WE REAP WHAT WE SOW: THE LEGAL LIABILITY RISKS OF GENETICALLY MODIFIED FOOD

Debra M. Strauss[*]

I. INTRODUCTION

TIME magazine recently declared:

> Biotech is the most rapidly adopted crop technology in human history—faster than the corn hybrids introduced in the U.S. in the 1930s and faster than the planting changes that took place during the Green Revolution.[1]

The latest daunting statistics for the planting of genetically modified (GM) crops confirm "Monsanto's stranglehold on the planet's food chain": 740 million acres (300 million hectacres), equally divided between North America and the rest of the world, mostly in Argentina and Brazil.[2] In 1996, two percent of U.S. soybeans had the Monsanto Roundup Ready® gene; in 2008, over 90 percent of the soybeans grown in the United States contained this gene.[3] In total, the current figures for GM crops commercialized in the United States are astonishing: soy (91%), cotton (71%), canola (88%), corn (85%), sugar beets (90%), Hawaiian papaya (more than 50%), alfalfa (currently on hold), zucchini and yellow squash (small amount), and tobacco (Quest® brand).[4] As a consequence, the list of foods on the U.S. shelves that contain a genetically modified ingredient is extensive, including the myriad of products derived from any of these soybeans or corn.[5]

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[*] Associate Professor of Business Law, Charles F. Dolan School of Business, Fairfield University; B.A., Cornell University; J.D., Yale Law School. Professor Strauss, a former Food and Drug Law Institute Scholar, currently teaches the legal environment of business, international law, and law and ethics. She has also developed a course on the international law and ethics of genetically modified food.

[1] Ken Stier, *Global Business: How Frankenfood Prevailed*, TIME, June 28, 2010, *available at* http://www.time.com/time/magazine/article/0,9171,1997448,00.html.

[2] *Id.*

[3] *Food, Inc.*, directed by Robert Kenner (Magnolia Pictures 2009); *see also* Stephanie E. Cox, Note, *Genetically Modified Organisms: Who Should Pay the Price for Pollen Drift Contamination?*, 13 DRAKE J. AGRIC. L. 401, 406 (2008) (noting 20% increase yearly in organics sales). With its Roundup Ready® seed, Monsanto infuses each cell with a resistance to the herbicide Roundup Ready®, also sold by Monsanto. When the fields are sprayed with this glyphosate herbicide, the weeds are killed and the GM crops are left standing. The resulting food products retain this herbicide resistance at the genetic level. *See* Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 167 (2006) [hereinafter Strauss, *Importing Caution*].

[4] Institute for Responsible Technology (IRT), GMOs in Food, http://www.responsibletechnology.org/GMFree/GMODangers/GMOsinFood/index.cfm (last visited July 30, 2010) (providing a summary list of crops, foods, and food ingredients that have been genetically modified as of May 2010); see also National Agricultural Statistics Service (NASS), Agricultural Statistics Board, U.S. Department of Agriculture: Acreage (2009), available at http://www.responsibletechnology.org/documentFiles/222.pdf? (providing information concerning total U.S. acreage of corn, soy, wheat, and cotton).

[5] IRT, s*upra* note 4. Genetically Modified Organisms (GMOs) are created when the genes of one organism are inserted into the DNA of another organism, causing the target trait to be expressed in that non-related species.

None of these products are labeled as containing genetically modified organisms (GMOs).[6] The U.S. market readily accepts these genetically engineered crops, while overseas they face more restrictions and fewer regulatory approvals, although some say that has been quietly changing.[7] Reflecting public attitudes as to who should bear the risk of potential harm, "GM free zones" where GM crops cannot be planted have been announced in countries throughout the world.[8]

In the United States, Monsanto has a 35% market share in corn seed, with its GM traits implanted in 85% of all U.S. corn due to the licensing of its technology.[9] With its profits recently dropping due to increased competition from China of its herbicide glyphosate and a farmer backlash against high-priced GM seeds, Monsanto plans to push its GM seeds even more aggressively by lowering prices for two recently introduced lines of GM seeds (a second generation of its Roundup® tolerant soybean and a line of herbicide-resistant and pest-resistant corn called SmartStax).[10] Monsanto is counting on U.S. farmers to buy enough of this Roundup Ready® 2 Yield to plant about 15 million acres for the 2011 growing season.[11] In addition, the biotechnology industry has been capitalizing on fears of a food shortage crisis based on population growth projections and the vulnerability of the global food supply to weather and potential catastrophic events.[12] The industry can be expected to continue to exploit these fears to push further adoption of their GM crops.

The genetically modified (GM) plants then produce GM foods and ingredients, which now occupy a vast majority of food products on U.S. grocery store shelves. In addition to herbicide-resistant varieties of soybeans, canola, cotton, corn, radicchio, rice, and sugar beet, genes derived from a bacterium in the soil used as an insecticide, *Bacillus thuringiensis* (Bt), have been inserted into crops to induce the plant to produce a toxin against certain insects, producing Bt-corn, Bt-cotton, Bt-potatoes, Bt-rice, and Bt-tomatoes. The United States has also approved virus- resistant varieties of papaya, potato, and squash, along with tomato and cantaloupe varieties containing a gene that slows the ripening process to allow fruit to ripen longer on the vine. *See* Strauss, *Importing Caution*, *supra* note 3, at 167-68 (explaining this technology and examples of GM crops).

[6] *See* Strauss, *Importing Caution*, *supra* note 3, at 182-89 (discussing the U.S. laissez-faire regulatory treatment of GMOs).

[7] As Brett Begemann, international executive vice president at Monsanto explains about the gradual and silent penetration of the European market, "Neither the government nor companies seem to see much upside in being more candid with the public." Stier, *supr*a note 1. While none are as openly welcoming to GM crops as the United States, there are now twenty-five countries that have planted biotech crops and an additional thirty-two countries that have approved biotech imports for either animal feed or food. *Id.*

[8] "Nearly two thousand jurisdictions in 22 countries in Europe have declared themselves GM free zones and the same holds true for parts of New Zealand, most states in Australia, Venezuela, most of Brazil, Angola, Sudan, and Zambia." Jeffrey M. Smith, "The Myth and Necessity of GM Free Zones," *Spilling the Beans*, Oct 1, 2004, http://www.seedsofdeception.com/utility/showArticle/?ObjectID=195&find=prodigene&happ=siteAdministrator [hereinafter Smith, *Myth*] (citing Stefania Bianchi, *Anti-GM Movement Spreads Across Europe*, INTER. PRESS SERVICE, April 22, 2004).

[9] *Id.* Although Monsanto holds the lead in the GM seed market and maintains a $1 billion R&D budget, internationally other companies currently include Switzerland's Syngenta, Pioneer Hi-Bred International which is part of DuPont, Dow AgroSciences and Germany's Bayer CropScience. "Competitors can become cross-licensing collaborators, even partners" as the companies seek to maximize their GM seed profits. *Id.*

[10] Scott Kilman, *Monsanto's Profit Drops 45% on Roundup Woes*, WALL ST. J., July 1, 2010, *available at* http://online.wsj.com/article/NA_WSJ_PUB:SB10001424052748703426004575338602676667626.html.

[11] *Id.*

[12] *See, e.g.,* David Thier, *Is the Next Global Food Crisis Now in the Making?*, July 17, 2010, *available at* http://www.aolnews.com/world/article/is-the-next-global-food-crisis-now-in-the-making/19557228.

Monsanto vigorously enforces its intellectual property rights, relentlessly pursuing farmers with seed contracts and lawsuits against any whose fields end up sprouting their genetically modified crops.[13] Clearly Monsanto has already established its dominance in ownership. But with great ownership comes great responsibility—and liability. The biotech industry claims that after almost fifteen years of GM crop use, there are no well-documented food-safety problems and no threat to biodiversity.[14] However, these claims are contradicted by reported incidents of superweeds and contamination, with potentially catastrophic events lurking on the horizon not too far-fetched to envision.

Despite the many promises of the prospective benefits of this technology that have not materialized, numerous risks to human health and the environment have been identified.[15] Potential risks include crop failures suffered by farmers, cross pollination of neighboring farms, and increased insect resistance, as well as health and environmental impacts on consumers.[16] The National Research Council has detailed the possible hazards that GM crops may pose in comparison to traditional crop breeding methods.[17] In citing the potential dangers of this technology, a study by the World Health Organization (WHO) identified additional costs from the issues of liability and compensation for economic loss due to contamination.[18] Indeed, one of

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[13] *See* Debra M. Strauss, *The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology*, 45 STAN. J. INT'L L. 287, 299 (2009) (analyzing the intellectual property treatment of genetically engineered seeds as asserted by the industry and proposing a model that would promote constructive innovation for the public benefit by encouraging "socially responsible technology") [hereinafter Strauss, *International Intellectual Property Rights*]; *see also Food, Inc.*, *supra* note 3 (noting that Monsanto has a staff of seventy-five for investigating the use of their seeds with private investigators and a hotline to report neighbors; their frequent lawsuits for patent infringement prompt settlements with farmers vastly outmatched in resources and scare the other farmers into compliance).

[14] Stier, *supra* note 1.

[15] *See* Debra M. Strauss, *Defying Nature: The Ethical Implications of Genetically Modified Plants,* 3 J. FOOD L. & POL'Y 1, 7–19 (2007) (debunking the myths that this technology would reduce world hunger, decrease pesticide usage, improve nutritional content, and increase farmers' income and contrasting these claims of potential benefits with the risks) [hereinafter Strauss, *Ethical Implications*].

[16] Concerns in the international community have focused particularly on allergenicity, antibiotic resistance, gastrointestinal problems, potential gene flow to other organisms, and destruction of biodiversity. For more background information on this technology, including the health and environmental risks, see Strauss, *Importing Caution*, *supra* note 3, at 169-75. *See also* Jeffrey M. Smith, *Monsanto Whistleblower Says Genetically Engineered Crops May Cause Disease*, *Spilling the Beans*, August 2006, *available at* http://www.seedsofdeception.com/Public/Newsletter/Aug2006-MonsantoWhistleblowerSaysG/index.cfm [hereinafter Smith, *Whistleblower*] (former Monsanto employee reporting that in GM cotton unknown proteins had been created during the gene insertion process—"one of the many possible dangers that are not being evaluated by the biotech industry's superficial safety assessments").

[17] NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 40-103 (2000) (analyzing the potential environmental and human health implications of pest-protected plants and recommending further study).

[18] World Health Organization (WHO), *Modern Food Biotechnology, Human Health and Development: an Evidence-Based Study*, at 53 (June 24, 2005), *available at* http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf. The WHO study also named the following human health risks: direct health effects (toxicity), tendencies to provoke allergic reaction (allergenicity), specific components with toxic properties, the stability of the inserted gene, nutritional impact, increased antibiotic resistance, and any

the most significant risks to consider is future liability from lawsuits, including lawsuits by and against farmers and/or biotechnology companies for possible harm and economic loss caused by bioengineered food crops. In view of the scientific uncertainty and potential for harm, consumer claims for injuries may also arise in the future from the failure to warn of the presence of genetically engineered components.

In analyzing the legal liability risks of GM crops and food, Part II of this article first explores the theories of liability under which farmers and consumers can recover for the harms caused by GMOs, including relief for their economic loss. In Part III, this article examines the very real incidents thus far and analyzes the lawsuits that have ensued in cases of contamination due to pollen drift and intermingling of seeds, highlighting the most recent landmark LibertyLink® rice litigation. Also explored are the roles of suppliers, trade associations, and international trade, as well as bills that have been introduced at the federal and state levels. Part IV presents policy considerations and discusses measures to manage these risks, proposing a regulatory approach of labeling, monitoring, and a stringent pre-market approval process. New legislation, preferably at the federal level, would give more clarity to the business community and assurance to consumers, farmers, and other stakeholders. In the absence of a stronger regulatory and statutory regime, the common law of torts will step in to fill the void through continual lawsuits that will plague the biotech industry. Accordingly, Part V concludes that the interests of GM seed companies, farmers, and consumers will converge in this area to mandate greater certainty and safety.

