Stewardship for Biotech Crops: Strategies for Improving Global Consumer Confidence

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STEWARDSHIP FOR BIOTECH CROPS: STRATEGIES FOR IMPROVING GLOBAL CONSUMER CONFIDENCE

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ABSTRACT: This article will review a decade's worth of voluntary liability prevention ("stewardship") in food biotechnology. Consumer confidence in the biotechnology industry has prevailed in the U.S., despite concerted efforts by anti-biotech activists to exaggerate the risks of biotech crops and some unfortunate lapses in biotech industry stewardship. However, there is a need for continuing scrutiny of stewardship standards that will help the biotechnology industry to protect U.S. leadership in grain exports and biotech innovation, given the recall and ensuing litigation over unapproved-for-food Starlink™ corn and the proliferation of "precautionary" regulatory approaches to biotech crops worldwide. Improved stewardship will help build global consumer confidence in biotech's ability to manage long-term, uncertain risks before they are manifest on a broad scale. One of the most significant threats driving improved stewardship of biotech crops in the post-Starlink™ era will be the threat of litigation from the plaintiffs' class action bar, now that courts may award damages to parties suffering economic injury from lost exports. Consumer confidence in biotech crops could be undermined by high-profile class action litigation. Moreover, the crucial linchpin in global markets, the U.S. challenge to European Union policy at the World Trade Organization, could turn upon a showing of improved biotech industry stewardship, which keeps biotech crops separate where particular crops are not approved for export to Europe or other markets.

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"Stewardship" is a biotechnology industry term for voluntary risk management efforts that minimize the environmental, economic, or health effects of crops produced using modern recombinant DNA biotechnology ("biotech crops").[1] Biotech industry stewardship standards currently vary between companies because of variations in knowledge, past corporate experience, and willingness of managers to take certain risks. This article will report on a few stewardship successes and failures and suggest methods for assuring a consistently high level of stewardship throughout the biotech industry.

The saga of Starlink™ corn and its sister crop, the Liberty Link™ soybean, will be reviewed in this paper as lessons in comparative biotech company stewardship (arising from the same biotech company managers). In the unfortunate case of Starlink™ corn, Aventis Crop Sciences recklessly took risks that led to the recall of Starlink™ corn and food products that contained any Starlink™ corn.[2] While the economic legacy of this recall is still being sorted out (with one recent class action settlement of $110 million), the legal legacy of Starlink™ corn will reshape the legal standards applied to biotech crops, both in the U.S. and in international environmental law.

Stewardship in biotech crops is being transformed in the aftermath of the recall of Starlink™ corn, which occurred around the same time that the world's first environmental agreement regulating biotechnology (the Cartagena Protocol on Biosafety ("biosafety protocol")) entered into force. The biosafety protocol arose under the authority of the Convention on Biological Diversity.[3] The U.S. is

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1. *See* Stanley H. Abramson & Thomas J. Carrato, *Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L.J. 241, 259 (2001) (Abramson and Carrato define product stewardship as "the legal, ethical, and moral obligation to assess products and technologies to ensure that they are safe as well as socially and environmentally responsible. Stewardship includes the assessment, based on sound scientific principles, of the potential impact of a particular product or technology on human health and the environment, as well as those actions and principles necessary to protect the integrity and viability of a particular product or technology.").

2. *In re* Starlink™ Corn Prods. Liab. Litig., 212 F. Supp. 2d 828, 834–35 (N.D. Ill. 2002). This consumer class action was brought by growers who suffered economic losses because of the widespread regulatory recall of Starlink™ corn, an insect-resistant, herbicide-resistant biotech corn produced by Aventis Crop Sciences USA. *Id.* at 833. Defendants' motion to dismiss was granted in part (because of Federal Insecticide Fungicide and Rodenticide Act preemption) for claims of consumer fraud under North Carolina law, conversion, and failure to warn, but the case was allowed to proceed on claims of public nuisance, private nuisance, strict product liability (design only), negligence *per se*, and Tennessee consumer fraud claims. *Id.* at 852. Damages sought included depressed corn prices from lost exports—a factual scenario which could be repeated for any biotech crops that cause trade disruption because of European Union anti-biotech policies. Estimates of the economic impact range as high as $1 billion, but this case settled for $110 million, with attorneys fees and costs taking a $40 million share.

3. *See* Convention on Biological Diversity, Cartagena Protocol on Biosafety, http://www.biodiv.org/biosafety/protocol.asp (last modified Sept. 25, 2002). The U.S. is remarkably isolated from the rest of the world when it comes to the international regulation of biotechnology, an industry in which the U.S. is the undisputed global leader. The U.S. is not a party to the Convention on Biological Diversity (despite active U.S. involvement in the concept of such a convention from its outset).

not a party to the biosafety protocol, and this isolation from other trading partners will create added pressure on biotech company stewardship programs.

The legal legacy of Starlink™ corn, combined with increasing pressure from overseas markets (which were stung by Starlink™ and demand segregation of crops), will drive stewardship standards higher, as economic liability risks from commingling biotech crops increasingly surface, in banned exports or recalls of food.

As a result, all biotech companies will need to continually re-evaluate their level of industry stewardship. Given the threat of more class action lawsuits seeking compensation for economic loss from export markets, the biotech industry may need to implement a higher level of product stewardship—even those that had set a high standard of their own already—because of the legal legacy of Starlink™.[4]

As the sun set on that last harvest in the 20th Century, Starlink™ corn provided the biotech industry with a glimpse at the future of liability for agricultural biotechnology. Starlink™ is setting significant precedents in common law and U.S. regulatory law; it is not a singular episode that will be distinguishable on its facts from cases in which future biotech crops cause similar economic dislocation.

Overseas less informed regulatory authorities may impose strict "zero tolerance" standards for a wide range of the biotech crops grown in the U.S. citing *Starlink*.[5] They will probably resist U.S. pressure to adopt more reasonable tolerances, given their uncertainty about health risks. While Aventis vigorously opposed the Environmental Protection Agency's (EPA) decision to impose a very low tolerance for Starlink™ corn in the U.S. food supply, the decision was foreseeable for any cautious student of regulatory policy. Allergens operate at microscopically low levels, because of the sensitivity of the human immune response. As a result, a very low tolerance for a possible allergen could reasonably be expected to be set by a cautious regulatory agency (one subject to the usual level of political pressure that accompanies agency action in the U.S.).

Given this trend toward zero tolerance, the Starlink™ recall in the U.S. may be the first in a series of such recalls that occur around the world.[6] Strong economic incentives existed to keep Starlink™ out of corn and other grain exports, so the EPA decision had the salutary effect of cleaning Starlink™ up to the level expected by foreign trading partners (who are even more wary of Starlink™'s potential allergenicity risks than the U.S. regulators), even if the EPA

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4. The biotech industry has risen to the occasion and set industry standards addressing specific threats to the environment and economic interests affecting large groups of stakeholders. In response to concerns over the potential resistance of insects, agbiotech companies voluntarily developed insect resistance management (IRM) programs. *See* Abramson & Carrato, *supra* note 1, at 261.

5. *See supra* note 2.

6. For example, Pringles were recalled in Japan because unapproved-in-Japan Bt potato was present at low levels in the chips. Reuters, Jae Hur, *Japan P & G Recalls Pringles* (July 17, 2001), *available at* http://www.biotech-info.net/springles.html.

did not expressly consider those economic impacts.[7] If the EPA had not set a near-zero tolerance, the grain exporters of the United States would still be maintaining their own costly testing programs to ensure that the export supply of corn was free from Starlink™.[8]

International consumer and regulatory attitudes toward any new biotech crops, not just Starlink™, appear to be growing increasingly hostile. The European Union (E.U.) regulatory approval process for biotech crops remains paralyzed by particular members that are beholden to a perceived loss of consumer confidence. The E.U. regulatory system stumbled in failing to detect and manage risks from biotech crops, "mad cows," or dioxin. As a result, the E.U. appears ready to insist upon a "precautionary approach" to biotech crops that will interminably delay the approval of new biotech crop "events" that could alter the known safety profile of common commodity crops.[9] A genetic "event" is biotech industry terminology for a recombinant alteration in the DNA of a biotech crop. The transformation of the crop provides grounds for issuance of a patent on the particular variety, because of the unique, original genetic "event."

This paper will provide an overview of the complex interplay between the biosafety protocol, the E.U.'s precautionary biotech bans, and the few high-profile failures of stewardship that have occurred in the U.S. in recent years. Part I will address the E.U.'s position on the precautionary approach to approval of biotech crops produced in the U.S. and its probable persistence over the coming decade.

Part II will briefly address the conundrum presented by corn exports and contrast the cataclysmic failure of Aventis in its Starlink™ corn stewardship with the successful Liberty Link™ soybean stewardship program. Starlink™ corn was commingled with export supplies of corn during the E.U.'s biotech crop import moratorium (the "biotech ban") that led the U.S. grain industry to stop shipping over 90% of U.S. corn export to the E.U. for five successive years at $200 million or more per season in lost exports of whole corn. While Starlink™ corn is the only "unapproved-in-E.U." variety that has resulted in a judicially approved class-action settlement, other varieties of biotech corn were sold that lacked E.U. regulatory approval and could be held liable for these economic loss claims.

The U.S. is initiating a World Trade Organization (WTO) challenge to the E.U. ban that caused these economic losses but improved industry stewardship

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7. It appears safe to assume, based on the continuing federal regulatory indifference to the economic loss caused by the commingling of biotech crops, that federal U.S. regulators will leave these export management issues for each of the 50 states to work out on their own.

8. *See* Reuters, Aya Takada, Japan Plans Tighter Rules on GMO Imports for Feed (Oct. 10, 2002) (Starlink™ found in corn exported from U.S. to Japan, where it was completely banned), *available at* http://www.planetark.org/dailynewsstory.cfm/newsID/18140/newsDate/11-Oct-2002/story.htm.

9. For an explanation of Europe's precautionary approach by one E.U. official, see Robert J. Coleman, Address on the U.S., Europe and Precaution: A Comparative Case Study Analysis of the Management of Risk in a Complex World (Coleman is the Director General, Health and Consumer Protection Directorate, European Commission), *available at* http://europa.eu.int/comm/dgs/health_consumer/library/speeches/speech139_en.pdf (Jan. 11, 2002).

will be integral to U.S. attempts to overturn E.U. policy using trade agreements. The U.S. may bring a billion-dollar claim to the WTO, but that claim may fail if biotech industry stewardship for unapproved-in-E.U. varieties is found to have been lacking. Biotech seed companies that failed to seek regulatory approval from the E.U. and then failed to segregate their unapproved-in-E.U. crop may create the bad facts that make bad law in a WTO challenge to the E.U. When the E.U. insists on a right to exclude Starlink™ corn (which the U.S. cannot seriously dispute) and extends that argument to biotech corn (which was never submitted to the E.U. for regulatory review), there may be little fully submitted corn left in the billion-dollar trade loss.

