>
> Still, as the access cases aptly demonstrate, the economic loss doctrine has grown beyond its original freedom-of-contract based policy justifications. Farmers' expectations of what they will receive for their crops are just that, expectations. Absent a physical injury, plaintiffs cannot recover for drops in market prices. Nor can they recover for any additional costs, such as testing procedures, imposed by the marketplace. But if there was some physical harm to plaintiffs' corn crop, the lack of a transaction with defendants affects what will be considered 'other property.'[83]

As can be understood from the quotations from *In re Starlink*, the court in the *Sample* case must decide whether cross-pollination or commingling of a fully-approved transgenic crop causes a physical harm to non-transgenic crops. If the court decides that a physical harm occurred, the court likely will allow the case to proceed to trial for proof of the harm under the negligence tort claim. If the court decides that no physical harm occurred, the court likely will hold that the economic loss doctrine bars the tort claim.

In addition to the negligence claim, the farmers in *Sample* also have sued under the doctrine of public nuisance. Public nuisance should be distinguished from private nuisance that was discussed earlier in this article.

As stated in the Restatement of Law, public nuisance is an unreasonable interference with a right common to the general public.[84] By focusing on public rights, the tort of public nuisance is not

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80. Restatement 3rd Prod. Liab. Comments a & e, at 293, 295.

81. In re StarLink, 212 F. Supp.2d, 832-37.

82. *Id.* at 835.

83. *Id.* at 837.

84. Restatement 2d Torts § 821B Public Nuisance reads:
(1) A public nuisance is an unreasonable interference with a right common to the general public.
(2) Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:

limited to plaintiffs who must prove damages to their interests in land. Plaintiffs who can prove a harm different in kind from the general public may use public nuisance to recover damages for themselves while simultaneously protecting public rights for themselves and others.[85]

In determining whether growing a fully-approved transgenic crop is a significant, unreasonable interference with a right common to the general public, the courts will likely consider two questions as decisive. First, what is the effect of compliance with the regulations applicable to transgenic crops, if proven true by the agricultural biotechnology companies?[86] Second, has there been an identified harm that, whatever the general utility of transgenic crops, it would be unreasonable to allow the identified harm without compensating for it?[87] This second question raises the deeper policy issue called the "socialization of harm," i.e., even if an identifiable harm exists, when should society as the whole bear the harm?[88]

Transgenic Crops Approved in the United States but Not Approved in Major Export Markets

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(a) Whether the conduct involves a significant interference with public health, the public safety, the public peace, the public comfort or the public convenience, or

(b) whether the conduct is proscribed by statute, ordinance or administrative regulation, or

(c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

85. Restatement 2d Torts § 821C and comments.

86. Restatement 2d Torts § 821B Comment f states: "Although it would be a nuisance at common law, conduct that is fully authorized by statute, ordinance or administrative regulation does not subject the actor to tort liability. Aside from the question of the validity of the legislative enactment, there is the question of its interpretation. Legislation prohibiting some but not other conduct is not ordinarily construed as authorizing the latter....In addition, if there has been established a comprehensive set of legislative acts or administrative regulations governing the details of a particular kind of conduct, the courts are slow to declare an activity to be a public nuisance if it complies with the regulations." *Id.* at 91

87. Restatement 2d Torts § 821B Comment i states: "In determining whether to award damages, the court's task is to decided whether it is unreasonable to engage in the conduct without paying for the harm done. Although a general activity may have great utility it may still be unreasonable to inflict the harm without compensating for it. In an action for injunction the question is whether the activity itself is so unreasonable that it must be stopped. It may be reasonable to continue an important activity if payment is made for the harm it is causing, but unreasonable to continue it without paying." *Id.* at 93.

88. In its discussion paper cited *supra* note 8, the Ministry for the Environment (New Zealand) frames the deeper policy issue in several passages:

"In particular, it would clearly be counter-productive to design liability rules that provided full compensation in all eventualities, if the practical consequence was that the costs and risks of engaging in the activity were prohibitive. Liability rules must fit with the basic goal of preserving opportunities." MFE (NZ), PUBLIC DISCUSSION PAPER – IMPROVING THE OPERATION OF THE HSNO ACT FOR NEW ORGANISMS, at 59.

"Any move to a more onerous liability regime may have negative impacts. Depending on the strength and design of the regime, it may create a disincentive for investment in GM and GM-based innovation. This disincentive may be particularly acute for those technologies at the 'cutting-edge' end of the spectrum, as there is less information on risks and ways to manage these risks." *Id.* at 64.

See generally, Dan L. Burk & Barbara A. Boczar, *Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 792 (1994).