II. THEORIES OF LIABILITY FOR HARM CAUSED BY GMOS

Theories of liability that may be applied in cases of harm caused by GMOs vary with the type of harm, context, and parties potentially injured as well those legally responsible for causing the problem. Some attention has been focused on potential liability for farmers who decide to plant GM crops, which might be contract-based liability that may arise under their technology agreements with seed companies or guarantees to crop purchasers or regulatory liability if their actions involve violations of statutes or the standards and procedures issued by administrative agencies such as approval for human consumption.[19] Farmers who plant GM crops may also be liable under tort-based theories when genetic drift or outcrossing occurs and the seed spreads to the fields of other farmers who had no desire to plant GM crops and now face problems

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unintended effects that could result from genetic modification. In addition, the study warned of potential risks for the environment such as: "unintended effects on non-target organisms, ecosystems, and biodiversity." *Id.* at iii, 20; *see also* Strauss, *Importing Caution*, *supra* note 3, at 169-70.

[19] *See* DAVID R. MOELLER, GMO LIABILITY THREATS FOR FARMERS: LEGAL ISSUES SURROUNDING THE PLANTING OF GENETICALLY MODIFIED CROPS 2 (Farmers' Legal Action Group, Inc. 2001) (focusing the potential legal risks farmers face with genetically modified organisms). For example, a farmer who warrantees that the crops were GMO-free may face liability for the buyer's expenses to reject and replace the crops, including further damages if the GM crop mingles with and contaminates other crops—possibly entire shipments to foreign countries. *Id.*

of contamination.[20] In addition, as noted above, there have been numerous cases based upon the intellectual property rights of the seed manufacturers, who have successfully sued the farmers of the recipient fields for patent infringement despite their lack of intent or desire to plant the patented GM seed.[21] However, these types of claims only address legal risks to farmers and not the seed companies who have created these products.

Another approach to harm caused by GM crops would direct liability onto the seed manufacturers in potential lawsuits by non-GM farmers and even consumers. This tort-based liability would include claims for contamination on behalf of farmers whose fields have been tainted with unwanted GMOs due to outcrossing, migration, commingling of seeds and the like. In empowering these farmers with a proactive cause of action, it must be acknowledged that the ensuing lawsuits both by and possibly against a different group of farmers—non-GM versus GM—at times would pit neighbor against neighbor for breach of their genetic fences.[22] Nonetheless, the emphasis here is on the defendant seed company who set this situation in motion, and, faced with the strong possibility of this form of liability, those farmers are theoretically free to choose not to plant GM seeds in the future. The damages may be high—especially if the plaintiff farmers face potential loss of organic certification—both on the individual farmers' level for injury to their crop and on the market level for loss of a domestic or international export market.

In lawsuits for contamination from cross pollination, one can easily envision liability through common law torts such as private and public nuisance, trespass, negligence, and strict liability.[23] For example, the situation could be viewed as a trespass if a farmer and/or seed company knew that genetic traits from a GM crop could enter a neighbor's property and that genetic drift does in fact occur, causing harm from contamination of the crop.[24] Although the trespass theory has been successfully applied in current times to other instances of pollution, on the theory that such physical invasion of particles interferes with one's exclusive possession of the

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[20] *Id.*; *see generally* Stephanie M. Bernhardt, *High Plains Drifting: Wind-Blown Seeds and the Intellectual Property Implications of the GMO Revolution*, 4 NW. J. TECH. & INTELL. PROP. 2, 2–6 (2005) (discussing this type of lawsuit and facts about windblown seeds).

[21] *See* Strauss, *International Intellectual Property Rights*, *supra* note 13, at 291-95 (discussing this use of U.S. patent law).

[22] *But see* Joshua B. Cannon, Note, *Statutory Stones and Regulatory Mortar: Using Negligence Per Se to Mend the Wall Between Farmers Growing Genetically Engineered Crops and their Neighbors*, 67 WASH. & LEE L. REV. 653, 657 (2010) (proposing negligence per se, or statutory negligence, as a possible solution to protect farmers whose crops are contaminated because the predictability of statutory or regulatory standards would also benefit GM growers).

[23] *See generally* Drew L. Keshen, *Legal Liability Issues in Agricultural Biotechnology*, 10 ENVTL. LIABILITY 203 (2002) (discussing trespass, negligence, and strict liability).

[24] *See* MOELLER, *supra* note 19, at 3; Cox, *supra* note 3, at 411 (exploring possible causes of action for pollen-drift contamination of organic or conventional crops through private nuisance, trespass, or strict liability, and proposing state legislation to protect farmers by holding growers and manufacturers liable for the harm); Paul J. Heald & James Charles Smith, *The Problem of Social Cost in a Genetically Modified Age*, 58 HASTINGS L.J. 87 (2006) (discussing the elements of trespass in the context of pollen drift as requiring proof of invasion, causation, and harm).

land, the issue of whether mere knowledge is enough or intentionality must be proven has not been determined in this context.[25] Similarly, a nuisance action would be based on the claim that there was an invasion of the farmer's use and enjoyment of his land.[26] A proposal to utilize the tort theory of anticipatory nuisance is appealing, as it would allow injunctive relief to prevent the harm from occurring in the first instance.[27] However, the high standard necessary for an injunction to issue might not be achievable as a practical matter in many cases.[28]

Strict liability for an unreasonably dangerous product would be particularly appropriate, as it would not require proof of intent or negligence on the part of the manufacturer and the causation of harm would be sufficient.[29] Courts have held strict liability to apply to comparably dangerous activities such as spraying pesticides.[30] Moreover, what constitutes an "abnormally dangerous product" involves a balancing test that would require the court to consider public policy interests.[31] Arguably, as a matter of public policy holding seed companies strictly liable would place responsibility on those best able to control the product and ensure its safety, providing proper incentives to prevent the harm from occurring in the future.

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[25] *See, e.g.,* Roger A. McEowen, *Legal Issues Related to the Use and Ownership of Genetically Modified Organisms*, 43 WASHBURN L.J. 611, 618 (2004); Richard Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 585, 600 (2000).

[26] Thomas P. Redick & Christina G. Bernstein, *Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles*, 30 ENVTL. L. REP. 10, 328, 337 (2000) (applying nuisance law to GM varieties not approved in EU, reasoning that a defendant who does not take reasonable steps to prevent an interference with plaintiff's enjoyment of property may be liable in nuisance); A. Bryan Endres, *"GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damages in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453, 493-94 (2000) (noting that for private nuisance, a plaintiff may not need to demonstrate that the defendant intended to allow pollen from genetically modified crops to cross-pollinate, and courts may refuse to balance the genetically modified crop's social and economic utility against its harm to the organic farmer's crops); Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PENN. L. REV. 1403, 1466 (1983) (utilizing common law nuisance and injunctive measures a mechanism for governing hazard). *But see* Neil Craik, Keith Culver & Norman Siebrasse, *Genetically Modified Crops and Nuisance: Exploring the Role of Precaution in Private Law,* 27 BUL. SCI. TECH. & SOC. 202, 206 (2007) (arguing that in nuisance suits for genetic contamination from GM crops, private law is poorly suited to apply the diffuse, policy-based risk allocation considerations raised by the precautionary principle).

[27] Margaret Rosso Grossman, *Anticipatory Nuisance and the Prevention of Environmental Harm and Economic Loss from GMOs in the United States*, 18 J. ENVTL. L. & PRAC. 107, 124 (2008) (reviewing private and public nuisance in the context of GMOs and analyzing the suitability of anticipatory nuisance seeking an injunction to prevent future harm from a defendant's proposed activity).

[28] *But see* John T. Walsh & Thomas P. Redick, *Managing Agricultural Risks in Biopharming: The Role of Injunctions*, 7 ABA AGRIC. MGMT. COM. NEWSL. 15, 15 (2003) ("the fact of future predictable losses of the same character, clearly create sufficient factual precedent for a threat of "irreparable harm" to merit an injunction against similar crops prior to sale").

[29] *See* Carie-Megan Flood, Note, *Pollen Drift and Potential Causes of Action*, 28 J. CORP. L. 473, 477-82 (2003) (recommending the trespass liability theory as suitable for claims by an individual plaintiff farmer and strict liability for abnormally dangerous activities as more appropriate where the damage extended beyond the individual farmer to the mass population).

[30] MOELLER, *supra* note 19, at 4; Endres, *supra* note 26, at 488-91 (analyzing strict liability cases in similar contexts).

[31] Cox, *supra* note 3, at 410-11.

Ultimately, tort-based liability of seed manufacturers and GM farmers to consumers, environmental organizations, trade associations, and the government may arise for harm to human health and the environment.[32] Consumer claims for injuries may also arise in the future from the failure to warn of the presence of genetically engineered components.[33] In view of the scientific uncertainty and potential for harm, the possibilities of major catastrophic incidents and future health claims are infinite. From a risk assessment point of view, biotech companies should have cause for concern.

III. RECENT INCIDENTS AND LAWSUITS SEEKING REDRESS

The logical gap between ownership and liability has long been illustrated by the pollen-drift cases, where farmers have been aggressively sued under the patent infringement laws by Monsanto for the unintentional seed drift into their fields.[34] The biotech company has notoriously prevailed despite the fact the farmers did not intend to use the genetically modified seed and might have suffered economic loss from the contamination, particularly if the farm was organic.[35] Commentators have argued that such a scenario could more appropriately be viewed as contamination and warrant a countersuit by the farmer.[36] As a matter of public policy, shifting legal liability onto the companies in the best position in terms of knowledge and control would provide the economic incentive for them to take adequate measures to prevent such pollen drift in the future.[37] Recent developments in case law suggest that such a shift has begun to take hold. Moreover, the voices of suppliers and trade associations have begun to impact these practices, along with the predominance of concerns for international trade. Yet the question remains whether the voice of consumers and non-GM farmers will, as a consequence, be heard through future U.S. legislation.

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[32] *See generally* Tana N. Vollendorf, Comment, *Genetically Modified Organisms: Someone is in the Kitchen with DNA—Who is Responsible When Someone Gets Burned?*, 21 MISS. C.L. REV. 43 (2001).

[33] *See generally* Katherine Van Tassel, *The Introduction of Biotech Food to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645 (2004).

[34] *See* Strauss, *International Intellectual Property Rights*, *supra* note 13, at 298. The case of Percy Schmeiser, a Canadian farmer aggressively pursued by Monsanto for patent infringement despite his lack of intention and the fact that his own long developed crop of corn was mutated by the Monsanto seed, is one of many dramatic examples. *Id.* at 295-97.

[35] *Id.* at 297 (theorizing that the inequity of resources has prevented farmers from pursuing their legal rights in this area).

[36] *See, e.g.,* Strauss, *International Intellectual Property Rights*, *supra* note 13, at 299; Margaret R. Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 247 (2002) (discussing common-law tort actions as a remedy to the general public and to property owners who have suffered economic losses from cross-pollution and commingling, "especially when growers plant GM crops not approved for all uses and by important trading partners").

[37] Strauss, *International Intellectual Property Rights*, *supra* note 13, at 297; *see also* Tim Van Pelt, *Is Changing Patent Infringement Liability the Appropriate Mechanism for Allocating the Cost of Pollen Drift?*, 31 IOWA J. CORP. L. 567, 577–78 (2006) (arguing that, because the pollen drift generates costs for the farmers who want to avoid passive infringement or who want to preserve genetic purity in their crops, the patent holder should be forced to internalize the costs related to the spread of its own patented genes).

A. The Farmers Strike Back: LibertyLink® Rice

Most significantly, the theory of liability for contamination has now been successfully applied by the courts in the landmark LibertyLink® rice lawsuits on behalf of farmers whose fields have been contaminated with unwanted GMOs due to outcrossing and migration, imposing multimillion dollar jury verdicts on the biotech company Bayer CropScience for its negligence in recklessly allowing this spread and the resulting harm to the U.S. long-grain rice crop.