Other governments have a right to impose reasonable premarket approval processes that are similar to, or even stricter than, the U.S. system. As a result, the U.S. should be concerned that some of the corn varieties that make up the billion-dollar WTO claim could prove to be legitimately banned varieties of corn (like Starlink™) or varieties that were never submitted for regulatory approval to the E.U. and hence were not unreasonably denied entry. Starlink™ corn is the prime example of a product that both the E.U. and U.S. chose to ban. Starlink™ was also banned in the U.S. after the EPA cancelled, or Aventis "voluntarily" revoked, Starlink™'s Federal Insecticide Fungicide and Rodenticide Act (FIFRA) registration.[10]

Part III will provide a review of ten years of biotech industry stewardship and the devastating, divisive economic impact in the U.S. of E.U. policies. Given zero tolerance standards that may be set for biotech crops by Starlink™ corn under the biosafety protocol, there are strong economic incentives, in terms of liability avoidance, for setting an industrywide stewardship standard with injunctive power to enforce violations of rogue biotech companies that threaten export markets. For unapproved-in-E.U. varieties of biotech crops, the E.U. continues to impose a zero tolerance standard.[11] Controlling the commingling of unapproved-in-E.U. biotech crops will prevent further class action lawsuits alleging economic liability and simultaneously set the stage for a WTO decision favoring the U.S. on the lack of scientific evidence to support the E.U.'s precaution toward biotech crops.

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10. Starlink™ was made resistant to insects by incorporating the Cry9(c) Bt protein, which made it subject to FIFRA. *In re* Starlink™ Corn Prods. Liab. Litig., 212 F. Supp. 2d 828, 835 (N.D. Ill. 2002).

11. The E.U. Commission has repeatedly stated that it will be rolling back its "zero forbearance" standard for certain events reviewed and cleared by its scientific advisors to 0.9% (still a commercially impracticable tolerance). If passed, this proposal will not alter the analysis in this article significantly; but it could marginally reduce the massive costs of E.U. policy. Jean Ferriere, Address on the E.U. Traceability Directive at Iowa State University (Nov. 14, 2003) (notes on file with author).

I. THE E.U.'S PROBLEMATIC PRECAUTIONARY APPROACH

The "precautionary principle" is an emerging concept in international environmental law that suggests that catastrophic ecological events can be prevented by acting upon limited, perhaps contradictory, scientific data.[12] This controversial principle is the cornerstone of the E.U.'s regulatory policy, particularly as to biotech crops, and it is a bone of contention between the E.U. and the U.S. For environmental activists, the precautionary principle would presume harm from various new technologies (biotech crops, chemicals, electromagnetic fields, etc.) before scientific evidence of harm has accumulated to the point where other causes of harm can reasonably be ruled out.[13]

Activists favoring the precautionary principle for particular technologies reason from examples of technological fiascos that emerged in mass tort litigation that swamped U.S. courts in the latter half of the 20th Century, such as asbestos litigation, chemical remediation, personal injury cases, or persistent organic pollutants such as Poly-chlorinate biphenyls (PCBs). For some technologies, there is a consensus among scientific risk assessors that the benefits of the products were vastly outweighed, in hindsight, by the enormous costs created by mishandling and lack of understanding of potential risks. As a result, the more scientifically oriented environmental activist would suggest that a hypothetical risk of catastrophic harm on the scale of asbestos should warrant imposing a ban on certain products based upon even remotely hypothetical (but catastrophic and

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12. *See* Rio Declaration on Environment and Development: Report of the Untied Nations Conference on Environment and Development, at Principle 15, U.N. Doc. A/Conf.151/26 (1992) ("Where there are threats of serious irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."), *available at* http://un.org/documents/ga/conf151/aconl5126-1annexI.htm (Aug. 12, 1992).

13. *See* Science and Environmental Health Network, The Precautionary Principle, http://www.sehn.org/precaution.html (last visited Nov. 9, 2003).

> This principle, formalized at the 1992 United Nations Conference on Environment and Development, emphasizes that the discipline of precaution be carefully exercised to avoid potential harm and unforeseen and unintended consequences. This principle requires that precaution should prevail whenever questions of human and environmental health are involved. It mandates restraint until cause and effect relationships are properly understood. It places the primary burden of demonstrating safety upon the developer. Thorough examination for the potential for harm is a prerequisite in determining and demonstrating such safety.

A Response to Issues and Values Related to Genetically Modified Organisms, Statement of the Rural Life Committee of the North Dakota Conference of Churches (2003), http://www.sehn.org/ ndcc.html (last visited Nov. 9, 2003). For a critique of this principle, see Henry I. Miller & Gregory Conko, *Precaution (of a Sort) Without Principle*, 13 PRIORITIES FOR HEALTH (Nov. 1, 2001) (citing examples of precaution toward chlorinated water in Peru accelerating a cholera outbreak in Latin America, killing over 11,000 people), *available at* http://www.acsh.org/publications/priorities/1303/coverstory.html. There are underlying values that guide risk assessment, which are discussed along with a general review of precaution in risk assessment at a highly intellectual level, if unintelligible to most. *See* ANDREW STIRLING, ON SCIENCE AND PRECAUTION IN THE MANAGEMENT OF TECHNICAL RISK (1999) (final report of a project for the EC Forward Studies Unit under the auspices of the ESTO Network), http://www.susx.ac.uk/Units/gec/gecko/r9e-prc-.htm (last visited Nov. 9, 2003).

undetectable) risks. Moreover, where new technologies are easily substituted for the potentially offending product, the relative cost of prevention is low, so the potential savings in future catastrophic risk may justify precaution, even for a hypothetical risk.

In the case of biotech crops, certain environmental activists consider the reproducing nature of biotech crops to create a particularly costly feature for any future corrective action.[14] As the Starlink™ episode has illustrated, a living organism that is grown on a broad commercial scale can be hard to eradicate completely. This may be compounded by its resistance to a given herbicide or pest, providing a slight advantage in competition with other crops.

The problem with applying precaution to innovative agricultural practices, however, is that existing agricultural practices often generate known risks, including some that are catastrophic. For example, biotech corn varieties significantly reduce formation of carcinogenic mycotoxins. FAO researchers estimate the health impact of these natural poisons on human and animal health to be catastrophic.[15] If the widespread use of biotech corn would reduce the incidence of this catastrophic public health problem in certain developing nations, and the owners of the technology were willing to share this technology with those who cannot afford it at full cost (as has occurred with HIV treatments), then the precautionary approach could dictate the use of biotech, in the view of a rational regulatory authority. This would require a more rapid deployment of these varieties of biotech corn.[16] In the U.S., for example, the EPA could dictate the use

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14. *See* GURDIAL SINGH NIJAR, DEVELOPING A LIABILITY AND REDRESS REGIME UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY FOR DAMAGE RESULTING FROM THE TRANSBOUNDARY MOVEMENTS OF GENETICALLY MODIFIED ORGANISMS (2000), *available at* http://www.twnside.org.sg/title/blp.pdf (last visited Dec. 2, 2003). Targets include "operator[s] responsible for . . . the failure to provide an adequate system of safety." *Id.* at 65.

15. Maitree Suttajit, Ph.D, *Prevention and Control of Mycotoxins, in* MYCOTOXIN PREVENTION AND CONTROL IN FOOD GRAINS (R.L. Semple et al. eds., 1989), *available at* http://www.fao.org/inpho/vlibrary/x0036e/X0036E00.htm (last visited Dec. 2, 2003).

16. Environmental law has historically involved "technology-forcing" regulation in air and water pollution, and biotech crops show every sign of becoming the "Best Available Technology" for managing certain forms of agricultural environmental pollution. *See* Kimball A. Nill et al., *Precautionary Priority in Approving Imports of Genetically Improved Commodity Crops*, 19 BIOTECH. L. REP. 546, 559 (2000) (suggesting that certain crops posing solutions to known risks, such as mycotoxins in corn or soil loss in soybean production, should be adopted more rapidly with minimal duplication of regulatory approval processes between trading partners to speed the adoption of agricultural practices that enhance environmental protection or food safety in an undisputed, measurable manner). Other examples of technology-forcing regulation can be found in international environmental law (for example, the Kyoto protocol on climate change would drive replacement technology that does not use fossil fuels, while the Montreal protocol on ozone has forced new refrigerant technologies to be adopted in place of ozone-depleting chemicals). These technology-forcing regulations generally lead to sharing that environmental knowledge with developing nations. *See, e.g.*, Alfred C. Aman, Jr., *The Earth As Eggshell Victim: A Global Perspective on Domestic Regulation*, 102 YALE L.J. 2107, 2121 (1993) ("Technology-forcing legislation can help promote new green technologies which then could be shared worldwide in some equitable manner."). Other commentators have expressed concern that international environmental agreements could create pressure to weaken the technology-forcing statutes in the U.S. Kal Raustiala, *The Political*

of certain biotech crops as the "best available technology" for particular environmental problems.[17] This would be true even if there were a lingering risk that the corn might be found to have hidden allergens or toxins and that it might become widely used before that risk were detected. The people involved might not survive to experience those risks if they need biotech corn to survive.

As a result, precaution can be applied to biotech crops in a paradoxical manner that leads to increased risks to human health or the environment. If the precautionary approach is to be applied to biotech crops and other alternatives for food production, then it must be applied equally to both biotech crops and their alternatives. In this manner, precaution will follow its own principle that we should follow Hippocrates and "first, do no harm."

The loss of consumer confidence in biotech crops in the E.U. and the resulting regulatory rejection of biotech crops by the E.U. could prove to be a regulatory paradigm with staying power, however, despite the flaws in its precautionary approaches to biotech crops. This approach could also spread to other nations rapidly through market forces (those who would export grain to the E.U.) and through international legal standards protecting those market forces. The impending entry into force of the Cartagena Protocol on Biosafety could provide cover for nations seeking to impose a precautionary approach to imports containing many of the biotech crops currently being grown in the U.S.

In defense of its precautionary approach and zero tolerance for traces of biotech crops, the E.U. may invoke *Starlink*'s zero tolerance precedent set by the U.S. EPA's Scientific Advisory Panel. As the E.U. gravitates toward a precautionary approach that is intractable, as it has done with the beef hormone issue,[18] the E.U. could trigger a domino effect. For each biotech crop the E.U. turns away, it

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Implications of the Enforcement Provisions of the NAFTA Environmental Side Agreement: The CEC as a Model for Future Accords, 25 ENVTL. L. 31, 54 (1995) (stating that under the North American Free Trade Agreement (NAFTA), the Commission for Environmental Cooperation (CEC) could enforce NAFTA's environmental side agreement against the United States to weaken U.S. technology-forcing statutes and environmental legislation). In the case of biotech crops, however, it would appear that the technology-forcing aspects of U.S. environmental law would drive increased use of biotech crops, while international environmental law will prevent these technologies from being shared with developing nations. Given a misguided implementation of the precautionary principle that the E.U. seeks, there could prove to be a much slower adoption of the best available agricultural technology worldwide.

17. The most commonly cited example for this could be the use of specialized biotech feeds that reduce the phosphorous content of animal waste generated at feedlots (various biotech companies are looking at creating corn or soybeans that would reduce phosphorous in the waste of animals eating it). The EPA has a new revised rule on Concentrated Animal Feeding Operations. *See* Ellen B. Steen, *New Clean Water Act Permitting Requirements for CAFOs*, 7 AGRIC. MGMT. COMMITTEE NEWSL. 1, 1 (2003) (ABA Section on Environment, Energy and Resources), *available at* http://www.abanet.org/environ/committees/agricult/newsletter/jan03/agmannews0103.pdf (last visited Nov. 9, 2003). The EPA could, in the future, specify the "best available technology" for reducing the flow of phosphorous from such operations under the National Pollution Discharge Elimination System (NPDES) permitting program under the Clean Water Act.

18. For a detailed discussion of the beef hormone dispute between the E.U. and U.S., see *infra* note 27.

could trigger a "slowest common unapproved denominator" (SCUD) effect, whereby nations hoping to export particular commodity crops—corn, soybeans, wheat, etc.—all gravitate to the E.U. standard. In order to export to the E.U., they must ban the use of crops not approved for export to the E.U.