If a particular transgenic crop is approved in the United States but is not approved in a major export market, agricultural biotechnology companies and their growers must assume that the export market has established a zero tolerance for that particular transgenic crop. Hence, the agricultural biotechnology companies and the farmers who would like to grow approved transgenic crops face the following choice – forgo the benefits of the approved transgenic crop or attempt to satisfy a zero tolerance standard for agricultural exports to the unapproving export market.

Agricultural biotechnology companies and their growers can develop or try to develop stewardship practices and standards for growing, harvesting, storing, and marketing transgenic crops that create an identity preservation system segregating transgenic crops from non-transgenic crops to achieve zero tolerance.[89] While it will be difficult to create these stewardship and identity preservation programs, it may also be futile because zero tolerance is likely unobtainable in the real world of farmers and the supply chain of agricultural products. When the European Commission asked its Scientific Committee on Plants about zero tolerance for unapproved transgenic crops, the Committee opined:

> "The Committee is of the opinion that a zero level of unauthorized GM seed is unobtainable in practice. A zero level would have severe consequences for part B [reference to EU law governing releases into the environment of transgenic crops] GM field releases, for biosafety research and for evaluation of new GM plant varieties."[90]

Moreover, if the Cartagena Biosafety Protocol comes into existence as a binding international treaty,[91] Article 18 of the Protocol may be interpreted to require a less-than-zero tolerance for unapproved transgenic crops. Less-than-zero tolerance occurs when an importing nation is legally authorized by the Protocol to refuse agricultural commodities if those commodities may contain an unapproved variety.[92] If the less-than-zero tolerance becomes international law, stewardship and identity preservation programs likely become irrelevant because the only way to avoid a may-contain refusal is to not field test nor commercialize any transgenic crop. The purpose of field testing is to gather data for the approval process. But if the field test itself triggers the may-contain refusal, the field

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89. Mr. Thomas Redick, an attorney in St. Louis, Missouri, has been an articulate and thoughtful proponent of these stewardship and identity preservation programs. *See generally*, Redick *Biopharming*, *supra* note 66 and Thomas Redick and Christina Bernstein, *Nuisance Law and the Prevention of "Genetic Pollution:" Declining a Dinner Date with Damocles*, 30 ENV'L L. REPT. 10328 (May 2000). *See also*, Smyth & Phillips, *supra* note 68.

90. EU Health & Consumer Protection Directorate-General, *Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds*, SCP/GMO-SEED-CONT/002-FINAL (2002).

91. As of September 17, 2002, thirty-six nations had ratified the Cartagena Biosafety Protocol. Fifty nations must ratify the Protocol before it becomes a binding international treaty upon those who have ratified or otherwise acceptably assented to the treaty. Data on ratification is on the Protocol homepage at http://www.biodiv.org/biosafety .

92. For an understanding of the possible impact of the Cartagena Protocol on Biosafety concerning the adventitious presence of unapproved transgenic crops in agricultural commodity shipments, see Report of the Meeting of Technical Experts on the Requirements of Paragraph 2(a) of Article 18 of the Cartagena Protocol on Biosafety, *Handling, Transport, Packaging and Identification of Living Modified Organisms (Article 18)*, UNEP/CBD/ICCP/3/7/Add.1 (Mar. 22, 2002).

test cannot be done, if the legal obligation is to protect the export market in a less-than-zero tolerance nation.

In a lawsuit brought by non-transgenic farmers or commodity organizations to prevent the introduction into field testing or commercial growing of a transgenic crop that is not approved in a major export market, the plaintiffs are most likely to rely prominently on the doctrine of public nuisance previously discussed. Those bringing the public nuisance lawsuit would allege that the introduction of the transgenic crop without export market approval would cause such wide-spread economic losses that a court should rule that the unapproved-in-export market transgenic crop is an unreasonable interference with the public peace, the public comfort, or the public convenience. The plaintiffs bringing this public nuisance suit would allege that the export market with its zero tolerance standard can best be protected (and possibly only be protected) through an injunctive remedy that the public nuisance liability claim allows.[93]

A court handling a public nuisance lawsuit requesting protection of export markets faces a daunting decision. If the court protects the export market, the court is effectively overruling the United States approval of the transgenic crop and allowing the hostility of export markets to control what agricultural biotechnology may be used in the United States. Moreover, especially when considering field trials and commercial production of pharmaceutical transgenic crops, the court would be ruling that export markets are more important than the development of new medicines and drugs. While such a decision would have significant impact for Americans, the impact may be even greater upon the citizens of the developing world.[94] By contrast, if the court protects the field testing and commercialization of transgenic crops approved in the United States, the court is subjecting American farmers to rejection in export markets that have a zero-tolerance or less-than-zero tolerance for transgenic crops that are unapproved in the export market. Courts will immediately and intuitively sense the difficult, complex, and future-defining policy issues involved in a public nuisance injunction lawsuit against transgenic crops.[95]