LibertyLink® rice (LL 601), a variety of genetically modified rice from the United States that was in an experimental trial phase and not approved for human consumption, was found on supermarket shelves in the EU.[38] The experimental rice was genetically modified to withstand higher doses of the Liberty® weed killer glufosinate, itself a controversial pesticide that may soon be banned from Europe as toxic.[39] Trace amounts of the LibertyLink® rice had somehow entered the commercial rice supply in all five of the Southern states that grow long-grain rice: Arkansas, Texas, Louisiana, Mississippi, and Missouri. By the time Bayer informed the U.S. Department of Agriculture (USDA), which announced the contamination in August 2006, the unapproved rice had crossed into food products.[40] As a result, Japan and the European Union (EU) placed strict limits on U.S. rice imports, with European nations requiring extensive testing to show lack of contamination and Japan banning American rice altogether; U.S. rice prices dropped dramatically. Within four days of the announcement, a decline in rice futures reportedly had cost U.S. growers about $150 million and by September, rice prices had declined 10 percent.[41]

In a highly unusual move, the USDA hastily "deregulated" the genetically modified rice retroactively, despite the fact that the vast majority of the comments it received on its proposed decision in September opposed the nonregulated status.[42]

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[38] *See* Physorg.com, *GM Rice from U.S. found in EU*, Sept. 13, 2006, http://www.physorg.com/news77388811.html (genetically modified rice from the United States discovered in the EU, in violation of a ban on import, growth and sale of such crops.).

[39] Canadian Biotechnology Action Network (CBAN), *Hands off Our Rice. Protect the World's Most Important Food From Genetic Engineering,* April 15, 2009, HEALTH ACTION NETWORK SOCIETY (HANS), https://www.hans.org/magazine/488/engineering-important-genetic-protect.

> We ask all governments around the world to protect consumers and farmers, their crops and fields by rejecting Bayer's GE rice, and to stop GE rice field trials . . . Rice is daily food for half of the world's population. Genetically engineered (GE) rice, on the other hand, is a threat to our health, our agriculture and our biodiversity.

Id.

[40] Marc Gunther, *Attack of the Mutant Rice*, FORTUNE, July 9, 2007, at 74, 76.

[41] Rick Weiss, *Gene-altered Profit-killer: A Slight Taint of Biotech Rice Puts Farmers' Overseas Sales in Peril*, WASH. POST, Sept. 21, 2006, at D01; *see also* U.S. Rice Producers Association, *Secretary Johanns: "Give Our Farmers Good Access to World Markets…,"* THE RICE ADVOCATE, July 8, 2005, at 1.

[42] The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture cleared the LLRICE601 (LibertyLink®) strain for human use on November 24, 2006 (71 Fed. Reg. 70360-70372). The published notice of its preliminary decision in September had prompted 15,871 comments, of which 15,517 opposed this nonregulated status. *See Regulatory Affairs—Agricultural and Environmental: Lawsuits over Liberty Link Rice Consolidated*, 26 BIOTECH L. REP. 20 (2007); *see also* Rachel Iadicicco &

Its investigation into the how the LibertyLink® rice entered the nation's long-grain rice supply—an inquiry it considered to be independent of the approval process—remains inconclusive.[43] This withdrawal of U.S. government oversight further exacerbated the international trade issue.[44] Roughly half of the U.S. rice crop, which was worth about $1.9 billion the previous year, is exported; and European and Asian markets have erected barriers that reflect their consumers' rejection of genetically modified foods.[45]

A class-action lawsuit was filed on May 17, 2007 by rice farmers in Arkansas, Missouri, Mississippi, Louisiana, and Texas against Bayer CropScience, alleging its genetically modified rice contaminated the crop and caused severe economic loss.[46] In the Complaint, the rice producers assert, among other claims, public nuisance, private nuisance, negligence *per se* (based on violations of federal and state statutory law), negligence, strict liability for ultrahazardous activities and

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Jerry Redding, Press Release, USDA: Animal and Plant Health Inspection Service (APHIS), *USDA Deregulates Line of Genetically Engineered Rice,* Nov. 24, 2006, http://www.aphis.usda.gov/newsroom/content/2006/11/rice_deregulate.shtml. The USDA press release noted that: "[d]eregulated items and their progeny are considered safe for the environment and can be grown without APHIS oversight." *Id.*

[43] *See* USDA APHIS, Report: "Report of LibertyLink Rice Incidents," Oct. 5, 2007, http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf; USDA APHIS Lessons Learned: "APHIS' Biotechnology Framework," Oct. 5, 2007, http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/LessonsLearned10-2007.pdf;FDA, CFSAN/Office of Food Additive Safety, "U.S. Food and Drug Administration's Statement on Report of Bioengineered Rice in the Food Supply," Aug. 2006, http://www.fda.gov/Food/Biotechnology/Announcements/ucm109411.htm.

> This rice variety, not intended for commercialization, was not submitted to FDA for evaluation under the Agency's voluntary biotechnology consultation process . . . Based on the available data and information, FDA has concluded that the presence of this bioengineered rice variety in the food and feed supply poses no food or feed safety concerns.

Id.

[44] Gunther, *supra* note 40, at 77; Christopher Lee, *Genetically Engineered Rice Wins USDA Approval,* WASH. POST, Nov. 25, 2006, http://www.washingtonpost.com/wp-dyn/content/article/2006/11/24/AR2006112401153.html ("In approving the rice, the USDA allowed Bayer to take a regulatory shortcut and skip many of the usual safety tests by declaring that the new variety is similar to ones already approved, in this case two varieties of biotech rice that Bayer never commercialized because farmers did not want them in their fields."); Jessica Fraser, *USDA Approves Genetically Engineered Rice that Contaminated U.S. Food Supply; Safety Tests Skipped,* NEWS TARGET, Nov. 29, 2006, http://www.naturalnews.com/021203.html.

[45] Gunther, *supra* note 40, at 77. For more on issues of international trade involving GM foods, see Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of GM Foods,* 45 AM. BUS. L.J. 775 (2008) (characterizing the EC-Biotech dispute as a disruption in trade between the United States and EU caused by their different regulatory approaches toward GMOs, which are in turn a reflection of the differing views and levels of concern about genetically modified food in the face of scientific uncertainty) [hereinafter Strauss, *Impact of the WTO*].

[46] *In Re Genetically Modified Rice Litigation*, 06-md-1811, U.S. District Court, Eastern District of Missouri.

strict product liability. They are seeking relief on their own behalf and on behalf of the other members of the proposed classes for compensatory and consequential damages, punitive or exemplary damages, and injunctive relief arising from the defendants' allegedly wrongful conduct. In August 2008, the judge overseeing the multidistrict litigation declined to certify it as a class action because in her view the mitigating responses of each farmer made their damage claims too different, such that "[i]ndividual circumstances affecting the calculation of individual plaintiffs' damages predominate over the common issues presented in plaintiffs' claims."[47] This ruling set in motion the potential for thousands of individual trials, scheduled as "test cases" on typical claims. Currently federal district judge Catherine Perry in St. Louis is overseeing approximately 3,000 lawsuits by rice farmers alleging that Bayer CropScience was careless in handling its experimental, genetically modified strain of long-grain rice, allowing it to contaminate the national crop.[48]

Since then, the individual jury verdicts in trials against Bayer have been mounting. In the first of the "bellwether trials," a St. Louis jury found Bayer CropScience and several of its affiliates negligent and awarded over $2 million in compensatory damages to two Missouri long-grain rice farmers, Ken Bell and John Hunter, for the economic loss they suffered due to the drop in U.S. rice prices and much lower demand for their rice since 2006 that resulted from the contamination of their crops.[49] The second trial awarded a total of $1.5 million to two Arkansas

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[47] *In Re Genetically Modified Rice Litigation*, 251 F.R.D. 392, 400 (E.D. Mo. 2008). Without addressing the merits of their claims, Judge Perry observed that:

> Some plaintiffs allege that as a result of this ban, they were forced to plant alternate, lower-yield seed varieties, thereby reducing the size of their harvests. Other plaintiffs allege that they were unable to obtain any rice seed because of the ban, and had to plant different crops altogether. Plaintiffs who produced rice during the 2007 crop year incurred added costs in testing and segregating their rice to make sure it was free of genetically-modified traits. Land, equipment, and storage facilities were also contaminated and had to be cleaned to prevent further contamination.

Id. at 394.

[48] Alison Frankel, *In Bellwether Trial in Billion-Dollar MDL, Bayer Found Liable for Crop Contamination*, Dec. 7, 2009, THE AMERICAN LAWYER, http://www.law.com. *See, e.g., In Re Genetically Modified Rice Litigation*, 2010 WL 2326036 (E.D. Mo. June 7, 2010) (pre-trial rulings granting defendants' motions for summary judgment on plaintiffs' claims under the North Carolina Unfair Trade Practices Act and plaintiffs' claims for negligence per se and for public and private nuisance; and granting plaintiffs' motions for summary judgment directed to certain affirmative defenses, determining as a matter of law that the regulations under the Plant Protection Act do not allow for low level or adventitious presence of regulated genetically modified rice in the commercial rice supply and declining to allow expert witness testimony to the contrary). For more information on the status of these lawsuits, see GM Rice Litigation, http://www.bayerrice litigation.com/Press.htm.

[49] Press Release, *Two Missouri Rice Farmers Awarded $2 Million in First Lawsuit Heard Against German-Based Bayer CropScience AG,* Dec. 4, 2009, http://www.bayerricelitigation.com/PDFs/Press%20Release/bayer%20press%20release%201.pdf?action=view&id=70; *see also* Andrew M. Harris & Joe Whittington, *$2 Million Verdict Against Bayer CropScience*, ST. LOUIS POST, Dec. 5, 2009, *available at* http://www.stltoday.com. *See In Re Genetically Modified Rice Litigation*, 2010 WL 2926207, at *1 (E.D. Mo. July 20, 2010) (denying defendants' motion for a new trial and defendants' other post-trial motions

long-grain rice farmers and one in Mississippi whose crops and livelihood were similarly harmed by the genetically modified rice. The plaintiffs' attorney, Don Downing, commented, "A second consecutive verdict against Bayer should send a clear and strong message to the company about its negligent conduct and the damages that conduct actually caused to American rice farmers, not only in this case but in the other matters that are scheduled for trial."[50] The award calculations were "based on the number of acres each farmer planted and the impact of the contamination on their land."[51] Two state court losses followed in Arkansas, the first for about $1 million, including $500,000 in punitive damages. In the previous three cases, Bayer faced $4.5 million of judgments. The jury verdict for the fourth trial (the second state court loss) exceeded the prior judgments by both monetary amount and type, adding significant punitive damages against the biotech company of $42 million along with compensatory damages of $5.9 million.[52] The dozen Arkansas farmers argued that, in addition to being negligent in its handling of the genetically modified rice, Bayer acted with malicious intent by not announcing the contamination of the commercial rice-seed pool when Bayer discovered it before the crops were sowed.[53] A fifth jury recently awarded damages of $500,248 to a Louisiana farmer who claimed that the company was negligent in testing its genetically modified seed, causing a plunge in exports to Europe.[54] As Don Downing observed:

> Five different juries under the laws of four different states in both federal and state courts now have unanimously found that Bayer was negligent and liable to rice farmers for damages. Not a single juror in any of the five trials found for Bayer.[55]

These trials represent the first step Judge Perry of the U.S. District Court for the Eastern District of Missouri ordered in the multidistrict litigation involving more than 6,000 rice producers in the five states. Bayer faces approximately 500 additional lawsuits in federal and state courts. As the cases continue through the summer of 2010 with a sixth case on trial in Arkansas state court followed by a federal trial in St. Louis in October, a major settlement becomes increasingly likely.[56] In the case of

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including renewed motion for summary judgment that was previously denied).