For example, the E.U. intends to use its interpretation of the biosafety protocol's precautionary approach and its companion concept of zero tolerance to defend its regulatory policy for particular biotech crops. These complementary principles of precaution and zero tolerance, if left unchallenged by the U.S., will eventually force "identity preservation" (crop segregation) in the U.S. of all new biotech crop varieties that lack regulatory approval in the E.U. This will cause a serious, continuing chilling effect on innovation in agricultural biotechnology, some of which are products that might address existing catastrophic harms to health or habitants. As a result, there are strong counterarguments to be made against applying the precautionary approach in the biosafety protocol to blindly ban biotech crops.

As the agricultural biotechnology industry in the U.S. enters the next 25 years of its existence (it is nearly 25 years since the first regulatory applications were prepared for biotech crops), there are clearly some lessons that must be borne in mind to avoid repeating past mistakes. The regulatory climate for biotech crops has reached what is likely to be seen, 50 years from now, as the low point in global consumer confidence in biotech crops. This paper will review the liability and regulatory precedents that *Starlink* has set in U.S. law and the truly crippling precedent of zero tolerance toward other biotech crops that *Starlink* could establish in key overseas markets. Unfortunately, *Starlink* could provide the E.U. with a start toward implementing its precautionary approach to all new biotech crops, with the SCUD effect following in the wake of regulatory approval delays in the E.U.

II. STEWARDSHIP STRATEGIES— SUFFERING SOY-CORN SUCCOTASH

Corn and soybeans were among the first commodity food crops in the U.S. to make widespread use of new biotech innovations. As a result, both corn and soybean markets in the U.S. have suffered from the precautionary approach[19] and zero tolerance standard for commingling that the E.U. imposes on unapproved biotech crops. The E.U. is a significant world buyer of grain, and its policies for delaying (and then suspending altogether) the approval process for biotech crops led directly to (1) the loss of one billion dollars in trade for whole corn exported from the U.S. and (2) the loss of innovative new biotech soybeans, which were not sold because of fear of multi-billion-dollar trade losses. E.U. policy could cause a domino effect in other major export markets of the U.S., as the E.U. inevitably

19. *See* Katherine Barrett, *The Case of Genetically Modified Organisms and the Precautionary Principle*, 4 NETWORKER (1999), *at* http://www.sehn.org/Volume_4-1_3.html (last visited Nov. 6, 2003) (articulating the precautionary approach as it applies to biotech crops).

drags other nations (any who hope to export to the E.U.) down to the E.U.'s level of precaution toward commodities shipments containing traces of unapproved biotech crops. U.S. corn exports have been barred since 1997, while soybean exports to E.U. continued, but only by sacrificing innovation in biotech varieties. Rice and wheat have suffered from E.U. policies that have kept new biotech varieties of those crops from being marketed.

The E.U.'s opposition to biotech crops forces other nations to adjust by denying these growers access to beneficial new biotech crops. For example, Brazil has rejected biotech crops in its rush to supply the E.U. In a similar manner, China and other Asian markets that have not yet approved most biotech crops may also want to export to the E.U. Zambia was willing to risk having thousands starve rather than permit food aid from the U.S. containing biotech corn.[20] These nations have economic incentives to adopt the E.U.'s precautionary approach. This growing refusal to approve biotech crops could create a phenomenon in international environmental law known as the "lowest common denominator" effect, whereby one nation can lead other nations, through competition, to adopt the lowest level of environmental protection available.[21] Ironically enough, the E.U.'s rejection of the latest innovations in biotech crops will lead to increased pesticide use, increased loss of precious topsoil (with associated water pollution from the run-off), and other negative environmental impacts—worldwide. All nations in the global grain trading system may feel compelled to conform to the most restrictive standard. This trend may continue even if rejecting certain biotech crops proves increasingly unwise, given well-documented potential benefits for human health and the environment,[22] as long as the E.U. allows perceived consumer sentiments to guide regulatory policy rather than scientific-risk assessments.

It follows, then, that the E.U.'s dilatory approach to approving new crops, along with its zero tolerance policy for unintentional commingling, is causing a SCUD effect. The E.U. will slow the process of widespread adoption of biotech crops that are fast proving to be the best available technology for managing the risks of pesticide misuse and soil loss in regions where state-of-the-art agricultural

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20. *See* Margaret Wilson, *Will Their Protests Leave Her Hungry? European Objections to GM Food Could Have a Devastating Effect on the Poorest Countries of Africa, Says Margaret Wilson*, DAILY TELEGRAPH (London), Nov. 20, 2002, at 26 (Peter Masunu, Zambian Department of Agriculture spokesman: "The Zambian government does not have the capacity to detect whether food is genetically modified, we have not yet ratified the [biosafety protocol] and we have no legislation in place on biotechnology and biosafety."); *cf.* ROBERT VINT, FORCE-FEEDING THE WORLD: AMERICA'S "GM OR DEATH" ULTIMATUM TO AFRICA REVEALS THE DEPRAVITY OF ITS GM MARKETING POLICY, *at* http://www.ukabc.org/forcefeeding.pdf. (Aug. 23, 2002).

21. *See* Sierra Club Fact Sheet, The World Trade Organization: Trading Away our Health and Heritage, *at* http://www.sierraclub.org/trade/summit/facthe.asp (last visited Nov. 9, 2003) ("The business of the WTO should be to raise the bar on environmental protection for all nations, not lower it to the lowest common denominator of rapacious resource extraction.") (quoting the *Seattle Post-Intelligencer*, May 30, 1998).

22. The most widely used biotech crop, herbicide-resistant soybeans, has numerous environmental benefits, including conservation of precious topsoil through "no till" farming.

management prevents the proper use of agricultural chemicals and soil conservation techniques. The SCUD acronym aptly describes the economic and environmental impact that the E.U.'s unreasonable regulatory policy toward biotech crops will have upon growers and grain exporters around the world. In particular, U.S. growers have grown dependent upon biotech crops and cannot quickly abandon them to avoid the E.U.'s Great Refusal. The economic loss alone will be measured in billions of dollars, perhaps exceeding the economic devastation (and even loss of life) caused by SCUD missiles launched in the Persian Gulf war.

As a representative of the World Health Organization recently stated in a presentation at the University of St. Louis Medical Center, the Zambian government's refusal to accept food aid (corn) from the U.S. during a famine (over fears of what E.U. customers might think if Zambia allowed this corn in the country) probably resulted in the loss of life. No one has been permitted to study that question because of the Zambian government's crackdown on the press and other exposure (via scientific study) of its mishandling of the famine there.[23]

As a result of E.U. policies, the two leading commodity crops that have been transformed using biotech innovation—corn and soybeans—will continue to suffer from the SCUD effect. Crops awaiting their turn of biotech enhancement, such as wheat and rice, will continue to suffer from delayed commercial deployment of new biotech varieties. The cost of innovation and the cost of segregating new innovations in the U.S. will continue to increase from the economic liability pressures created by these international events.

A. The Biosafety Protocol and Its Precautionary Approach

At the fall meeting of the Biotechnology Industry Organization (BIO) in September 1995, L. Val Giddings (then with the U.S. Department of Agriculture assigned to the U.S. State Department) warned that "the biosafety protocol is a train heading for a Volkswagen filled with $50 billion per year in U.S. agricultural assets."[24] He cautioned that a binding, precautionary biosafety protocol could significantly threaten the future export of grain (for example, soy and corn) from the U.S. At that time, no export bans were in place for biotech crops.

In 1995, a team of farmer leaders of the American Soybean Association (ASA) reported at that same BIO meeting on their successful tour of Europe promoting the potential future benefits of Roundup Ready™ soybeans. Those Monsanto-produced soybeans were approved for food and feed use in the E.U. shortly thereafter (albeit not for growing by E.U. farmers, who were denied the benefits and the ability to compete with U.S. growers with the best seed technology because of theoretical environmental concerns). While the biotech industry knew that significant

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23. Jorgen Schlundt, Director, Food Safety Department, World Health Organization, Can Biotech Food Be a Value for Public Health? Searching for a Holistic Evaluation, Address to the St. Louis University Medical School, Oct. 17, 2003 (notes on file with author).

24. L. Val Giddings, Address to the Fall Meeting of the Biotechnology Industry Organization (Sept. 26, 1995) (notes on file with author).

challenges lay ahead, it could not predict that the E.U., home to an emerging biotech industry of its own, would turn on agricultural biotechnology with a vengeance.

By January 2000, when the parties to the Convention on Biological Diversity gathered in Montreal to approve the final text of the Cartagena Protocol on Biosafety, the train wreck foreseen by Dr. Giddings had already begun to occur at the domestic level in the U.S., because of the E.U.'s moratorium (since 1997) on approval of biotech crops. Exports of whole corn from the U.S. to the E.U. had slowed to a halt in late 1998 because of E.U. concerns over the potential health, economic, and environmental impact of insect-resistant biotech corn (Bt corn). With approximately $200 million in corn trade lost per year, the U.S. corn export loss has accumulated to nearly one billion dollars in lost trade. This could be deemed the first billion dollars in the "$50 billion" train wreck predicted by Dr. Giddings.

This massive trade loss has triggered a legal challenge by the United States Trade Representative to E.U. policies at the WTO.[25] If the U.S. prevails, it could impose trade sanctions against the E.U. for its wrongful refusal to approve perfectly safe food crops posing manageable environmental risks. If the U.S. pursues this case before the WTO, it appears likely that the E.U. will invoke the precautionary approach language in the biosafety protocol as its support for delaying the approval process for Bt corn and other biotech crops.[26] A WTO holding supporting the E.U. and its reading of precautionary approach in the biosafety protocol could prove disastrous for the agricultural biotechnology industry in the U.S.

The WTO is the enforcement authority for various trade agreements that implicate the E.U.'s policies on biotech crops, including the Agreement on Sanitary and Phytosanitary Measures. These measures must meet the test of a valid scientific risk assessment that uses generally accepted scientific measures for determining sufficiency of the scientific evidence used to justify any precaution in approving imports of food or animal feed.

The E.U. lost a key case filed in 1997 before the WTO, where the E.U. asserted a precautionary approach to the import of beef from U.S. cattle treated with certain growth-promoting hormones.[27] The E.U. asserted scientific uncertainty

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25. Jeffrey Sparshott, *Zoellick: Biotech Food Ban a WTO Case*, WASH. TIMES, Jan. 10, 2003, at C08.

26. The biosafety protocol's precautionary approach can also be interpreted as requiring the prompt approval of certain biotech crops. For example, this precautionary language can be interpreted as favoring the rapid approval of Bt corn, given its improved food safety profile in areas prone to mycotoxin production in corn. *See* Nill et al., *supra* note 16, at 559.

27. WTO Appellate Body, EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/R/USA and WT/DS48/R/CAN ¶¶ 9.1–9.2 (Aug. 18, 1997) (adopted Feb. 13, 1998) [hereinafter *Beef Hormone*]. In the U.S. beef hormone WTO case, the E.U. asserted that its reading of the precautionary principle was a "general customary rule of international law." The E.U. asserted the precautionary principle in stating that its precautionary measures toward beef from hormone-fed animals conformed to the requirements of the Sanitary and Phytosanitary Standard Agreement. *Id.*

about hazards, not scientific proof of hazards. This hypothetical harm was offered as a general exercise in precaution, notwithstanding the lack of a scientific risk assessment showing that such beef presented a discernable risk to human health.[28] In the *Beef Hormone* case, the WTO Appellate Panel overruled the E.U. ban on the imports of beef from cattle that were fed small amounts of growth-promoting hormones. The WTO Appellate Body upheld the panel's finding that the E.U. ban violated Articles 5.1, 5.2, and 3.3 of the Agreement on Sanitary and Phytosanitary Measures for the E.U.'s failure to follow a scientific risk assessment that conformed to Articles 5.1 and 5.2.