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93. Restatement 2nd Torts § 821(C)(2) (who may maintain a proceeding to enjoin a public nuisance). To the author's knowledge, no lawsuit seeking a public nuisance injunction remedy has been filed in the United States. The *In re Starlink* and *Sample v. Monsanto Company* lawsuits seek damages, not an injunction, and neither involves the fact pattern of a transgenic crop approved in the United States but not approved in a major export market. StarLink™ had limited approval in the United States; the *Sample* litigation involves transgenic crops fully approved both in the United States and in major export markets. As part of the Saskatchewan lawsuit, the Saskatchewan organic growers do seek a public nuisance injunction against the release of transgenic wheat. For the Saskatchewan lawsuit, see *supra* note 77.

94. Peter Singer & Abdallah Daar, *Harnessing Genomics and Biotechnology to Improve Global Health Equity*, 294 SCIENCE 87 (Oct. 5, 2001) (e.g. biotechnology for vaccines for HIV-AIDS, malaria, hepatitis B, human papilloma virus associated with cervical cancer). *See generally*, Abdallah Daar et. al, *Top Ten Biotechnologies for Improving Health in Developing Countries*, 32 NATURE GENETICS 229 (2002). The full report from which this peer-reviewed article came is available at http://www.utoronto.ca/jcb. *See also*, *America's First "Agripharmas,"* SOYBEAN DIGEST (Oct. 14, 2002) [stating advantages of producing pharmaceuticals through transgenic crops as lower production costs, more scalable (planting fields is quicker and easier than building manufacturing facilities), and easily delivered as oral pharmaceuticals not needing refrigeration or needles].

95. If a court were to issue a public nuisance injunction against a crop fully approved under United States regulations, one could ask about the competence of a court using public nuisance to trump a regulatory program that the legislature has created. This article does not explore the complex and difficult issues about the appropriate spheres of power between courts and legislatures concerning the interaction between tort law and administrative regulations.

Conclusion

When a court faces a public nuisance injunction lawsuit, the reader realizes that the article has come full circle. While the geographical location is in the judicial forum, the public nuisance injunction lawsuit against transgenic crops returns the focus to the fundamental policy issue. Is agricultural biotechnology so fundamentally different from other agricultural technologies that agricultural biotechnology should be governed by an expanded and specialized legal liability regime?

As legislatures and courts engage the fundamental policy question set forth in the preceding paragraph, legislators and judges should not forget that the legal liability issues discussed in this article could arise also with agricultural breeding techniques that do not involve molecular techniques commonly described as agricultural biotechnology.[96] For example, many present day agricultural crops were created through chemical or radiation mutagenesis.[97] Pollen flow from mutagenic crops or volunteer mutagenic plants could give rise to the demand for zero tolerance of mutant varieties, as has been the oft-expressed demand against transgenic crops. One need only think of the persistent and powerful concerns about irradiation for food safety[98] to understand that modern mutagenic agricultural crops are only a lawsuit away from the small risk of potential legal liability. If transgenic crops set the precedent for significant legal liability for governmentally-approved agricultural crops, the small risk of potential legal liability for mutagenic crops becomes slightly larger. However, if mutagenic crops do not give rise to an expanded, specialized legal liability, the principle of treating-like-cases-alike may apply to mean that transgenic crops too should be free of expanded, specialized legal liability.

This article was prepared in November, 2002.

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96. *Cf.* NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS (1989). On pages thirty to thirty-two of this book, the National Research Council explains the southern corn leaf blight epidemic of 1970 that occurred with hybridization techniques. The explanation concludes, "The southern corn leaf blight epidemic was a highly publicized event: an epidemic ensued, and economic loss resulted. The year 1970 was certainly a bad year for corn production, but it was by no means a national catastrophe; corn production was back to almost normal within a year. Because an occasional unexpected crop loss may occur, it is important to have an arsenal of genetic modifications, techniques and genetic resources available that can be used promptly to limit unacceptable losses. New molecular methods for gene introduction will be beneficial in this regard." *Id.* at pp. 31-32. *Cf. also*, Drew Kershen, *The Concept of Natural: Implications for Biotechnology Regulation*, 3 AGBIOFORUM 69 (2000) (discussion of different regulatory responses to Bt sprays and Bt crops with respect to the issue of the emergence of insect resistance), available at http://www.agbioforum.org.

97. For a list of 2253 mutant varieties, consult FAO/IAEA Mutant Variety Database available at http://www-infocris.iaea.org/MVD.

98. For discussion of issues surrounding irradiation technology, read MORTON SATIN, FOOD IRRADIATION: A GUIDEBOOK (2nd ed. 1996).

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