[50] Press Release, *Second Bayer 'Bellwether' Trial Results in Another Verdict for Plaintiffs: $1.5 Million Award to Rice Farmers in Arkansas Mississippi*, Feb. 5, 2010, http://www.bayerricelitigation.com/PDFs/Press%20Release/bayer%20press%20release%202.pdf?newsid=117843&type_news=latest. *See In Re Genetically Modified Rice Litigation*, 2010 WL 2926214, at *4 (E.D. Mo. July 20, 2010) (denying defendants' post-trial motions).

[51] *Id.*

[52] Associated Press, *Jury Tells Bayer to Pay Ark. Rice Farmers $48M*, April 15, 2010, http://www.bayerricelitigation.com/PDFs/SKELLY67_1271429373912.pdf.

[53] *Id.*

[54] Margaret Cronin Fisk & Joe Whittington, *Bayer Loses Fifth Straight Trial Over U.S. Rice Crops*, July 15, 2010, http://greenbio.checkbiotech.org/news/bayer_loses_fifth_straight_trial_over_us_rice_crops.

[55] *Id.*

[56] Plaintiffs' attorney Downing emphasized that they will continue to push these cases to trial "until Bayer decides it is willing to provide fair compensation through settlement"; and mediation discussions are ongoing in the federal lawsuits in St. Louis. A CropScience spokesman, Greg Coffey, said the company is "hopeful that all parties might approach resolution in a positive and reasonable manner." *Id. See also* Christopher Tritto,

genetically modified rice, this litigation can be expected soon to reach a critical mass reminiscent of the tobacco litigation as previously predicted.[57] Will there be a similar massive settlement and an accompanying shift in assumptions on the horizon?

It is significant to note that there are no claims in the rice litigation that LibertyLink® harmed or risked human health. Rather, the farmers claim that the contamination of the commercial rice crop caused them economic loss in the European market for long-grain rice in sales that have not rebounded.[58] If such claims are filed in the future on behalf of consumers for these or other genetically modified crops, one can only imagine the magnitude of the liability that would be faced by the biotech companies and possibly the farmers who planted these crops.

B. The Foundation is Set: StarLink® Corn, Canada Canola, GM Alfalfa, ProdiGene, and Others

This is not the first time such a suit has been filed in the United States due to outcrossing contamination. In 2004, the nation's corn farmers received more than $100 million from the settlement of a case in which a genetically engineered variety of corn known as StarLink®, which had been approved only for animal feed, was found in taco shells and corn chips, among other products. StarLink®, a corn genetically engineered with a Cry9C protein to protect crops against certain insects, was considered suitable only for animal feed because of concerns that it could cause allergic reactions in humans; but StarLink® accidentally entered the food supply, prompting a large scale recall of about 300 corn products.[59] Although it had been planted in less than one percent of U.S. corn acreage, StarLink® was found in 22 percent of the corn samples tested by the USDA.[60] After an extensive program to remove it, three years later StarLink® was still detected in more than one percent of corn samples.[61] The testing/screening program was discontinued in 2008.[62]

Rice Man Cometh: Don Downing v. Bayer, ST. LOUIS BUS. J., July 23, 2010, *available at* http://stlouis.bizjournals.com/stlouis/stories/2010/07/26/story2.html?b=1280116800^3694491 &s=industry&i=legal.

[57] *See* Strauss, *International Intellectual Property Rights*, *supra* note 13, at 299 ("This new approach by the farmers—a class action so widespread that it represents the industry as a whole—if successful, may be the beginning of a turning tide, as was seen in the tobacco litigation.")

[58] *Id.*

[59] *See* Strauss, *Importing Caution*, *supra* note 3, at 173-74; Martin A. Lee, *Food Fight: International Protests Mount Against Genetically Engineered Crops*, S.F. BAY GUARDIAN, June 25, 2001, *available at* http://www.commondreams.org/views01/0628-01.htm ("While acknowledging that nearly a half billion bushels of corn in storage nationwide contain StarLink, Aventis denies that it poses a health risk to humans.").

[60] Smith, *Myth*, *supra* note 8.

[61] *Id.*

[62] StarLink Information Center, "FDA Withdraws STARLINK Corn Testing Guidance," April 25, 2008, http://www.starlinkcorn.com/ (last visited July 25, 2010) (stating that the FDA later withdrew its requirement of testing/screening the U.S. corn supply to minimize the production of human food products with corn containing the Cry9C protein, based on an EPA White Paper that "conclude[d] that the protein has been sufficiently removed from the human food supply to render the level of risk low enough that continued testing for the protein in yellow corn at dry mills and mass production facilities provides no added public health protection."); FDA, Guidance for Industry on the Food and Drug Administration Recommendations for

In addition, the cross-contamination had an impact on international trade, causing a drop in Japanese imports of U.S. corn by 1.3 million metric tons (8 percent in volume terms) in 2001.[63] The Japanese government now mandates the segregation of unapproved biotechnology food and feed ingredients from the export channel, with a zero tolerance for unapproved GM varieties that are found in foods.[64]

As a result of the StarLink® corn contamination, consumers and farmers in class action lawsuits sued the biotech manufacturer, Aventis, under several theories of liability, including negligence, strict liability, and nuisance.[65] This incident has been scrutinized as a lesson that "if a company makes a mistake in commercializing a transgenic crop, the cost of civil liability for food biotechnology can be very high."[66] In this case, the company shouldered the cost of recalling the product and destroying the remaining seed inventory, detecting and eliminating any residual StarLink® in the U.S. corn supply, and settling class actions with consumers who allegedly suffered allergic reactions (despite the fact that no such reactions were proven) for nine million dollars and corn growers who allegedly suffered depressed corn prices as a result for another $110 million.[67] Aventis ultimately sold its crop science unit to Bayer, the same division that is now facing the consequences of its second contamination debacle with LibertyLink® rice.[68]

Most significantly in terms of liability, the StarLink® cases confirmed that "negligence, negligence *per se*, strict liability in tort, trespass, private nuisance, public nuisance, and others are all theories under which the company which markets a product might be liable for damage that would result."[69] Although the lawsuits were settled and there was no decision on the merits of the case, these bases for legal liability for crop contamination did survive a motion to dismiss.[70] In addition, the foundation was established for a new concept of economic loss—that the contamination of the crop caused a depressing effect on the prices of an entire crop market, and every farmer who sold any corn that year was in fact damaged because of depressed prices—a notion that could also apply when a genetically engineered crop is fully approved in the U.S. but is

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Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Withdrawal of Guidance, 73 Fed. Reg. 22716 (April 25, 2008).

[63] James Stamps, *Trade in Biotechnology Food Products*, INT'L ECON. REV. 5, 13-14 (2002).

[64] *Id.* at 14; *see also* CropChoice News, *Japan Shuns Corn over GE Issue, Organic Consumers Association*, Apr. 9, 2001, *available at* http://www.purefood.org/gefood/japanshuns.cfm. *See* The Organic and Non-GMO Report, *Japan's legislation on labeling of genetically engineered foods*, http://www.non-gmoreport.com/Japan_legislation_labeling_GM_foods.php (last visited Aug. 1, 2010).

[65] *In re StarLink Corn Products Liability Litigation,* 212 F. Supp. 2d 828, 833 (N.D. Ill. 2002); *see* Cox, *supra* note 3, at 411.

[66] Donald Uchtmann, *Liability Issues: Lessons from StarLink*, 10 RICH. J.L. & TECH. 23 (2004).

[67] *Id.*

[68] Gunther, *supra* note 40, at 76.

[69] Uchtmann, *supra* note 66, at 23.

[70] *Id.;* Grossman, *supra* note 27, at 120-21 (analyzing judge's treatment of private and public nuisance claims in allowing StarLink litigation to proceed on these theories); *Starlink*, 212 F. Supp 2d at 848. *But see* Cox, *supra* note 3, at 412 (viewing this question of legal liability as open because there was no decision on the merits of this case).

not approved in major export markets.[71] This economic loss doctrine is now being successfully tested in the LibertyLink® rice litigation.

Similarly, in Canada, two certified organic farmers brought a class action against Monsanto Canada and Aventis (later amended to be Bayer CropScience) in 2002 for damages resulting from the widespread contamination of their crops by GM canola and for an injunction to prevent the commercial introduction of GM wheat.[72] The genetically herbicide-resistant canola inexplicably appeared to have spread to a wild relative.[73] The plaintiffs alleged that as a result of losing their organic certification and their ability to grow and market organic canola after Monsanto's Roundup Ready® canola and Bayer's Liberty Link® canola had been found growing on their land, "few, if any, certified organic grain farmers are now growing canola. The crop, as an important tool in the crop rotations of organic farmers, and as an organic grain commodity, has been lost to certified organic farmers in Saskatchewan."[74] They based their liability claims on the tort theories of: negligence, for the seed companies' breaching their duty "to ensure that their GM canola would not infiltrate and contaminate farmland . . . to warn growers about cross-pollination and . . . to advise growers of farming practices that would limit the spread of their GM canola"; nuisance that "interfered with certified organic grain farmers' use and enjoyment of their land"; strict liability for "having engaged in a non-natural use of land, and allowing the escape of something likely to do mischief and damage"; and trespass for the "introduction of GM canola and its unconfined release" into the environment.[75] However, in that case the judge denied the motion for class certification and indicated doubt as to the viability of some of these claims. She found that, although some farmers may have been hurt, there was no evidence that organic farmers as a class have suffered because some of them were able to find markets for their canola; moreover, there lacked a plausible legal basis for imposing liability on the defendant on the grounds of negligence (for want of duty of care), nuisance, and trespass.[76]

Unfortunately, other examples are becoming increasingly abundant, producing mounting evidence of safety breaches that may soon surpass mere negligence. In the summer of 2006, creeping bentgrass under development by the

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[71] Uchtmann, *supra* note 66, at 23.

[72] *Hoffman and Beaudoin v. Monsanto Canada*, Sask. Q.B., No. 67 of 2002, http://www.saskorganic.com /oapf/pdf/amended-claim.pdf.

[73] Martin Philipson, *Agricultural Law: Containing the GM Revolution*, 48 BIOTECHNOLOGY & DEV. MONITOR 2 (Dec. 2001), *cited in* Rachel Durkee Walker & Jill Doerfler, *Wild Rice: The Minnesota Legislature, a Distinctive Crop, GMOs, and OJIBWE Perspectives,* 32 HAMLINE L. REV. 499, 519 (2009) (statement to Missouri legislature citing examples of the dangers of GMOs).

[74] Statement of Claim in the Court of Queen's Bench, http://www.saskorganic.com/oapf/pdf/stmt-of-claim.pdf (Jan. 10, 2002).

[75] *Id.*; *see also* Jane Matthews Glenn, *Footloose: Civil Responsibility for GMO Gene Wandering in Canada*, 43 WASHBURN L.J. 547, 551 (2004).

[76] Lara Khoury & Stuart Smyth, *Reasonable Foreseeability and Liability in Relation to Genetically Modified Organisms*, 27 BUL. SCI. TECH. & SOC. 215, 221 (2007). *See generally* Heather McLeod-Kilmurray, *Hoffman v. Monsanto: Courts, Class Actions, and the Perceptions of the Problem of GM Drift*, 27 BUL. SCI. TECH. & SOC. 188 (2007).