While the WTO requested that the E.U. conform to its Agreement on Sanitary and Phytosanitary Measures obligations, the E.U. has not done so to date. The *Beef Hormone* decision came down on January 16, 1998, just before the fourth negotiating session on the biosafety protocol. Since this decision came in the midst of negotiations for the biosafety protocol, the timing of this seminal trade decision may help to explain the E.U.'s decision to insist upon including a precautionary approach to biotechnology in the final text of the preamble to the biosafety protocol, which opened for signature in January 2000 and entered into force on September 11, 2003. Within days of the protocol opening for signature, the E.U. blindsided U.S. observers of the protocol process by issuing a long-delayed white paper on precaution that made clear to everyone what the E.U. had in mind when it insisted on including precautionary approach language in the protocol.

Under the new international regime emerging through protocol talks, there could be a requirement to label each corn- or soybean-containing commodity shipment from the U.S. with a list of the biotech crops that it "may contain," including Starlink™ corn or other non-food-approved crops that a commodities ship "may contain."[29] This new E.U. regime could quickly accumulate additional billion-dollar economic impacts to U.S. agricultural commodity exports. To address this risk, the U.S. grain export industries can prepare a matrix of biotech events and E.U. approval status and ensure that submissions are made for any varieties that are not subject to the strict identity preservation that the E.U. expects to see. Corn of U.S. origin is the right WTO subject, and it should ensure that it is ready for its big date at the WTO. This effort will also protect biotech companies from unnecessary litigation risks now that the plaintiffs' class action bar has been mobilized by money.

While the E.U. lost that WTO case, the E.U. continues to exclude U.S. beef imports. This is most apparent on the issue of food safety, which is the legal reason given for the E.U. to implement GM labeling. The *Beef Hormone* case held that international acceptance of the precautionary principle was unclear and that "outside the field of international environmental law, [the precautionary principle] still awaits authoritative formulation." *Id.* ¶ 123.

28. *Id.* ¶ 123.

29. Under Article 18 of the Cartagena Protocol on Biosafety, commodities shipments must declare (on their invoice) whether they "may contain" biotech crops. Convention on Biological Diversity, Cartagena Protocol on Biosafety, http://www.biodiv.org/biosafety/articles.asp?lg=08a=bsp-18 (Sept. 11, 2003).

B. The Probable Persistence of Precaution and Zero Tolerance

Given the E.U.'s proposal to continue with a cumbersome regulatory approach and given that the E.U. law may permit member states to flout its authority,[30] there is very little doubt that the U.S. will eventually have to engage the E.U. in the "Battle Royale of the 21st Century"[31] over bans on imports of U.S.-origin biotech crops.

Because the traditional science of risk assessment was not on their side, the E.U. and various zealous anti-biotech nongovernmental organizations have urged upon the world a simplistic vision of the precautionary approach to biotech crops, viewing risks in isolation and ignoring status quo risks. This approach, at its simplest level, would shift the burden of proof to require conclusive proof of safety as to each biotech crop variety and would simultaneously limit the introduction of evidence about the relative risk of not introducing the benefits or reduced risks of the new biotech variety.

There are clearly hazards involved in turning the scientific risk assessment paradigm on its head. While there are some good reasons for suspecting all new technology might be harmful (because asbestos, tobacco, mad cow disease, and other latent effects were not noted until harm became widespread), the precautionary approach has to be applied with care, or it will do more harm than good. In particular, it is hazardous to assume that harm will be caused by any biotech crop variety when there is conclusive scientific proof that widespread use will not cause harm and would reduce known hazards from existing historical agricultural methods. For example, existing organic corn growing methods may increase carcinogenic mycotoxin risk compared to biotech corn varieties. If a particular variety of Bt corn is used widely in the U.S. for years and shows no sign of any health risks or unmanageable environmental risks, then conclusive proof of no harm should suffice for approval. When the same crop is shown to correct an existing public health problem, like mycotoxin risks, then that crop should be more rapidly deployed (using the precautionary principle's mandate to act against catastrophic harm even when scientific validation is still pending).

Indeed, history may place certain applications of biotech crops, like the widely used biotech corn and soybeans that are the focus of this article, firmly in the realm of best available technology for controlling particular negative environmental

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30. *See* Tamara L. Joseph, *Preaching Heresy: Permitting Member States to Enforce Stricter Environmental Laws than the European Community*, 20 YALE J. INT'L L. 227, 234 (1995); TREATY ESTABLISHING THE EUROPEAN COMMUNITY, Nov. 10, 1997, O.J. (C340) art. 189 [hereinafter EC TREATY] ("A directive shall be binding, as to the result to be achieved, upon each member state to which it is addressed, but shall leave to the national authorities the choice of form and methods.").

31. *See* Reuters, *U.S. Opposed to Segregation of Genetically Modified Crops* (July 9, 1997), *at* http://users.westnet.gr/~cgian/glick.htm (last visited Nov. 9, 2003) (citing Dan Glickman, U.S. Secretary of Agriculture).

impacts,[32] or even product liability for food. Over time, the E.U.'s precautionary approach to biotech corn and soybeans will almost certainly be proven to be harmful to consumers and the environment. In time, this could turn the tide toward biotech crops.

Moreover, when the E.U. blithely suggests that all imports of commodity crops containing biotech innovations should be traceable to their source and segregated to allow consumer choice, this position ignores the reality of open global trading of commodity crops. To require segregation to zero tolerance is the functional equivalent of a ban on a biotech crop's commercial use because of the greatly increased costs of production that such segregation would impose.[33] As a result, E.U. policies force consumers in its trading partners to shun biotech corn, risking harm from mycotoxins.

For E.U. consumers who would prefer to avoid biotech crops in their food, this inability to segregate biotech crops completely after commercial launch clearly presents a problem. Unless they can ban biotech crops from commercial use in the U.S., they will be forced to pay more to eat "non-GMO" foods, which are increasingly being forced to take extra measures to remain free of biotech crops in the U.S., Brazil,[34] and other major grain exporters. Relatively wealthy E.U. consumers will no longer benefit from the huge economies of scale (and low operating and capital costs) that consumers currently enjoy through large-scale commingling of bulk commodities. The less wealthy E.U. consumers appear to have little voice in policy or are unaware of the games being played to increase the cost of basic food inputs. With the added reductions in production costs that the U.S. has seen with biotech crops, this commodity trading system is a powerful tool for feeding large numbers of people at low cost.

Commodity corn and soybeans are traded on a massive scale, with thousands of farms commingling their harvests and transporting them around the world on large vessels (including the massive "Panamax" vessels). The economies of scale that attend this massive commingling are not limited to the obvious capital costs spared by having a single large transport system (rather than multiple smaller vessels all carrying the same cargo). There are also important steps taken in

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32. *See generally* ROBERT WISNER, MARKET RISKS OF GENETICALLY MODIFIED WHEAT: THE POTENTIAL SHORT-TERM IMPACTS OF GMO SPRING WHEAT INTRODUCTION ON U.S. WHEAT EXPORT MARKETS AND PRICES 2 (2003), *available at* http://www.worc.org/pdfs/wisnerfinal.pdf (Oct. 30, 2003).

33. *See generally* GREGORY K. PRICE ET AL., U.S. DEP'T OF AGRIC., E.U. TRACEABILITY AND THE U.S. SOYBEAN SECTOR, abstract *available at* http://www.economia.uniroma2.it/conferenze/icabr/abstract/price.htm (last visited Nov. 9, 2003). The author cautions the reader to be wary of anyone who speculates that traceability of crops can be achieved cheaply.

34. The combined economic and environmental benefits of the herbicide-resistant Roundup Ready™ soybean (*see infra* note 39) have led Brazilian growers to steal them via black market channels to the point where black market GMO soy makes up 25% to 50% of the non-GMO harvest in certain regions of Brazil. *Report: Monsanto Begins Collecting Royalties on Soy in Brazil*, ST. LOUIS BUS. J., Nov. 5, 2003, ¶ 5, *available at* http://stlouis.bizjournals.com/stlouis/stories/2003/11/03/daily52.html; Reuters, Reese Ewing, Brazil Black Market in GM Soybeans Booming (Aug. 9, 2001), *available at* http://www.gene.ch/genet/2001/Aug/msg00036.html.

commingling wet and dry commodities to manage moisture levels. These moisture control measures help to prevent the formation of toxic fungi.

With E.U. public opinion increasingly shunning biotech crops, however, the E.U.'s longstanding precautionary import-approval moratorium and zero tolerance approach to biotech crops may be here to stay until a formal WTO case is brought. This opposition is being driven by well-intended activists backed by powerful "non-GMO" commercial interests and solid E.U. consumer demand.

To protect these commercial interests, the E.U. will seek legal high ground to support unfounded fears of biotech. Its interpretation of a precautionary approach to biotech crops is the legal high ground the E.U. plans to defend. It is questionable, however, whether the law of international trade as encoded in the General Agreement on Tariffs and Trade (GATT) can accommodate such commercial interests without a scientific basis for discriminating against biotech crops. To support its position under existing GATT law, the E.U. will have to have scientific evidence of potential harmful effects from biotech crops.

While the E.U. will resort to the precautionary approach toward biotech corn and soybeans provided by the U.S., the evidence is building in favor of biotech corn and soybeans. Both of these crops are proving their worth in terms of consumer safety (excluding Starlink™ corn) and environmental benefits, such as soil conservation and reduction in agricultural usage of nonrenewable resources.[35] As a result, the U.S. has a solid scientific case for proving, as to Bt corn at least, that these varieties of corn are healthier and better for the environment in most cases.[36] Evidence of harm, moreover, is clearly lacking under traditional scientific risk assessment (which admittedly cannot predict all future events).

Scientific risk assessment presumes safety until the risk of harm is documented and would accept clearly beneficial technologies rather than delay their use for fear of future unforeseeable and highly improbable adverse events. Because common-sense application of a precautionary approach to biotech crops must also look at risks of alternatives (including continuing the status quo), and existing alternatives pose greater risks to human health in the case of biotech corn and soybeans, scientific evidence does not support the E.U.'s so-called precautionary position on biotech soybeans.

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35. No-till conservation practices have increased substantially since herbicide-resistant biotech soybeans came on the market in 1996. Environmentally, beneficial conservation tillage practices promote soil and water quality, improve habitat for birds, and lead to cleaner water and reduced greenhouse gases and farm fuel use. RICHARD FAWCETT & DAN TOWERY, CONSERVATION TECH. INFO. CTR., CONSERVATION TILLAGE AND PLANT BIOTECHNOLOGY: HOW NEW TECHNOLOGIES CAN IMPROVE THE ENVIRONMENT BY REDUCING THE NEED TO PLOW 12 (2001), *available at* http://www.etic.purdue.edu/CTIC/BiotechPaper.pdf (last visited Nov. 9, 2003); *see also* Press Release, American Soybean Association, ASA Study Confirms Environmental Benefits of Biotech Soybeans (Nov. 12, 2001), *available at* http://www.soygrowers.com/newsroom/releases/2001%20releases/r111201.htm.