Scotts Miracle-Gro Company and Monsanto was discovered to have escaped into the wild from Oregon test sites that had been used a few years earlier.[77] The genetically engineered grass (GTCB), intended for use on golf courses and not yet approved by the USDA, contained a bacterial gene that made it resistant to the herbicide glyphosate, sold commercially as Roundup®. Apparently the wind had dispersed the seeds and the pollen had crossed with other varieties. Scientists have expressed concern that the variety will cross pollinate with other grass varieties and may contaminate the commercial grass seed supply—70 percent of which is grown in Oregon.[78] Another risk is the creation of "superweeds," making the weedy grasses harder to control with glyphosate, a widely used herbicide and leading to more toxic herbicides.[79] In the litigation that ensued, the plaintiffs alleged that by permitting the field tests, the Animal and Plant Health Inspection Service (APHIS) had violated the Plant Protection Act (PPA), the Administrative Procedure Act (APA), and the National Environmental Policy Act (NEPA).[80] They claimed that APHIS had failed to consider whether this crop is a plant pest under the PPA, evaluate the environmental impact under NEPA, and follow its own regulations. The court held that the denial of plaintiffs' petition to list GTCB as a noxious weed was arbitrary and capricious, as was its failure to require an environmental impact assessment.[81]

In another case in Hawaii, a federal judge in August 2006 ruled that the drug-producing GM crops grown in Hawaii violated both the Endangered Species Act (ESA) and NEPA.[82] Several companies had run field tests from 2001 to 2003 of corn and sugarcane genetically engineered to produce experimental vaccines, hormones, and cancer-fighting agents. In view of concerns for Hawaii's fragile ecosystem, the court held that APHIS had violated ESA because it had failed to obtain information about endangered and threatened species in the area of the permits and NEPA for failing to prepare an environmental assessment or impact statement.[83]

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[77] Andrew Pollack, *Grass Created in Lab is Found in the Wild,* N.Y. TIMES, Aug. 16, 2006, *available at* http://www.nytimes.com/2006/08/16/science/16grass.html, *cited in* Walker & Doerfler, *supra* note 73, at 518 (as evidence that the regulators are not regulating) [hereinafter Pollack, *Grass*].

[78] Smith, *Whistleblower, supra* note 16.

[79] Pollack, *Grass, supra* note 77; *see also* William Neuman & Andrew Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, *available at* http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?ref=food_prices (Roundup-resistant weeds like horseweed and giant ragweed are forcing farmers to spray fields with more toxic herbicides and to use more expensive techniques previously abandoned— more labor-intensive methods like pulling weeds and regular plowing.). The National Research Council has also issued its own warning about the emergence of resistant weeds and other risks as limiting the potential benefits of GM crops. NATIONAL RESEARCH COUNCIL, THE IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES 2 (April 13, 2010), *available at* http://www.nationalacademies.org/includes/genengcrops.pdf.

[80] *International Center for Technology Assessment v. Johanns*, 473 F. Supp. 2d 9, 12-13 (D.D.C. 2007). The Scotts Company intervened in the case as a defendant. *See* Grossman, *supra* note 27, at 147-149 (discussing this case and others as illustrating the type of environmental damage feared from GM crops).

[81] 473 F. Supp. 2d at 29-30; Plant Protection Act, 7 U.S.C. §§ 7701-7758; Administrative Procedure Act, 5 U.S.C. §§ 500-706; National Environmental Policy Act, 42 U.S.C. §§ 4321-4370f.

[82] *Center for Food Safety v. Johanns*, 451 F. Supp. 2d 1165, 1182-83 (D. Haw. 2006).

[83] 451 F. Supp. 2d at 1183. *See* Grossman, *supra* note 27, at 149-51.

However, by the time this court decision took place, the field tests had already been completed and the potential damage done. As further evidence of this type of harm, in September 2004 citizen groups revealed that tests of nearly 20,000 papaya seeds on the Big Island of Hawaii determined that half were genetically modified; to make matters worse, 80 percent were from organic farms, while 20 percent were from home gardens and wild papaya trees.[84] Likewise in Japan, although transgenic canola is not grown commercially there, it was discovered growing near some ports and roadsides; scientists theorized that imported seeds had escaped during transportation to oil-processing facilities.[85]

Additional controversies have occurred in California, where in two separate federal lawsuits plaintiffs, consisting of farmers, the Sierra Club, and other consumer organizations, successfully challenged the USDA's decision to deregulate Monsanto's glyphosate-resistant sugar beets and alfalfa despite considerable questions about potential environmental degradation and without an environmental impact statement (EIS).[86] In the GM sugar beet case, the District Judge ruled in September 2009 that the USDA failed to adequately assess the environmental impact of Monsanto's Roundup Ready® sugar beets before introducing them into the food supply, but in a later decision denied plaintiffs' motion for a preliminary injunction.[87] In the GM alfalfa case, in 2008 the United States Court of Appeals for the Ninth Circuit upheld the District Court's 2007 decision issuing an injunction and ordering an EIS.[88] However, on June 21, 2010, the U.S. Supreme Court ruled 7 to 1 in favor of Monsanto, stating in its opinion that the District Court had abused its discretion in granting an injunction prohibiting partial deregulation of the Roundup Ready® alfalfa. APHIS must still complete the EIS, but can decide to partially deregulate the alfalfa, allowing it to be planted before the EIS is finished.[89] As the Supreme Court's "first-ever ruling on genetically modified crops," this decision was viewed as "a victory for Monsanto and others in the agricultural biotechnology industry, with potential

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[84] Smith, *Myth*, *supra* note 8, at 1.

[85] Pollack, *Grass, supra* note 77, *cited in* Walker & Doerfler, *supra* note 73 (as example of danger of allowing field testing of genetically modified crops).

[86] *Center for Food Safety et al. v. Vilsack*, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009) (APHIS required to prepare EIS for GM sugar beets); *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007) (issuing injunction against planting GM alfalfa). *See* Grossman, *supra* note 27, at 151-53 (discussing alfalfa case).

[87] *See* Caroline Scott-Thomas, *Judge rules against Monsanto's GM sugar beets*, Food navigator-usa.com, Sept. 23, 2009; Environmental News Network, *Battle lines drawn over GM sugar beets*, March 6, 2008, *available at* http://www.enn.com/agriculture/article/32414. *But see Center for Food Safety et al. v. Schafer*, 2010 WL 964017, *4-5 (N.D. Cal. 2010) (denial of injunction in Roundup Ready® sugar beet litigation). In weighing the equities of the parties and denying the injunction, the court did express serious reservations: "In light of Plaintiffs' showing of irreparable harm to the environment, the Court is troubled by maintaining the status quo that consists of ninety-five percent of sugar beets being genetically engineered while APHIS conducts the environmental review that should have occurred before the sugar beets were deregulated." *Id*. at *5.

[88] *Geertson Seed Farms v. Johanns,* 541 F.3d 938, 947-48 (9th Cir. 2008) (upholding permanent injunction against use of Roundup Ready® alfalfa).

[89] *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2761 (2010).

implications for other cases."[90] Yet this impact may be overstated, as the ruling was by its terms narrow and limited.[91] The Supreme Court did not go so far as to approve the GM alfalfa or address safety concerns; at most, it shifted some regulatory responsibility away from the courts and back on the regulatory agencies charged in the first instance with these oversight responsibilities.

In another incident back in 2002, an experimental crop of corn engineered by ProdiGene to produce pharmaceuticals began sprouting in soybean fields designated for human and animal consumption near the company's Nebraska and Iowa sites.[92] The USDA seized 500,000 bushels of tainted soybeans before they reached the market and charged ProdiGene nearly $3 million in fines and disposal costs. The culprit in that contamination was not only pollen drift but the commingling of plants from improper handling, prompting APHIS to propose tightening guidelines for field testing plant-made pharmaceuticals (PMPs) to mandate that no food crops could be grown in the same field in the following planting season and that experimental PMPs be grown further away from conventional crops, as well as the use of segregated equipment and cleaning protocols.[93] Even conventional food and grain producers and the National Corn Growers Association call for more stringent requirements.[94] As these events have demonstrated, potential liability is not merely theoretical; as a consequence, "[u]nless

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[90] *See* Andrew Pollack, *Justices Back Monsanto on Biotech Seed Planting*, N.Y. TIMES, June 21, 2010, *available at* http://www.nytimes.com/2010/06/22/business/22bizcourt.html?scp=1&sq=Justices+Back+Monsanto+on+Biotech+Seed+Planting&st=nyt; *see also* American Soybean Association (ASA), Ag-Regulatory Approvals Backgrounder, http://www.soygrowers.com/issues/ag-related_regulatory_approvals.htm ("This ruling has had the positive effect of returning the decision on how applications for new biotech traits will be handled to APHIS, rather than the courts.").

[91] *See Monsanto*, 130 S. Ct. at 2747.

> Because petitioners and the Government do not argue otherwise, the Court assumes without deciding that the District Court acted lawfully in vacating the agency's decision to completely deregulate RRA. The Court therefore addresses only the injunction prohibiting APHIS from deregulating RRA pending completion of the EIS, and the nationwide injunction prohibiting almost all RRA planting during the pendency of the EIS process.

Id.

[92] Arlene Weintraub, *What's So Scary About Rice? Biotech Crops Can Make Drugs—But They Must Be Kept Out of the Food Chain*, BUS. WK., Aug. 1, 2005, at 58; *see also* The Pew Initiative on Food and Biotechnology, *Pharming Reaps Regulatory Changes*, May 15, 2003, *available at* http://lists.iatp.org/listarchive/archive.cfm?id=74423 (finding that seeds inadvertently left behind in former test sites mingled with soybeans that were harvested and stored before the situation was discovered). Two months earlier, Prodigene had to destroy 155 acres of corn in Iowa due to contamination suspected from the wind-blown pollen of its drug-producing plants. *See* Karen Perry Stillerman, *Pharmaceutical Food Crops in a Field Near You,* Union of Concerned Scientists, http://www.ucsusa.org/food_and_agriculture/science_and_impacts/impacts_genetic_engineering/pcc-article.html.

[93] *See* John S. Harbison, *The War on GMOs: A Report from the Front*, National AgLaw Center, Aug. 2004, at 2-3, http://www.nationalaglawcenter.org/assets/articles/harbison_gmos.pdf; Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11337-01 (proposed March 10, 2003) (to be codified at 7 C.F.R. Part 340); Environmental Impact Statement; Introduction of Genetically Engineered Organisms, 69 Fed. Reg. 3271-01 (proposed January 23, 2004) (to be codified at 7 C.F.R. Part 340).

[94] Harbison, *supra* note 93, at 3.

companies and the agencies that regulate them implement safeguards to prevent these food-safety fears from becoming a reality, this biotech method of drug production faces an unsteady future."[95]

C. The Suppliers Demand: Ventria Rice, Anheuser-Busch, and the Role of Trade Associations

In the marketplace rules of biotechnology, suppliers can have a significant impact. In large measure they have been sensitive to consumer preference and steered clear of GM crops, clearly making these demands known to the farmers and biotech companies. An example came recently in the context of GM drug-producing rice and beer. When a small biotechnology company, Ventria Biosciences, revealed its plans to insert human genes into rice plants to produce two proteins normally found in breast milk, tears, and saliva, to create "therapeutic food products to treat stomach disorders," Anheuser-Busch threatened to boycott all Missouri rice. The company feared contamination of the rice plants that are a key ingredient in its beer.[96] Although the state of Missouri listened and Anheuser-Busch succeeded in protecting its supply of rice plants there, while California similarly sustained its farmers' objections, Ventria simply moved to a less resistant locale; in May 2005, USDA approved Ventria's application for pharma rice plants on up to 3,200 acres in Kansas instead.[97]

Because using this GM method to produce drugs in mass quantities of field plantings is less costly than a traditional biotechnology factory, several other biotechnology companies are experimenting with variations of drug-producing plants.[98] A consulting firm forecasts that plant-manufactured drugs will expand into a $2.2 billion-per-year industry by 2011.[99]

Experts warn that pollen from GM drug plants could drift into fields containing food crops and create contaminated hybrids; or a bird could ingest the bioengineered seeds and deposit them in a field hundreds of miles away.[100] Along with risks to the consumer and the environment come significant potential

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[95] Strauss, *Importing Caution*, *supra* note 3, at 174; *see also* Weintraub, *supra* note 92, at 58-59; Union of Concerned Scientists, *How Does Seed Contamination Occur,* Dec. 15 2004, http://www.ucsusa.org/food_and_agriculture/science_and_impacts/impacts_genetic_engineering/how-does-seed-contamination.html.