36. Drew Kershen, *Avoiding GMOS May Increase Legal Risks*, 55 FOOD TECH. 124, 124 (2001), *available at* http://www.ift.org/publications/docshop/ft_shop/10-01/10_01_pdfs/10-01-backpage.pdf (last visited Nov. 9, 2003); Council for Biotechnology Information, Bt Corn and Mycotoxins, *at* http://www.whybiotech.com/index.asp?id=1238 (Mar. 4, 2001).

Assuming that the WTO will not step in and alter the course of E.U. policy for many years to come, the SCUD effect will continue to impede the biotech crop variety product pipeline and lead to class action litigation in the U.S. (for the economic impact of products the E.U. will not approve but which impact U.S. exports). The *Beef Hormone* WTO victory[38] that the U.S. had in 1998 did not change E.U. policy; the ban on imports of U.S. beef continued. As a result, it is safe to assume that the WTO challenge will only be the first step toward reversing the SCUD effect.

As a result, commercial launches of new biotech soybean varieties in the U.S. have been barred or carefully contained inside tight closed-loop systems. The SCUD effect inhibits biotech innovation, squandering research and development dollars. New biotech rice, wheat, or soybean varieties have not been introduced on a broad scale since 1997, despite considerable potential benefits.[39] It is hard to measure the lost benefits of technological innovation that has never been permitted to flourish. This is a cost of the precautionary approach that makes one wonder—would we have had alternating current electricity and the contemporary information technology revolution if Thomas Edison's recommended precautionary approach to alternating current had been heeded?[40]

The second SCUD effect is more like the sort of explosive outcome of an economically devastating missile landing in the American heartland. In the case of corn, there was a strategic decision made by the corn industry leaders—from biotech corn seed companies to growers to grain companies—that the U.S. corn industry needed all the biotech innovation that the biotech industry had to offer. As a result, U.S. corn growers did not follow a zero tolerance system for segregating varieties that were not approved for export to the E.U. (in contrast to soybeans).[41] This led the E.U. to ban corn imports from the U.S. (while the E.U. allowed U.S. imports of soybeans containing the approved-for-import Roundup Ready™ soybean). At $200 million in annual lost export sales, beginning in 1998, this ban on U.S.-origin corn is approaching one billion dollars. This is the other, more

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38. WTO Appellate Body, EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R and WT/DS48/AB/R, ¶¶ 121–25 (Jan. 16, 1998).

39. The benefits of the first genetically improved biotech soybean in widespread use—the Roundup Ready Soybean produced by Monsanto—are widely recognized now. Soil conservation is among the undisputable ecological gains created by use of the herbicide-resistant soybean. Presumably the use of glyphosate is less environmentally problematic than some alternative herbicides, such as atrazine.

40. Thomas Edison conducted a "public safety" campaign against his competitor, Westinghouse, to persuade the public to reject Alternating Current (AC) in favor of his safer but weaker-powered Direct Current (DC) technology. His electrocution of animals, designed to provoke outrage against Westinghouse technology, led to the electric chair, not to wider use of safer DC current. *See, e.g., CellPals!, Death, Money: The Electric Chair, at* http://www.cellpals.com/deathrow.htm (last visited Nov. 9, 2003).

41. The corn system (known as "channeling") has sought to minimize the level of E.U. unapproved varieties. *See* National Corn Growers Association, Know Before You Grow: Approval Status of Biotech Corn Hybrids, *available at* http://www.ncga.com/biotechnology/know_where/know_grow_approved.htm (last modified Oct. 9, 2003).

readily measurable economic impact of the SCUD effect—massive trade losses in amounts worth taking to the WTO.

The SCUD effect in corn has also led to litigation in the U.S. that has allowed third-party growers whose crops were contaminated by an unapproved-in-E.U. crop (Starlink™ corn) to recover from the biotech company and the company that sold that crop.[42] As a result, the SCUD effect can lead to class action lawsuits alleging massive nuisances caused by crops that are not approved for export to the E.U. if those crops are found to have unreasonably caused economic loss that is recoverable under a particular state's law.

It is clear, therefore, that the SCUD effect could lead to loss of both biotech benefits and massive trade losses. In particular jurisdictions, the loss of those benefits will be detectable in varying standards of living and a decline in human health, from mycotoxins, malnutrition, and other negative impacts of the E.U.'s precautionary approach to biotech crops. The examples that follow briefly illustrate the impacts that the E.U.'s zero tolerance toward new biotech crops has caused.

1. *The Sad Saga of Starlink™ Corn Stewardship*

Before the Starlink™ corn litigation entered the courtroom, no American court had ever held, in recorded case law, that pollen drift to neighboring fields causing economic loss could give rise to nuisance liability. It was also unclear whether farmers could use state consumer fraud statutes for the failure to disclose the economic risks of commingling Starlink™ corn or other biotech crops that cannot commingle with food nor be exported to major overseas markets. With the decision in *In re Starlink* issuing from the U.S. District Court in the Northern District of Illinois, however, the duties of biotech companies have become much clearer. Cataclysmic economic liability may arise for a biotech company without documented harm to human health or the environment. The economic loss suffered by neighboring growers from precautionary regulatory positions taken toward biotech crops could be recoverable losses under nuisance and product liability law. These risks are large enough to drive some biotech companies out of business if stewardship measures fail. As a result, increased levels of industry stewardship will be required to prevent further litigation over agricultural commodity export losses. With leadership of key trade associations, the biotech industry can adopt uniform industry standards for identity preservation that are enforceable against rogue biotech companies that recklessly threaten the entire biotech industry's ability to operate.

Starlink™'s legal legacy is not limited to common law nuisance or product liability. Regulatory policy in the U.S. may continue to evolve in response to *Starlink* as new rules address tolerances for non-GMO food and planting distances for commodity crops used to produce biopharming compounds. The EPA and FDA are in the business of protecting consumers from real and potential threats, even where science is not yet ready to reach a firm conclusion.

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42. *In re* Starlink Corn Prods. Liab. Litig., 212 F. Supp. 828 (N.D. Ill. 2002).

"Starlink™ Logistics, Inc." is the entity created for the purpose of managing the massive liabilities that the Starlink™ recall will create.[43] Neighboring farmers recently agreed to accept $110 million for alleged economic loss, including alleged impacts on corn exports, using nuisance, product liability, and consumer fraud theories. *In Re Starlink* will not be appealed because of a pending settlement by Aventis' successor-in-interest, Starlink™ Logistics, Inc. As a result, this seminal U.S. decision stands as a precedent that can be cited by other courts facing the economic costs of sale of an unapproved variety. This massive settlement reflects, in large part, the loss of export markets in corn (including part of the one billion-dollar trade loss in E.U. exports since 1997).

Starlink™'s biggest legal legacy may not be the estimated billion-dollar cost of recalling the corn. After the Starlink™ corn commingled with other corn bound for food use, the EPA's scientific advisory panel imposed a zero tolerance standard for the commingling of Starlink™ during the recall. As a result, zero tolerance export bans may proliferate worldwide. The economic impact of Starlink™ may broaden to tens of billions of dollars in lost exports, given the regulatory legacy of zero tolerance for commingling that Starlink™ may leave in its wake.

This legal debacle was both predicted and preventable. Nuisance law has often found that "severe pecuniary loss" may give rise to a nuisance claim.[44] As Professor Prosser explained in his treatise on Torts, the common law doctrine of nuisance is famed for its flexibility, potentially covering everything under the sun, from a cockroach baked in a pie to pollen wafting across fields.[45] The flexible nature of nuisance was also cited by Professor Barry Furrow in a seminal 1983 journal article, where he suggested that nuisance law could provide a regulatory function for new risks of biotechnology that eluded regulatory attention.[46] The Starlink™ case proved his theories correct.

In the Starlink™ litigation, the U.S. District Court for the Northern District of Illinois (under Multi-District Litigation procedures) held that farmer plaintiffs had stated a claim for nuisance that could include economic losses. For purposes of nuisance law, the drifting of Starlink™ pollen need not cause human injury; economic loss suffices. These farmer actions also included a claim for injunctive relief, seeking an order "requiring abatement of the nuisance created by Aventis by requiring Aventis to decontaminate all soil, farming equipment, storage equipment, harvest equipment, transportation facilities, grain elevators, and non-Starlink™

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43. *See* Starlink™ Logistics, Inc., Non-Starlink™ Farmers Settlement Notice, *at* http://www.starlinkcorn.com/starlinkcorn.htm (last modified Feb. 12, 2003).

44. *See, e.g.* Nebraska Innkeepers, Inc. v. Pittsburgh-Des Moines Corp., 345 N.W.2d 124, 129–30 (Iowa 1984).

45. Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403, 1439 (1983) (citing to W. PROSSER, LAW OF TORTS 591–93 (4th ed. 1971)). For more recent discussions of nuisance law and biotech crops, see 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 (2000); Richard A. Repp, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 585 (2000).

46. *See* Furrow, *supra* note 45.

seed supplies to prevent future contamination for the 2001 growing season and beyond."[47]

While the Starlink™ case settled recently for $110 million, these Starlink™-related nuisance claims might not have made it to trial without other challenges under various state statutes and precedents. The right-to-farm statutes in existence in all 50 states are often narrowly construed as covering only existing farm uses that cause odor or annoyances.[48] Thus, negligent farming (for example, growing an unapproved crop variety too close to a neighbor's similar crops) could lead to nuisance liability despite the existence of these laws. The 660-foot separation distance for Starlink™—a buffer zone established by EPA to prevent pollen drift—was intended to set a standard for reasonable behavior. Failure to maintain that buffer zone could establish negligence, even if the negligence was exacerbated by a particularly ambitious group of pollinating bees.

That 660-foot field separation distance was a requirement imposed by the Starlink™ Corn Growers Agreement. Aventis and its licensees did not get signatures on that Growers Agreement document from all buyers of Starlink™ corn seed. It should thus come as no surprise that not all growers followed the stewardship program. A "signature audit" of grower agreements (confirming that growers, not seed salesmen, signed each grower agreement) is a good first step in ensuring the integrity of a stewardship program seeking identity preservation in the zero tolerance range. Third-party audits to determine whether growers are aware of, and are following, the stewardship manual are also advisable. The ASA's steps for segregating crops are appended to this article and are briefly discussed below.

In re: Starlink is just one trial court decision, which other courts may not find persuasive. For future biotech company class action defendants, for example, there may be a viable defense under the "economic loss" doctrine, which many courts use to limit damages for economic loss arising in a chain of contractual commerce. The rulings in economic loss cases will depend upon the facts. For example, farmers could be more like land-based businessmen hurt by the decline in tourism following an ocean oil spill (no nuisance recovery) or, as occurred in *Starlink*, more like fishermen whose livelihood was hurt by the same oil spill (allowed to pursue nuisance claim).[49] Similarly, if a third-party grower might have a claim for harm, would the indirect economic loss of downstream buyers of an unapproved

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47. Plaintiffs' Complaint at 61, Furlong v. Aventis CropScience USA Holding, Inc., No. 01-CV-17 (N.D. Iowa 2001); Notice of Pendancy of Class Action, Settlement Class Certification, Proposed Settlement and Fairness Hearing, *In re* Starlink™ Cord Prods. Liab. Litig., 212 F. Supp. 2d 828 (N.D. Ill. 2002) (discussing the claims in the settlement summary). This injunctive relief precedent contains the seed of future containment of unapproved-in-E.U. varieties of seeds.

48. *See* Anita Zurbrugg, American Farmland Trust, Right-to-Farm Laws: Has Illinois' Right-to-Farm Law Been Compromised by Recent Court Decisions?, *at* http://www.farmlandinfo.org/fic/laws/state/summs/ilrtflaw.html (last visited Dec. 2, 2003).

49. *See* Pruitt v. Allied Chemical Corp., 523 F. Supp. 975, 980 (E.D. Va. 1981) (holding that area restaurateurs and marina owners suffering economic harm could not sue a polluter under a nuisance theory, while local fishermen could); Burgess v. M/V Tamano, 370 F. Supp. 247 (D.C. Me. 1973).

variety be recoverable? These questions remain open and subject to vigorous debate.

These questions may be resolved in the context of unapproved-in-E.U. varieties that are fully approved in the U.S. for both food and feed. Litigation is pending in the Eastern District of Missouri alleging economic losses from biotech corn varieties that were not approved for export to the E.U. and were sold without full disclosure of this material fact.[50] The issues involved in the litigation of liability for commingling of biotech crops are sufficiently complex that commentators can vary considerably in their opinions relating to biotech crop liability, particularly on the issue of liability for crops whose economic loss is created by the growers' choice of markets (export, organic, non-GMO, etc.).[51]

2. *The Story Behind Starlink™: Liberty Link™ Soybeans*

As will be described below, there is a long history of careful industry stewardship for biotech soybeans that could have been readily adapted to Starklink™ corn.[52] The Starlink™ litigation is most notable for the largely untold story of how it could have been prevented if Aventis had followed (for Starlink™) a stewardship plan as tight as the one the American Soybean Association developed for the Liberty Link™ soybean.

The story behind Starlink™ corn began in late 1997, when the ASA realized that the E.U. had no present intention of approving new varieties of genetically enhanced (GE) crops for import. Corn containing biotech varieties not yet approved in E.U. were being channeled away from export shipments in the hope of preserving the flow of corn export to the E.U. Subsequent events revealed that "channeling" of corn was insufficient to keep unapproved-in-E.U. varieties contained.

To prevent commingling of unapproved-in-E.U. varieties of GM soybeans, in late 1997 ASA called upon the relevant eleven biotech seed companies to refrain from marketing any new variety of GM soybean that lacked approval in major overseas markets, in particular the lucrative E.U. market. Certain biotech companies pled E.U. intransigence in delaying approval; others finally admitted that they had not filed the necessary paperwork for E.U. approval.

Aventis disregarded this ASA request at first, proceeding with plans to market the Liberty Link™ Soybean, which was approved for sale in the U.S. but was not

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50. Robert Schubert, *Monsanto Still Suing Nelsons, Other Growers*, CROP CHOICE NEWS, May 21, 2001, *at* http://www.cropchoice.com/leadstry.asp?recid=326 (last visited Nov. 4, 2003).

51. Drew Kershen, Legal Liability Issues in Agricultural Biotechnology, 10 ENVTL. LIABILITY 203 (2002), *available at* http://www.nationalaglawcenter.org/publications/articles/kershen.pdf (last visited Nov. 4, 2003).

52. ASA negotiated a "stop sale" of Liberty Link™ soybeans with Aventis (then known as AgrEvo) in 1998 when Aventis was also marketing Starlink™ corn, but the information about careful stewardship to avoid commingling was not transmitted within Aventis to the Starlink™ program coordinators. With better intracompany communication about stewardship, Aventis could have minimized or even prevented the commingling of Starlink™ corn.

approved for export to the E.U. after harvest (and could cause, if commingled with export soybeans, the loss of up to $3 billion in annual soybean exports).

To save soybean exports from cataclysmic commingling, ASA entered into several months of negotiations to educate the corporate predecessor of Aventis, AgrEvo U.S.A., about the potential risk of pollen transfer or movement of seeds between fields (a potential private nuisance) and post-harvest commingling in the soybean export flows (a potential public nuisance). ASA asked Aventis to follow a detailed identity preservation system. Aventis disputed costly requirements at first, including the contested items of (1) a high premium for growers (to do extra work required), (2) dedicated domestic facilities to divert the GM soybeans away from export channels, and (3) most contentious of all, an assumption of financial liability for any nuisances or other liability that growers and Aventis might jointly cause. A copy of ASA's policy statement and "11-point plan" for avoiding unapproved soybean commingling is appended.

While Aventis filed the necessary paperwork to begin the approval process in some countries during 1998, Starlink's™ self-pollinating sister crop, the Liberty Link™ soybean, was not commercially launched in early 1999. This was because of the efforts of the American Soybean Association to control liability risks for U.S. soybean industry and Aventis (that is, its corporate predecessor, AgrEvo). At the urging of the ASA, Aventis ultimately again made a commendable, cautious decision in 1999 to avoid marketing the Liberty Link™ soybean, ensuring that billions of dollars in soybean trade could continue to flow into the E.U. The business press reported that Aventis had invested millions of dollars in developing the Liberty Link™ soybean, which it now had to delay for several years in deploying.[53] Going forward, Aventis' Soybean Stewardship plan could be a useful tool for prevention of future commingling incidents on the scale of *Starlink*. The ASA considers this plan to be a standard of care that can be followed by other companies.

ASA stopped another potential nuisance class action in 1999 when it persuaded Dupont to undertake careful identity preservation for its new "high-oleic" soybean. In 1999, Dupont followed ASA's lead on its biotech high-oleic soybean variety, satisfying E.U. demands for total segregation (zero tolerance). After Pioneer was acquired by Dupont (a company that has endured mass tort litigation on the chemical side), the Dupont attorneys and marketing personnel involved in the launch of the unapproved-in-E.U. high-oleic biotech soybean variety acted responsibly when the ASA asked them to similarly follow a strict closed-loop stewardship program.

As a result, despite scrutiny from the E.U., U.S. commodity soybean exports continued to flow after the limited commercial launch of the high-oleic soybean. With mad cow disease mandating alternative feed to formerly used meat and bone

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53. Gregg Hillyer, *Sign on the Dotted Line: Grower Agreements Are Becoming a Part of Doing Business If You Want to Use Biotech Seed*, PROGRESSIVE FARMER TODAY, http://www.ukabc.org/roundup1.html (last visited Dec. 2, 2003).

meal for livestock, the U.S. soy exports to the E.U. were needed (including genetically improved varieties approved in the E.U.), so U.S. soybean exports increased despite E.U. consumer movement toward non-GMO soy inputs in food. Dupont took the ASA information about identity preservation and made a stewardship program that worked. In the process, Dupont learned about establishing similar programs for "output" traits that could not be commingled with food (and require strict purity, necessitating control of any inflow of pollen). These output traits could be the highly profitable future products of agricultural biotechnology.

If companies and growers fail in their joint stewardship efforts, growers involved in the program may end up as defendants in a nuisance lawsuit. This could lead to a claim for comparative fault against the seed company.[54] Substantial economic harm might also merit an exception to right-to-farm protection, as courts might declare that the statute otherwise would effect an unconstitutional "taking" of the neighbor's property.[55]

The soy marketplace in biotech crops has matured to the point where it can provide an easily implemented model for export market protection and liability prevention. Because soybeans are the largest commodity export from the U.S., with the widest use of biotech varieties (that is, 75% of planted acres in 2002), they have received the most careful strategic planning to prevent billion-dollar liabilities from arising. The soybean stewardship model has been tested and reduced to practice in the U.S. It does not require extensive legislative or regulatory changes but can be adopted voluntarily, using contracts. The ASA engages in a process of education, exhortation, negotiation, and threat of injunctive relief against biotech seed providers whose marketing practices threaten soy export markets. This approach has achieved necessary liability prevention for biotech companies who were apparently unaware of the economic threat those marketing practices posed to themselves and their grower customers.

In the coming age of the Cartagena Protocol on Biosafety,[56] the stewardship measures developed for U.S. soybean production could help keep other crops flowing to export markets.

D. The Biotech Industry's Track Record, Pre Starlink™

Since Aventis knew precisely how to avoid liability in its proposed Liberty Link™ soybean launch, yet simultaneously launched the biggest liability in the history of agricultural biotechnology to date, it is a poster child (in memoriam) for collective industry action in setting identity preservation standards that manage

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54. *See In re* Starlink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828 (N.D. Ill. 2002); Selma Pressure Treating Co. v. Osmose Wood Preserving Co., 221 Cal. App. 3d 1601 (1990) (chemical supplier's negligent failure to warn facility operator of improper chemical disposal practices could be a substantial factor in the creation of a nuisance and require supplier to indemnify operator).

55. Bormann v. Bd. of Supervisors, 584 N.W.2d 309 (Iowa 1998).

56. *See* Convention on Biological Diversity, *at* http://www.biodiv.org/biosafety (last visited Nov. 22, 2003).

liability risks effectively, with feedback loops from growers, other biotech companies, and the increasingly wary grain industry.

Confidence-building measures in agricultural biotechnology should begin with the dissemination of information about the high level of due care that has historically been exercised in the absence of precautionary regulatory oversight and the ease of applying such care on an industrywide basis. In the following cases, companies using genetic engineering took steps to refrain from marketing biotech products or, in the case of l-tryptophan, recalled products several months before the U.S. Food and Drug Administration actually ordered a recall. This long history of voluntary risk management measures should provide ample data to support continuing industry stewardship, eventually increasing confidence of regulatory agencies and consumers in biotech crops.

1. *The L-Tryptophan Recall and Ensuing Mass Tort Litigation —1989 to Present*

The zero tolerance advocates in the public debate over biotech food safety continually return to the l-tryptophan recall that occurred in 1990, invoking death and disability from genetic engineering. The truth about l-tryptophan is worth revisiting as a study in industry responsibility for presumably "untraceable" liability problems.

L-tryptophan was a food supplement produced by a Japanese chemical company (Showa Denko KK) and sold by various U.S. natural food companies throughout the 1980s. The production process after 1987 featured a process change using a genetically engineered bacterium that was enhanced to increase the production of l-tryptophan. Sometime after beginning the use of this new bacterium, a decision was made to reduce the filtration used in the subsequent production process. This may have allowed impurities to slip through the quality control process.

A hypothetical link to adverse human health effects was suggested by a physician in New Mexico, who suggested in the autumn of 1989 that l-tryptophan was causing a constellation of immune-related symptoms (eventually to be called "eosinophilia myalgia syndrome" or "EMS"). The federal Centers for Disease Control investigated and came to a preliminary conclusion that a few lots of Showa Denko KK's l-tryptophan were causing the illness, which triggered an immediate voluntary recall by the manufacturer.[57]

Showa Denko KK funded extensive medical research to try to determine what caused the illness attributed to its products. It provided humanitarian assistance to persons alleging illness, without requiring a jury finding of fault. It settled thousands of cases, paying several billion dollars in settlements and defense costs.[58]

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57. Several months later in early 1990, the FDA ordered a recall that merely confirmed the voluntary risk management measure already taken by the manufacturer.

58. *See, e.g.*, NATHAN BATALION, 50 HARMFUL EFFECTS OF GENETICALLY MODIFIED FOODS (2000) (citing Arthur N. Mayeno & Gerald J. Gleich, *Eosinophilia-myalgia Syndrome and*

After nearly ten years of well-funded research, there is still insufficient scientific evidence to link the fermentation process, which used a bioengineered bacterium, to the disease EMS. Various confounding factors (raw material impurities, filtration methods, etc.) make detective work difficult.[59] Authoritative reviews by various stakeholders, including the experts for plaintiffs at the Mayo Clinic, have produced many varying hypotheses of how harm occurred. It appears likely, however, that with better filtration, there would have been fewer impurities to trigger the still hypothetical link to harm.