[96] Weintraub, *supra* note 92, at 58.

[97] The USDA granted Ventria's application over the objections conveyed in 20,000 comments from citizens, activist, farmers, and rice industry groups. Gunther, *supra* note 40, at 78, 80.

[98] Weintraub, *supra* note 92, at 58. "A traditional biotech factory might cost Ventria … $125 million," but rice yields "the same output for $4 million." Chief Executive Officer Scott Deeter says "he intends to pass the savings to consumers." *Id.*

[99] *Id.*

[100] Margaret Mellon, Director of the Food and Environment program for the Union of Concerned Scientists in Washington, D.C. warns that it is "virtually certain this stuff will make it into food-grade rice." *Id.* "[W]hen you're genetically engineering bioactive molecules—drugs—into crops and they're growing outdoors, you must be able to assure those [engineered traits] don't move to food crops. Otherwise you're imposing health and environmental risks." *Online Extra: The Side Effects of Drugged Crops*, BUS. WK., July 26, 2005, http://www.businessweek.com/magazine/content/05_31/b3945092mz018.htm. *See* Strauss, *Importing Caution*, *supra* note 3, at 173-74.

consequences for international trade, as $1.3 billion in annual U.S. rice sales to foreign countries are at stake.[101] As was seen in the above examples, if drugs migrate into commodity crops, many of these countries, already wary of biotech crops, would buy their agricultural products elsewhere.[102]

Opponents to these pharma crops include consumer and environmental advocates, and many farmers, and farmer organizations such as the American Farm Bureau and the National Farmers Union. Even others in industry have resisted the use of biotech crops for drug production; the U.S. Rice Federation, an industry group, opposed Ventria's pharma rice, pointing to LibertyLink® and asserting that it does not believe the USDA can protect "the environment and the public's food and feed supply from unwanted intrusions of genetically engineered materials."[103] The agency itself inspires little confidence with its track record of environmental and food contamination from escaped GMOs. In an internal audit of APHIS in 2005, the USDA's inspector general disclosed that the agency charged with regulating field trials had no knowledge of the location of some field trials, did no independent testing of nearby crops, and failed to require biotech firms to submit protocols.[104] Citing multiple inadequacies, the report observed: "In fact, at various stages of the field test process—from approval of applications to inspection of fields—weaknesses in APHIS regulations and internal management controls increase the risk that regulated genetically engineered organisms (GEO) will inadvertently persist in the environment before they are deemed safe to grow without regulation."[105] The audit concluded: "APHIS' current regulations, policies, and procedures do not go far enough to ensure the safe introduction of agricultural biotechnology."[106] Moreover, a 2004 report by the National Research Council urged the government to improve its management and supervision, but acknowledged that "there is no way to guarantee that field trialed crops will not pollute the environment."[107] Allowing the industry to monitor itself is essentially a tort waiting to happen.

Thus, trade associations have become proactive in having their voices fill the regulatory void. In addition to the U.S. Rice Federation, other examples include the American Soybean Association, representing farmers who face potential nuisance liability suits, which asked seed manufacturers not to sell unapproved varieties

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[101] Weintraub, *supra* note 92, at 58.

[102] *Id.; Online Extra, supra* note 100; *see also* Debra M. Strauss, *Genetically Modified Organisms in Food: A Model of Labeling and Monitoring With Positive Implications for International Trade*, 40 INT'L LAW. 95, 96 (2006) (analyzing the differing regulatory approaches of the United States and the EU as a reflection of the cultural views of risk and scientific uncertainty with an impact on international trade)[hereinafter Strauss, *A Model of Labeling*].

[103] Gunther, *supra* note 40, at 78.

[104] Office of Inspector General: Southwest Region, Audit Report, Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits (2005), *available at* http://www.usda.gov/oig/webdocs/50601-08-TE.pdf.

[105] *Id.* at i.

[106] *Id.* at iv.

[107] Smith, *Whistleblower*, *supra* note 16(citing Justin Gillis, *Genetically Modified Organisms Not Easily Contained; National Research Council Panel Urges More Work to Protect Against Contamination of Food Supply*, WASH. POST, Jan. 21, 2004).

commercially and set minimum requirements for segregating unapproved GM soybeans.[108] "These steps have helped to avoid commingling of approved varieties with GM varieties not acceptable to trading partners, particularly in the EU."[109] To minimize impediments to trade, the National Corn Growers Association has also advised its members to be aware of the approval status of the seed they select and to direct those that are not approved by the EU into the domestic market not into export channels.[110] In addition, in the case of Agrisure RW corn (MIR604, developed by Syngenta to be resistant to rootworm), the North American Export Grain Association voiced opposition, citing Syngenta's "erosion of corporate responsibility to maintain major export markets … [and] disregard of the single largest market for US corn, Japan."[111] The Biotechnology Industry Organization (BIO), which has over 1100 members, launched its own Product Launch Stewardship Policy in May 2007 in part to avoid trade disruptions by targeting key markets that will accept GMOs.[112] However, industry cannot be relied on to self-police, as it must be remembered that their motivation comes from their own financial interests (i.e., fear of lawsuits) and its priority of promoting these genetically engineered products as long as they are profitable still remains.[113]

D. The International Marketplace Rules

As evidenced in the above instances, concern for international trade fuels the actions of farmers and trade organizations. It would be logical to expect, then, that the strict regulatory approach of the international community should have an impact on the domestic agenda. Although it has lifted its moratorium on the approval of GM foods, the EU still maintains its stringent labeling and approval directives, which make the introduction of GMOs a far slower process and necessitate segregating U.S.

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[108] *See* ASA, Policy Resolution on Biotechnology Approvals and Minimum Requirements for Attempted Identity-Preserved Production, Harvesting, and Utilization of Biotechnology-enhanced Varieties/Hybrids that are Unapproved for Export to Major Markets (2000), http://www.soygrowers.com/publications/minrequire-IP.htm.

[109] Grossman, *supra* note 27, at 166.

[110] National Corn Growers Association, Know Before You Grow, http://www.ncga.com/know-you-grow (last visited July 29, 2010) ("This is why NCGA works with technology providers to publicize regular updates on the approval status of these events. Regardless of export status, there is an ample market for U.S. biotech corn – approximately 42 percent of all U.S.-grown corn is fed to domestic livestock.").

[111] Gary C. Martin, North American Export Grain Association (NAEGA), Comment on Docket No APHIS-2006-0157, at 2 (Mar. 12, 2007). Syngenta had decided to market its genetically engineered corn despite its lack of regulatory approval for export, prompting strong objections from others in the supply chain, including the Japanese Feed Trade Association. *See* Grossman, *supra* note 27, at 154-56.

[112] *See* Excellence Through Stewardship, Advancing Best Practices in Agricultural Biotechnology, http://www.excellencethroughstewardship.org/ (self-described as "the first biotechnology industry-coordinated initiative to promote the global adoption of stewardship programs and quality management systems for the full life cycle of biotechnology-derived plant products") (last visited July 29, 2010).

[113] *See, e.g.,* ASA, Ag-Regulatory Approvals Backgrounder, *supra* note 90 (ASA supports increasing funding for the Biotechnology Regulatory Service at APHIS/USDA by $6.0 million to accelerated approvals of pending applications for new biotech traits); *see also* Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 596 (2003).

crops that might enter export channels.[114] The EU also balances complex issues of national sovereignty that must be taken into consideration when faced with the attempts of its member states to assert control of their countries' food supplies and erect additional barriers against GMOs.[115] Another important trading partner, Japan, maintains its zero tolerance policy for unapproved GMOs as well as strict handling and labeling guidelines.[116]

Even more broadly, the Cartagena Protocol on Biosafety embodies an international consensus with which U.S. law and trade policy conflict.[117] As an important precedent, the World Trade Organization (WTO) ruling on EU-Biotech in its support of the U.S. position undermined the authority of the Biosafety Protocol, which allows its member states to take a precautionary approach to regulating GMOs when there is scientific uncertainty.[118] Dennis Olson, Director of the Trade

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[114] *See* Strauss, *Impact of the WTO*, *supra* note 45, at 808-11 (analyzing the WTO decision in the EU-Biotech case on the moratorium as well as its impact on current and future EU regulations); *see also* Thomas P. Redick & Michael J. Adrian, *Do European Union Non-Tariff Barriers Create Economic Nuisances in the United States?*, 1 J. FOOD L. & POL'Y 87, 87–88 (2005) (arguing that the EU's new traceability system for biotech crops will lead to the proliferation of nontariff barriers affecting biotech crops and proposing legal mechanisms to prevent liability for those impacted at every stage in the chain of commerce).

[115] *See* Strauss, *Impact of the WTO*, *supra* note 45, at 814-21. For more on the implications of this WTO decision for national sovereignty, see Debra M. Strauss & Melanie C. Strauss, *Globalization and National Sovereignty: Controlling the International Food Supply in the Age of Biotechnology,* 15 J. LEGAL STUD. BUS. 75 (2009) (analyzing the implications of the WTO's food trade dispute decision on nation-state control in the regulation of its food supply, and multilateral environmental and trade agreements; concluding that the WTO has exceeded its scope of international trade and that perhaps another supranational organization should be formed to regulate the world's food supply as a scientific and policy-making entity that would take into account public health, safety, and sustainability) [hereinafter Strauss & Strauss, *Globalization and National Sovereignty*].

[116] For a product to be labeled as "Non-GM," the GM content of the food must fall below 5 percent and the processor must be able to show that all non-GM ingredients were identity preserved from production through processing. There are also special guidelines for handling IP corn and soybeans for export to Japan. *See* The Organic and Non-GMO Report, *supra* note 64.

[117] Strauss, *Impact of the WTO*, *supra* note 45, at 815; Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000), *available at* http://www.cbd.int/biosafety. The Biosafety Protocol was put forth in January 2000 and went into effect on September 11, 2003, the ninetieth day after receiving the fifty instruments of ratification by states or regional economic integration organizations that are parties to the UN Convention on Biological Diversity (CBD), which was adopted in Rio de Janeiro in 1992 and has been ratified by190 parties. *See* IISD Linkages, A Brief Introduction to the Convention on Biological Diversity, http://www.iisd.ca/biodiv/cbdintro.html (last updated Feb. 18, 2000). As of August 2010, 193 parties had ratified the Protocol. The United States, which had signed the CBD, but had not ratified it, is not among them. For a list of the status of the ratifying parties, see The Convention on Biological Diversity, List of Parties, http://www.cbd.int/convention/parties/list.shtml (last visited Aug. 1, 2010). *See also* Richard J. Blaustein, *The United States needs to join the rest of the world in ratifying the Convention on Biological Diversity*, LEGAL TIMES, Nov. 7, 2005.