The lessons from this episode that are pertinent to risk management for biotech crops are as follows:

(1) the biotech industry should institute its own system for initiating voluntary recalls, as Showa Denko did, before significant harm (even merely hypothetical harm) can occur.

(2) periodic auditing of Starlink™ stewardship, as it unfolded in its careless manner, would have cut the losses suffered by Aventis and the entire U.S. chain of commerce in corn products.

(3) the companies involved in agricultural biotechnology need to understand the risks of becoming involved in mass tort litigation over purely hypothetical health risks and the potentially cataclysmic costs associated with a widespread recall.[60]

(4) agricultural biotechnology needs to recognize that it will be asked for defense and indemnity from the entire chain of commerce, should there be a recall and associated class actions filed for personal injury. Agricultural biotechnology companies accused of negligence in stewardship will want to control the litigation and avoid being adverse to their customers (for example, growers, elevators, food processors, food companies, etc.), as the manufacturer of l-tryptophan chose to be. This joint defense approach is common in mass tort cases.

In sum, the l-tryptophan saga is merely one mass tort in a long-lived industry that creates mass tort liability from hypothetical harm. Starlink™, l-tryptophan's successor in billion-dollar liabilities, shows that there may be very costly "smoke" long before anyone actually finds a "fire" (that is, a personal injury genuinely attributable to biotechnology). As a result, an extra ounce or two of prevention in agricultural biotechnology (that is, a few hundred thousand dollars of liability

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Tryptophan Production: A Cautionary Tale, 12 TRENDS BIOTECH. 346 (1994)), *available at* http://creativehealth.netfirms.com/50harm1.shtml (last visited Nov. 26, 2003).

59. *See* Gerald J. Gleich, M.D., *Current Status of Research on the Eosinophilia-Myalgia Syndrome*, GENETICALLY MODIFIED FOOD NEWS, Apr.1, 2000, *at* http://home.intekom/tm_info/rw00401.htm (last visited Nov. 4, 2003) ("[T]he EMS epidemic was a tragic experiment in which we learned that certain contaminants in Showa Denko L-tryptophan cause disease. But which contaminants and how did they cause disease? . . . The failure of both the bioassay and the animal feeding experiments to yield robust and reproducible results has been a major disappointment.").

60. While there is a continuing debate over the cause of EMS in particular cases (which means, of course, that there is a possibility that the company could be exonerated by an alternative cause in many cases), the manufacturer has nevertheless incurred billions of dollars worth of combined costs of settlements, product recall, expert witnesses, and attorneys fees. Like Starlink™, there is no scientific evidence of harm; yet billions of dollars will change hands in the absence of firm scientific evidence, given the recall and ensuring litigation (however groundless it may be, in terms of "sound science").

prevention) will be worth more than several pounds of cure, if a single billion-dollar loss can be prevented.

2. *Pioneer's Decision Not to Market an Allergenic Soybean*

The agricultural biotechnology industry has already applied vast resources to find any theoretical threat from biotech crops. As further evidence of the appropriate standard of care for biotech companies marketing potential allergens, and proof that industry stewardship can work, the story of Pioneer's Brazil nut allergen merits retelling.

In 1993, world-class, third-party scientists doing research funded by Pioneer Hi Bred International, Inc. identified a possible Brazil nut allergen in the high-methionine biotech soybean then being developed by Pioneer.[61] Not long after these preliminary findings of allergenicity were first discovered, Pioneer stopped all field testing and destroyed all seeds and plants outside the laboratory.[62] The allergen thus never had a remote chance of entering the human food supply.[63]

Pioneer could have marketed its soybean with adequate risk management measures in place. With sound stewardship, this chicken feed could be segregated from food. Pioneer chose to exercise a form of precaution common to corporations faced with liability risks (these liability risks often dwarf regulatory recall risks and are factored in accordingly). As precautionary corporate decisions like Pioneer's accumulate, moreover, they establish a standard of care that could be used to hold other, less cautious companies liable for any harm they cause.

As a result, if *Starlink* had gone to trial, the decision by Pioneer might have been used to establish the common law standard of care that Aventis should have followed when it decided to market Starlink™ corn. Aventis could also have used the American Soybean Association's suggested standards for identity preservation for prevention of commingling (the Liberty Link™ Stewardship Plan) or other similar standard of care (for example, the American Seed Trade Association's guidance on planting distances to avoid cross-pollination).

In the aftermath of Starlink™ corn, the Pioneer standard of care is but one example of a high level of industry stewardship, which if applied and enforced throughout the biotech industry would benefit the entire industry (by protecting key players from enterprise-threatening liabilities and the industry from the bad law that is made from bad facts).

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61. The findings of these independent scientists were published in *The New England Journal of Medicine* in 1996. *See* Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688–92 (1996), *available at* http://www.mindfully.org/Farm/Green-Revolution-Allergen.htm (Mar. 14, 1996).

62. Pioneer, *Biotechnology—Biotech Soybeans and Brazil Nut Protein, at* http://www.pioneer.com/biotech/brazil_nut/default.htm (last modified July 23, 2003).

63. *Id.*

E. Stopping Unapproved-in-E.U. Analogs to Starlink™

This long history of industry stewardship illustrates the ability of the biotech seed industry to implement sound stewardship, with a well-informed, risk-averse corporate culture like that of Pioneer. Fortunately, Monsanto and the other major players in biotech industry have state-of-the-art stewardship tools at their disposal. In particular, Monsanto's stewardship processes are relatively transparent and open to improvement with feedback from grain customers.

A collective industry approach to managing the risks of unapproved-in-E.U. crops is clearly required. There are ample precedents for collective restraint in causing economical troublesome impacts that threaten the continued viability of a strategically important U.S. industry. When the biotech industry realized that the Bt problems used to modify corn, cotton, and other crops could induce resistance in insects, their trade associations (the Biotechnology Industry Organization and the American Crop Protection Association, both based in Washington, D.C.) set up committees to develop innovative industry standards to prevent this environmental impact from occurring.[64] The EPA worked closely with these committees to develop voluntary, contractual approaches to managing insect resistance. The same coordinated approach can be undertaken to prevent continuing class action litigation over unapproved-in-E.U. varieties that threaten export markets if they are commingled with other crops.

While the legal precedent in *Starlink* arose from its unique facts, there are precedents that may be applied in the context of an unapproved-in-E.U. variety of corn that causes significant economic loss. For example, the commingling of Monsanto's unapproved-in-E.U. rootworm corn, which recently secured E.P.A. approval for marketing in the U.S., could lead to a continuing loss of E.U. exports of whole corn. Some grain industry experts are also concerned that sales of corn gluten could be affected by the sales of varieties of corn that the E.U. has not reviewed and approved for import. Pioneer and Dow Heculex are selling a variety of corn, which poses similar economic risks if it is commingled with exports to the E.U. This in turn creates a significant liability risk should export markets cause a readily documented drop in corn prices.

The biotech industry's stewardship for export markets is illustrated best by the decision of Dow AgroSciences to hold Herculex™ corn pending regulatory approval in Japan. Japan delayed approving Herculex™ in 2002, getting around to animal feed approval only in May 2002 and human food use in June 2002. The U.S. is Japan's dominant corn supplier (over 90%), and the U.S. grain industry is united on the common objective of keeping corn exports flowing.[65] Dow is taking

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64. *See, e.g., Resistance Management for Plant Pesticides Already Conducted Voluntarily, Industry Says*, 20 CHEM. REG. REP. 1665 (1997).

65. *See* Takada, *supra* note 8.

careful steps to "channel" this corn, with instruction from The National Corn Growers Association.[66]

As noted above, Aventis and Dupont made wise decisions when they were confronted with the economic risks of marketing an unapproved-in-E.U. biotech soybean. Dow and Monsanto have both observed care in avoiding marketing of varieties of unapproved-in-Japan corn that could commingle and cause loss of corn exports to Japan. The feedback system in soybeans depended upon the active efforts of a grower association that found its export markets worth protecting, at the cost of losing a "me too" product like the Liberty Link™ soybean (which provides growers with a benefit—a herbicide-resistant soybean variety—that is similar to products already on the market).

When stewardship information or a precautionary corporate culture is lacking, however, grain companies and growers should be given enhanced power to restrain a negligent biotech seed marketing program, using injunctive relief that is empowered by contractual clauses inserted into a standard form biotech crop contract. If growers and biotech companies agree upon a particular form contract, one that allows a third-party certifier, other biotech companies, grain companies, or other growers to enjoin an unfairly competing grower who is cutting corners on stewardship, this powerful tool can be used by alert growers and biotech companies to enforce stewardship requirements long before problems reach the scale of another Starlink™ corn.

Action need not await the creation of a contractual right to injunctive relief. The threat of injunctive relief against biotech companies with inadequate stewardship was used to restrain the sale of Liberty Link™ soybeans. The legal basis for the ASA's threat of injunctive relief prior to sale was the ancient and rarely invoked doctrine of "anticipatory nuisance,"[67] along with ASA's more credible warning of a massive compensatory damages lawsuit (the latter threat was validated by the $110 million settlement of the Starlink™ corn class action). As a result, even if the injunctive relief is denied, it sends up a signal flare to the plaintiffs' bar to be on the watch for future compensatory damages. As a result, well-managed biotech companies are generally very attentive when their customers (for example, soybean growers) alert the company to a potential billion-dollar liability threat that could be created by the biotech company's marketing practices.

As is noted above at Part II.C.2, this system for identity preservation could have been used by Aventis to mitigate the compensable economic impacts from

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66. Telephone communication from Richard Tolman, CEO of National Corn Growers Association, April 22, 2003.

67. *See, e.g.*, Missouri v. Illinois, 180 U.S. 208 (1901) (federal common law allows an injunction for an anticipatory nuisance); Charles J. Doane, Comment, *Beyond Fear: Articulating a Modern Doctrine in Anticipatory Nuisance for Enjoining Improbable Threats of Catastrophic Harm*, 17 B.C. ENVTL. AFF. L. REV. 441 (1990) (cases summarized through 1990: state case law may impose a higher standard of proof for anticipatory nuisance injunction); Rutter v. Carroll's Foods of the Midwest, Inc., 50 F. Supp. 2d 876 (N.D. Iowa 1999) (motion to dismiss claim for anticipatory nuisance denied, but other viable bases for injunctive relief were allowed against pork feeding-finishing operation).

commingling of Starlink™ corn. There are many claims now being made to seek compensation for the losses caused by Starlink™. These losses were quite predictable with Starlink™, given the parallel history of the Liberty Link™ negotiations, which warned Aventis of a potential "billion-dollar cataclysm" in soybean exports if the Aventis stewardship program were to fail. This unfortunate Starlink™ episode has left behind a regulatory precedent for imposing a virtual zero tolerance in the recall context and a legal precedent allowing growers nationwide to recover the economic loss from depressed grain prices. These twin precedents arguably provide any party in the chain of commodity commerce with ample authority for demanding proof from biotech companies of sound steward-ship, with a credible threat of injunctive relief looming over the stewardship program should it show signs of failure.

Given the magnitude of the economic harm caused by an unapproved-in-overseas-markets variety, like Starlink™ corn or Liberty Link™ soybean, the attorney general in a farming state could seek to apply public nuisance law via persuading a sympathetic state or federal court judge to declare the sale of an unapproved-in-E.U. biotech seed to be a public nuisance. Given the added element of inadequate disclosure to farmers that may be present, the consumer fraud statutes of many states might also be invoked. Where no adequate consumer fraud statute is on the books, the law of nuisance can adapt to stop a fraud in progress (if it occurs against a large enough group) on grounds that it constitutes a foreseeable public nuisance.