[118] Julia Watson, *Eat to Live: Europe, WTO in food fight*, UPI, Feb. 10, 2006, *available at* http://www.tradeobservatory.org/headlines.cfm?refID=78529. *See generally* SABRINA SHAW & RISA SCHWARTZ, UNITED NATIONS UNIVERSITY INSTITUTE OF ADVANCED STUDIES, TRADING PRECAUTION: THE PRECAUTIONARY PRINCIPLE AND THE WTO, UNU-IAS REPORT (2005), *available at* http://www.ias.unu.edu/binaries2/Precautionary%20Principle%20and%20WTO.pdf.

and Agriculture Project at the Institute for Agriculture and Trade Policy (IATP), noted that:

> There is already a broad international consensus on how to handle GE crops at the international level established at the Cartagena Protocol. This consensus acknowledges that each country has the right to regulate GE crops based on precautionary principles, to require labeling of GE crops, and to protect farmers and others from unfair liability arising from the release of GE crops into the environment and food distribution system. Now, the WTO's unelected legal tribunal, at the request of the U.S. government, has chosen to pre-empt a strong democratic international consensus.[119]

Critics have identified the problem of disrupted trade and economic loss caused by these conflicting systems: "The sale in the United States of a biotech crop that cannot be exported to the E.U. represents an economic threat to crops bound for export … These crops cannot reach their intended market if the unapproved biotech crop mixes with it in the field, through pollen drift, a 'volunteer' emerging from grain left on the ground in a prior harvest, or through post-harvest commingling."[120] The inconsistency with international standards and principles will continue to lead to trade obstacles until the U.S. biotech industry conforms its practices.[121]

E. The Voice of the People: Channeled through Legislation?

Biotechnology companies and the farmers who grow GM crops may face more potential liability under federal and state statutes in the future. New legislation has been proposed that has thus far been largely unsuccessful in obtaining approval.[122]

At the federal level, only bills supporting biotechnology passed during the most recent five-year period reported by the Pew Initiative on Food and Biotechnology

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[119] Press Release, Institute for Agriculture and Trade Policy, WTO Ruling on Genetically Engineered Crops Would Override International, National and Local Protections: Preliminary Ruling Favors U.S. Biotech Companies Over Precautionary Regulation (Feb. 7, 2006), http://www.iatp.org/iatp/library/admin/uploadedfiles/WTO_Ruling_on_Genetically_Engineered_Crops_Wou.pdf. *See* Strauss & Strauss, *Globalization and National Sovereignty*, *supra* note 115, at 86-92 (discussing how decreased economic nationalism impedes state sovereignty). *See generally* Robert F. Blomquist, *Globoecopragmatism: How to Think (and How Not to Think) About Trade and the Environment*, 55 KAN. L. REV. 129 (2006) (analyzing PETER SINGER, ONE WORLD: THE ETHICS OF GLOBALIZATION (2004), which argues that the WTO erodes national sovereignty, is undemocratic, exacerbates world poverty, and places economic considerations ahead of concerns for the environment, animal welfare, and human rights).

[120] Redick & Adrian, *supra* note 114, at 116-17; *see also* Thomas P. Redick, *The Cartagena Protocol on Biosafety: Precautionary Priority in Biotech Crop Approvals and Containment of Commodity Shipments,* 18 COLO. J. INT'L ENVTL. L. & POL'Y 51 (2007).

[121] *See* Strauss, *A Model of Labeling*, *supra* note 102, at 118-19 ("If neither the U.S. government nor the industry moves forward to address these risks in a meaningful way, increased public awareness and pressure from abroad may spark a backlash that further impedes international trade and may eventually necessitate a ban of GMOs in the U.S. food supply.").

[122] *See* Strauss, *Importing Caution, supra* note 3, at 186-87.

(PIFB) (2001-2006).[123] None of the GM-restrictive legislation in this area was enacted, but several bills were introduced.[124] In May 2002, H.R. 4814 was one of five bills introduced by Representative Dennis Kucinich (D-Ohio) that sought to expand the regulation of agricultural biotechnology. H.R. 4812, the Genetically Engineered Crop and Animal Farmer Protection Act, would "provide additional protections for farmers and ranchers that may be harmed economically by genetically engineered seeds, plants, or animals," establishing a Farmer's Bill of Rights "to ensure fairness for farmers and ranchers in their dealings with biotechnology companies that sell genetically engineered seeds, plants, or animals."[125] Among these protections, the bill would require disclosure by the biotechnology companies of the legal and environmental risks that the use of the genetically engineered seeds, plants, or animals may pose to the purchaser; prevent noncompetitive practices involving technology fees; preclude the biotechnology company from limiting liability for harm that may result from the release of genetically engineered material into the environment; and prohibit the sale of certain nonfertile plant seeds (a seed that is genetically engineered to produce a plant whose seeds are not capable of reproduction). Finally, H.R. 4816, the Genetically Engineered Organism Liability Act, would hold biotechnology companies liable to any party for injuries caused by the release of a genetically engineered organism into the environment.[126] The list of potential injuries included crop failures suffered by farmers, cross pollination of neighboring farms, and increased insect resistance, as well as health and environmental impacts on consumers.[127] All of these proposals died in subcommittees.

Nevertheless, Rep. Kucinich has again introduced similar bills in the current Congress.[128] The purpose of these bills is:

> To provide additional protections for farmers and ranchers that may be harmed economically by genetically engineered seeds, plants, or animals, to ensure fairness for farmers and ranchers in their dealings with biotech companies that sell genetically engineered seeds, plants, or animals, to assign liability for injury caused by genetically engineered organisms, and for other purposes.[129]

The Genetically Engineered Organism Liability Act of 2010 further states that: "(1) a biotech company shall be liable to any party injured by the release of a

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[123] Pew Initiative on Food and Biotechnology (PIFB) Legislative Tracker 2006, Legislative Activity 2001-2006 Related to Agricultural Biotechnology (Feb. 2007), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/PIFB_Legislative_Tracker.pdf.
[124] *Id*.
[125] Genetically Engineered Crop and Animal Farmer Protection Act of 2002, H.R. 4812, 107th Cong. (2002).
[126] Genetically Engineered Organism Liability Act of 2002, H.R. 4816, 107th Cong. (2002).
[127] *Id.*
[128] Genetically Engineered Technology Farmer Protection Act, H.R. 5579, 111th Cong. (2010); Genetically Engineered Food Right to Know Act, H.R. 5577, 111th Cong. (2010); Genetically Engineered Safety Act-Genetically Engineered Pharmaceutical and Industrial Crop Safety Act of 2010, H.R. 5578 , 111th Cong. (2010).
[129] *Id*.

genetically engineered organism into the environment if the injury results from such genetic engineering; and (2) liability may not be waived or otherwise avoided by contract."[130] Introduced on June 23, 2010, the bills were submitted to the appropriate House committees.

The most recent PIFB report on state legislative activity indicates that in 2005, increasing initiatives arose at the state and local levels. Michael Fernandez, executive director of the Pew Initiative on Food and Biotechnology, explained: "As agricultural biotechnology progresses, and farmers, the food industry and consumers continue to adapt to it, state legislatures are at the forefront. States sometimes have little choice but to address new policy issues, even before they emerge at the federal level."[131] State legislatures increasingly introduced bills that attempted to preempt local and county initiatives to limit or prohibit GM seeds and crops, prompted by concerns that local regulations could be inconsistent with, and more restrictive than, statewide policies.[132]

In addition, states sought to balance the competing interests of different stakeholders. While many of the bills supported agricultural biotechnology as a means of promoting economic growth, others aimed to manage the potential economic conflicts between farmers who use GM crops and those using conventional or organic techniques. This category of "liability and contracts" encompassed 15% of the bills introduced in 2005-2006 and 11% of adopted legislation in 2005-2006, compared to 3% in 2003-2004.[133] Most notable was legislation proposed in Vermont ("the Farmer Protection Act") that was vetoed by the Governor. Prompted by concerns about the unintended presence of GM crops in conventional and organic crops, this bill (SB 18) would have held manufacturers strictly liable for damage caused by GM material, while an alternate House version (HB 309) would have required that manufacturers be found negligent to be held

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[130] Genetically Engineered Organism Liability Act of 2010, H.R. 5579, 111th Cong. (2010).

[131] PIFB, Report: State Legislatures Continue to Be Active in Addressing Challenges Associated With Agricultural Biotechnology **(**June 22, 2006**),** http://www.pewtrusts.org/our_work_report_detail.aspx?id=20040&category=442 [hereinafter PEW Report]; *see also* Michael R. Taylor, Jody S. Tick & Diane M. Sherman, Tending the Fields: State & Federal Roles in the Oversight of Genetically Modified Crops (Dec. 2004), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Tending_Fields_Biotech1204.pdf (examining the role of state governments in the regulatory oversight of crops and foods produced using the tools of modern biotechnology).

[132] Pew Initiative on Food and Biotechnology (PIFB), Factsheet: State Legislative Activity Related to Agricultural Biotechnology in 2005-2006 (February 2007), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/PIFB_State_Legislature_2005-2006Session.pdf [hereinafter PEW Legislative Activities].

[133] PEW Legislative Activities, *supra* note 132. At the same time, state legislators proposed contrasting legislation in support of agricultural biotechnology, which constituted the second most prominent category of bills in 2005-2006, both in terms of introduced bills (22%) and adopted bills (33%). (By comparison, in 2003-2004, 34% of introduced bills and 57% of adopted bills supported biotechnology.) Proposed support included favorable tax treatment for investment, bond issues for laboratories and infrastructure, and the establishment of high-level commissions to promote the industry. Bills supportive of biotechnology combined with preemption bills, comprised two-thirds of adopted bills in 2005-2006, indicating that adopted legislation in 2005-2006 was "largely supportive of agricultural biotechnology." *Id.*

responsible.[134] Some of the proposed legislation aimed to impose moratoria on GM crops and animals (16%, as compared to 6% in 2003-2004); 8% proposed to impose labeling requirements (compared to 7%); 9% involved studies and taskforces (compared to 19%); and 1% concerned crop destruction (compared to a similarly small number in 2003-2004).[135] Through these conflicting bills, the states attempted to implement coexistence strategies.[136]

Of the total bills and resolutions introduced in state legislatures in 2005-2006, 27 (20%) passed.[137] Most of the new state laws supported biotechnology, disallowed local and county initiatives, or criminalized the destruction of crops. Only a few of the many labeling bills introduced were adopted: Alaska enacted a labeling statute (SB 25), which requires that GM fish be conspicuously labeled before being sold for human consumption; Maine provided for voluntary labeling of foods designated as GM free (LD 1733); and Vermont mandated labeling of seed as GM (HB 777).[138] In addition, one bill on the subject of liability and agricultural contracts previously became law in Illinois.[139]

Calls have been renewed for a greater statutory response, particularly on the state level.[140] Some experts prefer these decisions be made by the legislatures rather than the courts: "An appropriate statutory and regulatory regime enacted with the purpose of establishing standards of care for growers of GE crops would place the important policy questions presented by gene flow squarely in the hands of the political branches of government."[141] As the voice of consumers grows stronger, and as word of contamination and potentially other incidents spreads, so do the prospects that United States may react to a changing political climate with the passage of new federal and state legislation that clearly delineates liability for the future harms caused by genetically modified crops and GMOs in food.

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[134] *Id.*
[135] *Id.*
[136] *See* A. Bryan Endres, *Coexistence Strategies in a Biotech World: Exploring Statutory Grower Protections*, 13 MO. ENVTL. L. & POL'Y REV. 206 (2006).
[137] *Id*.
[138] *See* PEW Report, *supra* note 131; PIFB Legislative Tracker 2006, *supra* note 124.
[139] Illinois HB 264, Agricultural Producer Protection Act, outlines requirements for contracts between producers and purchasers of grain and suggests that any requirements pertaining to GMO content should be considered for inclusion in an accompanying materials sheet. *See* PIFB Legislative Tracker 2006, *supra* note 124.
[140] *See, e..g.,* Cox, *supra* note 3 (proposing state legislation); Walker & Doerfler, *supra* note 73 (addressing statutory action in Missouri); DREW L. KERSHAN, PROPOSED LIABILITY FOR TRANSGENIC CROPS 3 (2005), *available at* http://www.legis.state.ia.us/lasdocs/IntComHand/2006/IHDLA016.pdf.
[141] Cannon, *supra* note 22, at 679 (preferring legislative and administrative statements on standards of care to the courts' in private tort actions); *see also* Kanchana Kariyawasam, *Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on World Agriculture*, 19 PAC. RIM L. & POL'Y J. 459, 482 (2010) (analyzing the level of protection provided by Australia's Gene Technology Act of 2000 and arguing that it should be strengthened by following the liability legislation of Germany, which "allocates liability for the financial risk arising from the cultivation of GMOs, with a general focus on responsible parties meeting the costs and a clear intent to protect non-GM farmers").

IV. PROPOSALS FOR INDUSTRY AND THE STAKEHOLDERS

In considering the best measures to manage these risks, first and foremost would be a U.S. regulatory approach that would implement labeling, monitoring, and a stringent pre-market approval process.[142] The most effective notification mechanism both for consumers in the United States and importers from abroad would be mandatory positive labeling indicating the presence or possible presence of GMOs—those products "made with GM ingredients" or that "may contain genetically modified ingredients." Voluntary negative labeling for foods that are "not made with GM processes" or "not produced through bioengineering," while a positive marketing tool to consumers, alone will not be adequate.[143] Following the recommendations of the National Research Council, the United States should implement a safety assessment prior to and after commercialization, involve federal agencies in the determination, use standardized sampling methodologies, and improve tracing and tracking methods.[144] Changes in the storage and transportation structure are also necessary to segregate more effectively biotechnology agricultural products from conventional varieties.[145]

In addition, legislation should be passed—preferably on the federal level to prevent a patchwork of inconsistent state laws—that would clearly place liability onto the manufacturers of GM products. Local grass roots initiatives to further protect gardens and farmlands from GMOs contamination should not be suppressed at either the state or federal level. The ownership of these products has already been established through patents. Making tort law consistent with intellectual property law would be both logical and sound as a matter of public policy. With ownership comes great responsibility and—depending on how those products are conceived and produced—potential liability.

Liability would most appropriately be based on a torts theory where manufacturers would be held strictly liable for the injuries caused by their biotech products, including harm to the environment, human health, and economic loss due to loss of international markets.[146] Holding biotech companies liable for the results of their genetic engineering would comport with public policy because it would shift liability to those best able to control the product, ensure its safety, conduct rigorous testing, and disseminate critical information such as the size of buffer zones needed

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[142] *See* Strauss, *Importing Caution*, *supra* note 3, at 189-95 (proposing that, like the EU and international community, the United States adopt a more cautious model of labeling and monitoring); *see also* Strauss, *Ethical Implications*, *supra* note 15, at 8-9 (discussing the failed promise of this technology and presenting an ethical framework in support of labeling and monitoring).

[143] Strauss, *Importing Caution*, *supra* note 3, at 193-94.

[144] *Id.* at 194 (citing NATIONAL RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 3-4 (July 2004), *available at* http://www.nap.edu/html/ge_foods/ge-foods-reportbrief.pdf).

[145] Strauss, *Importing Caution*, *supra* note 3, at 195.

[146] *See, e.g.,* Dan L. Burk & Barbara A. Boczar, *Biotechnology and Tort Liability, A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791, 794 (1994) (arguing that, absent a special liability system, the costs of liability will make the biotech industry uncompetitive internationally).

around GM plants. This approach would put responsibility and thus incentives in the proper place. In the absence of regulation by the FDA and USDA/APHIS, the biotech companies are in the best position to self-police their genetically engineered creations and more likely to do so if they will be held accountable for any injuries that flow as a consequence.

The most difficult hurdle for potential plaintiffs in cases involving environmental and human injury will be proving causation but, like the tobacco industry model, when a scientific breakthrough in this area occurs through studies and unfortunately an incident or health crisis, liability and change will follow. It would be in the best interests of the industry as well as the public to be proactive and work to be sure that these products do not carry such risks. In the face of current scientific uncertainty, who should bear the risks of these products? In the U.S. regulatory world the answer of the responsible agencies charged in this area has been the public. Unlike the stringent regulatory approach of the EU and the international community which reacts in the opposite manner to the scientific uncertainty and places the burden on the biotech companies to prove safety before allowing these products into the market, the United States takes a laissez faire approach and does not provide a regulatory structure or special restrictions for these products.[147]

While it would be preferable to restrict GM products at the outset before they have been let loose on the public in its food supply, this approach does not appear to be on the horizon. As a conservative estimate, more than 75 percent of the products in U.S. grocery stores contain GM ingredients.[148] Most recently, the FDA has extended this approach and, arguably, exacerbated this situation by approving the use of milk and meat from cloned animals without labeling or monitoring, using the same reasoning of "substantial equivalence" that it has used for GM foods.[149]

At the same time, organics are becoming big business. Americans' purchases have increased by twenty percent each year and organic producers are being bought out by big companies like Kellogg and Kraft; even megastores like Walmart have added organic food lines admittedly because of the economics driven by customer preferences.[150] Consumer demand is filling the void left by

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[147] *See* Strauss, *Importing Caution*, *supra* note 3, at 176-89 (analyzing the U.S. and EU regulatory treatment of GMOs); Strauss, *A Model of Labeling*, *supra* note 102, at 97-107; *see also* David G. Owen, *Bending Nature, Bending Law*, 62 FLA. L. REV. 569, 571 (2010) ("It is the job of law, drawing from customs, morals, and practical politics, to prescribe who bears the economic risk of harmful consequences from bending nature—those who exploit it or those who are harmed thereby.").

[148] The Grocery Manufacturers of America (GMA) estimates that 75% of all processed foods in the United States contain a GM ingredient, including almost every product with a corn or soy ingredient and some containing canola or cottonseed oil. *See* Americans Clueless About Gene-Altered Foods (Mar. 23, 2005), http://www.msnbc.msn.com/id/7277844/ (statement of Stephanie Childs, Grocery Manufacturers of America); *see also* IRT, *supra* note 4.

[149] *See* Animal Cloning Risk Assessment, 73 Fed. Reg. 2923 (Jan. 16, 2008); FDA, CVM and Animal Cloning, http://www.fda.gov/cvm/cloning.htm (last visited July 30, 2010).

[150] *Food, Inc.*, *supra* note 3; *see also* MICHAEL POLLAN, THE OMNIVORE'S DILEMMA 154-58 (Penguin Books 2006) (discussing the growth of the organic food industry).

administrative agencies and the government.[151] Perhaps the private sector can likewise spur the biotech industry to make food safety a priority.

As a general matter, the business world prefers certainty and clear standards to meet.[152] Ironically, in the absence of federal standards, the industry cannot avail itself of the state of the art or government specification defenses.[153] Shifting this dilemma to the private sector in the lawsuit arena would, paradoxically, provide some structure to manage the risks. A clear federal statute demarking liability would provide the most certain signal to the stakeholder parties. If that does not come to pass, the common law of torts will step in to fill the void, plaintiff by plaintiff, and ultimately through the powerful class action vehicle.[154]

It should be noted that assumption of risk could not be used as a defense to a product liability claim by the biotech industry unless the products were clearly labeled as genetically modified and the public warned of any potential hazards. The consumer must be aware of whether a product contains GM ingredients, along with the potential risks; and voluntarily assume these risks through their purchases and intentional ingestion of these foods.[155] Of course, this labeling and informational campaign approach would only enable the assumption of risk defense to be raised; a

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[151] *Food, Inc.*, *supra* note 3. However, organics alone are not the answer because, due to higher prices and limited availability, they are effectively out of reach for many consumers. Change must occur at the policy level, as the government still has a responsibility to the American public to guaranty the safety of the mainstream food supply for the average consumer. *See* Strauss, *Ethical Implications*, *supra* note 15, at 28.

[152] "Some scientists and biotechnology executives say that by having the Food and Drug Administration spell out the rules of the game, big investors would finally be willing to put up money to create a market in so-called transgenic livestock." Andrew Pollack, *Without U.S. Rules, Biotech Food Lacks Investors*, N.Y. TIMES, July 30, 2007 (Barbara Glenn, the managing director for animal issues at the Biotechnology Industry Organization, a trade group, publically supports tougher standards: "Our overarching goal is to have public confidence in our products. We won't have that unless we have a very strong review process.").

[153] The state of the art defense is available in many products liability and toxic torts cases, founded upon the notion that since little or no knowledge of the hazard in question existed at the time, the manufacturer or other defendant responsible for the alleged hazard should not be held liable. However, the degree of success of this defense depends entirely on the jury; while it may limit the amount of damages, most juries will not allow this defense to avoid liability altogether. *See* Louis Genevie, *The State-of-the-Art Defense*, For the Defense (1992), *available at* http://www.litstrat.com/Articles/STATE_OF_ART_DEFENSE.pdf. *See generally* CONSTANCE E. BAGLEY & DIANE SAVAGE, MANAGERS AND THE LEGAL ENVIRONMENT: STRATEGIES FOR THE 21ST CENTURY 353 (6th ed. 2010) (discussing components and viability of state-of-the-art defense, with availability varying by state). The government-contractor defense may be available in cases where the product was a joint venture with the government or produced under a contract according to specifications set by the government. *Id.* at 352.

[154] *See, e.g.,* Cox, *supra* note 3, at 417 (exploring common law tort claims and proposing state legislation to protect farmers by holding growers and manufacturers liable for the harm); *see also* Khoury & Smyth, *supra* note 76, at 11 (making a similar observation regarding the absence of statutes in Canada and, as a consequence, common law tort actions stepping in to fill in the void); Blake Denton, *Regulating the Regulators: The Increased Role for the Federal Judiciary in Monitoring the Debate over Genetically Modified Crops*, 25 U.C.L.A. J. ENVTL. L. & POL'Y 333 (2007) (observing that in the absence of a stricter regulatory structure and oversight in the United States, more such lawsuits are likely to be brought in the coming years by opponents of GMOs).

[155] Under the doctrine of assumption of risk, when a person "voluntarily and unreasonably assumes the risk of a known danger, the manufacturer is not liable for any resulting injury." BAGLEY & SAVAGE, *supra* note 153, at 350.

jury would still have to be satisfied that these risks were clearly undertaken by the consumer. Moreover, a manufacturer's responsibility to the public and greater ability to minimize these risks should ultimately be given more weight in the equation to assess liability. Nonetheless, there may be reduced costs in the form of a significantly diminished risk of liability from lawsuits, at least with respect to potential claims for injuries that may occur due to a failure to warn.[156] Since such labeling and warnings are not currently required under federal law, voluntary labeling and information dissemination would be a wise approach for biotech.

V. CONCLUSION

Ultimately, the risks of harm to human health and the environment, as translated into these multifaceted layers of legal liability, may justify a moratorium or ban in the use of GMOs in food and commercial medical applications. Until then, individual farmers would be better able to make choices about whether to plant GM crops if they are made aware of their potential liability and given critical information such as the need for sufficient buffer zones and proper segregation methods—including the cost of leaving large tracts of their land fallow, testing their crops, and cleaning their equipment—in order to minimize their legal jeopardy. Through their own evaluation of costs and benefits, these farmers may decide that any involvement with GMOs is not worth engendering these hazards and expenses. Perhaps additional measures can be developed to protect non-GM farmers and empower them to segregate and protect their crops, such as developing a non-GM certification and requiring special handling before their products enter the domestic market or export channels.[157]

Most importantly, biotech companies must be sent a clear message that they will be held financially accountable for the harm caused by their genetically engineered products—injuries and damages that are no longer merely theoretical. As landmark multimillion dollar cases such as the LibertyLink® rice litigation proceed through the courts, this message is reaching a crescendo. Perhaps statutory liability and a transformation in the regulatory regime will follow. Through this risk analysis, the industry might be persuaded that safety is good business to ensure that, in the long-run, they continue to reap what they sow.

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[156] *See* Strauss, *Importing Caution*, *supra* note 3, at 192.

[157] *See, e.g.*, Ken Roseboro, "Certification Seen As a Key to Success in Non-GMO Markets," Jan. 5, 2004, http://www.non-gm-farmers.com/news_print.asp?ID=960; Non-GMO Project, http://www.nongmoproject.org/industry/become-non-gmo-project-verified/ ("The Non-GMO Project offers North America's *only* independent verification for products made according to best practices for GMO avoidance."); Cert ID Non-GMO Standard, http://www.cert-id.eu/Certification-Programmes/NonGMO.aspx (international independent certification company based in Europe).