The ASA has overseen development of closed-loop identity preservation methodologies that can be adapted to unapproved-overseas crops other than soybeans. The main features include: (1) securing timely regulatory applications for approval in major markets such as Japan, the E.U., and other large trading partners for particular biotech crops, (2) developing time-tested controls to ensure closed-loop identity preservation for biotech crops lacking overseas approval, (3) documented chains of delivery to processing and consumption points inside America, and (4) compliance with stewardship plans developed by seed companies and growers, who can work together to develop standards for particular grains (like the 11-point plan that the ASA has developed for soybeans, a copy of which is appended hereto).

There would appear to be an imminent need for development of biotech industry standards for identity preservation of: (1) varieties of GM crops that lack overseas approvals and (2) the steady stream of new varieties of industrial (that is, chemical-containing) and plant-made pharmaceutical crop production systems that are entering test trials and, in some cases, commercial production. Commercial production of plant-made pharmaceuticals appear to present a risk of repeating the food-commingling debacle that led to the Starlink™ recall, if they are not carefully managed, as shown by two "near miss" incidents that were caught in time by U.S.

regulators during 2002.[68] These incidents have triggered criticism of biotech industry stewardship at the highest level of respected scientific oversight[69] and drove the industry to propose enhanced stewardship measures, particularly for industrial or pharmaceutical containing plants.[70]

With the factual precedent of irreparable harm from Starlink™ corn, any biotech company stewardship program that lacks adequate controls will provide facts in support of an injunction prior to sale. While Starlink™ corn was clearly sold without a full disclosure to all growers of the risks of commingling, creating a consumer fraud that could be actionable under statutes protecting consumers, there is no reason to allow a repeat of this behavior by any biotech company.

While the main focus of this article is voluntary stewardship, which is purely a matter of contract law (and the prevention of tort liability), there are innovative options available to jurisdictions that create "grower district" implementing statutes. There are models currently in use in California, Idaho, and Washington. California has segregated varieties of cotton for decades using statutory mechanisms,[71] and it recently addressed the threat posed by unapproved biotech Liberty Link™ rice (produced by Aventis Crop Sciences before its post-Starlink™ corporate demise) by enacting AB 2622, a bill promoted by the California Rice Commission and grower groups. This statute benefits rice producers and handlers in California by controlling biotech rice introductions (which pose economic risks), imported exotic pests, weeds and specific diseases like rice blast and bakanae. The

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68. *See* Reuters, K.T. Arasu, U.S. Firm Clueless Over Starlink Slip Despite Tests (Jan. 2, 2003), *available at* http://131.104.232.9/agnet/2003/1-2003/agnet_january_3.htm#US%20FIRM%20CLUELESS. *See* Press Release, USDA, USDA Announces Actions Regarding Plant Protection Act Violations Involving Prodigene, Inc. (Dec. 6, 2002) (Prodigene ordered to pay civil penalty of $250,000 and reimburse USDA for costs (over $3 million) to destroy over 500,000 bushels of soybeans that had biopharmaceutical corn potentially commingled (truly thorough genetic testing was impracticable given low grain prices) through Prodigene's failure to comply with regulations mandating destruction of "volunteer" corn plants), *at* http://www.usda.gov/news/releases/2002/12/0498.htm.

69. The National Academy of Science's National Research Council issued a multi-stakeholder report that expressed concerns over the level of post-market surveillance that occurs after biotech crops have entered the marketplace. COMM. ON ENVTL. IMPACTS ASSOCIATED WITH COMMERCIALIZATION OF TRANSGENIC PLANTS & BD. ON AGRIC. & NATURAL RES., NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 192 (2002) (stating that precommercialization quality testing and postcommercialization monitoring should be increased industrywide), *available at* http://www.nap.edu/books/0309082633/html.

70. Press Release, Grassley Continues Efforts to Support Biotech Crop Production in Iowa: Senator Works with USDA, Iowa State to Ensure Fair Treatment for Iowa Producers (Nov. 4, 2002) (stating "[BIO] is responding to the demands of special interest, not the demands of science. I'll continue to work to ensure that Iowa is not unjustly left out of corn-based pharmaceutical crop production"), *available at* http://www.grassley.senate.gov/releases/2002/p02r11-04.htm.

71. *See, e.g.*, CAL. FOOD & AGRIC. CODE §§ 52851, 52901 et seq. (Deerings 1997). Activities involving "nonapproved varieties" must comply with regulations to protect and "maintain the integrity of approved Alcala or Pima cotton and to prevent contamination of those types of cotton." *Id.* § 52901.

statutory scheme[72] also allows the industry to control the mixing of different rice varieties. While the statute does not mention biotechnology, making it a "Trojan horse" for biotech lobbyists and persons who search databases, its intent was clearly directed, in large part, at managing the economic impacts of biotech crops.

Idaho state law[73] and Washington state law[74] create grower districts to manage segregation of rapeseed production, with both the edible canola[75] and industrial rapeseed[76] forms of the *brassica plant*. These crops are grown pursuant to strict identity preservation or isolation requirements. In Idaho, the state Department of Agriculture can impose a $1,000 penalty per violation.[77] Washington's law created a rapeseed commission[78] and local boards that evaluate the economic pros and cons, choosing a dominant type (rapeseed or canola) within the district. Of the two schemes, the Washington statute more closely approximates contractual stewardship because producers participate in choosing the dominant crop.

Given the experience in California (which basically banned biotech rice's commercial launch by its statutory scheme) and the biotech industry's widely publicized voluntary moratorium on biopharming in the corn belt in late 2002, there is room for a combination of legal tools to come to the rescue of beleaguered biotech companies. Stewardship standards, as practiced by individual biotech companies, are a seed that should be shared and planted in all industry contracts with growers. Those contracting growers can also use state-level political mechanisms to build safe zones where stewardship can be practiced without the billion-dollar commingling risks, thereby collectively reducing the risks to all concerned and maximizing both the profit margin and the public's appreciation of the benefits of biotech crops.

BIO imposed a temporary nationwide grower district in late 2002, when it announced that BIO members would not grow plant-made pharmaceuticals in the

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72. *See, e.g.*, CAL. FOOD & AGRIC. CODE § 55060 (Deerings 2001) (seller of rice seed causing "commercial impact" must pay the CA Rice Commission an annual assessment to cover identify preservation expenses associated with crop segregation).

73. IDAHO CODE § 22-108 (Lexis 2003) (setting forth authority for the Secretary of Agriculture to create rapeseed production districts and setting penalties for the violation of those provisions).

74. *See* Rapeseed Production and Establishment of Districts, WASH. ADMIN. CODE §§ 16-570-010 to 16-570-040 (2003) (setting forth the administrative provisions governing the Washington production districts).

75. *See generally* Matti Sovero, *Rapeseed, A New Oilseed Crop for the United States*, *in* NEW CROPS 302–07 (J. Janick & J.E. Simon eds., 1993) (discussing the U.S. development of canola, its health characteristics, and popularity), *available at* http://www.hort.purdue.edu/newcrop/proceedings 1993/v2-302.html#Canola (last modified Apr. 15, 1997).

76. Duane L. Johnson & Robert L. Croissant, Rapeseed/Canola Production, CROP SERIES, Sept. 1992, at 1 (noting the industrial uses of rapeseed and its toxic effects), *available at* http://www.ext.colostate.edu/pubs/crops/00110.pdf (last visited Nov. 9, 2003).

77. IDAPA 02.06.13 (2003) (stating the regulatory provisions for rapeseed districts established by the Secretary of Agriculture), *available at* http://www2.state.id.us/adm/adminrules/rules/idapa02/0613.pdf (last visited Nov. 9, 2003).

78. *See* WASH. ADMIN. CODE § 16-570-020(3) (2003) (requiring the creation of a local board to govern each district); *id.* § 16-570-030 (setting forth the duties of the rapeseed production district boards).

corn belt.[79] BIO would contend, however, that a statewide ban on biotech crops could be a violation of international trade agreements.[80]

Given the long legal shadow cast by the Starlink™ recall, further economic impacts on U.S. exports cannot be ignored in assessing potential liability risks. With billion-dollar export losses creating parallel billion-dollar liability risks that are now suitable for resolution in class actions alleging nuisance, trespass, and consumer fraud, no well-managed biotech company can dispute the urgent need to segregate varieties of biotech crops grown in the U.S. that lack overseas regulatory approval.

The E.U. will continue to act as the slowest common unapproved denominator worldwide, even if it can come up with an operating approval regulatory process. In preparing to do legal battle with the E.U. to overturn morally and ecologically bankrupt policies, the U.S. needs to protect its grain exports from the SCUD effect, using all the legal tools it can muster.

The development of an industrywide approach to control of unapproved-in-E.U. varieties has proven to work well in soybeans, and it can provide the corn industry with options for building both the armor of identity preservation and the sword of a reasonably "clean" shot at beating the E.U. before the WTO.

The biotechnology industry in the U.S. is a strategically critical technology, like semiconductors or other advanced technologies. This industry cannot afford a repeat of the costly recall of Starlink™ corn. High levels of biotech crop stewardship will speed consumer and regulatory acceptance. While the E.U. will continue to force upon global consumers a non-GMO vision of food that is less safe and less environmentally sound, this is not a sustainable legal or ethical approach to controlling global commodities trade.

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79. Justin Gillis, *Biotech Industry Adopts Precaution: Altered Plants Banned Near Major Food Crops*, WASH. POST, Oct. 22, 2002, at E1, *available at* http://www.washingtonpost.com/wp-dyn/articles/A61908-2002Oct21.html; Press Release, Australian Biotechnology Organisation (AusBiotech), Australia Confuses International Partners (Aug. 18, 2003), *available at* http://www.lifesciencenetwork.com/news-detail.asp?newsID=4526.

80. *Id.*

APPENDIX

American Soybean Association Policy Resolution on Biotechnology Approvals[81]

While we strongly support development of new biotechnology-enhanced crops, the action of commingling biotechnology-enhanced varieties/hybrids that are not yet approved for export to major foreign markets with either traditional or approved biotechnology-enhanced crops, endangers U.S. commodity and product exports. Therefore, we require due diligence of biotech and seed companies involved in the commercialization of biotechnology-enhanced crops to:

1. Obtain international clearances for the importation of biotechnology-enhanced varieties/hybrids into major export markets on a timely basis, before these varieties/hybrids are commercialized in the U.S. market;
2. Institute controls necessary to ensure that the commodity and products produced from biotechnology-enhanced varieties/hybrids are kept out of export channels until international clearances are obtained; and
3. Establish the documentary evidence that may be needed to document to foreign government authorities that all the commodity and products produced from biotechnology-enhanced varieties have been utilized in the U.S. market, until international clearances are obtained; [and]

[4.] Follow ASA established criteria or standards for evaluating control and release of new biotechnology-enhanced or specialty soybean varieties.

American Soybean Association Minimum Requirements for Attempted Identity-Preserved Production, Harvesting, and Utilization of Biotechnology-Enhanced Varieties/Hybrids That Are Unapproved for Export to Major Markets[82]

1. There must be a contract between the seed company and each farmer, requiring delivery of all production from the biotechnology-derived seed, allowing on-farm midseason field inspections, requiring minimum isolation distances from other types of the crop, and other requirements inherent in certified seed production. All unused seed must be returned to the seed company for proper disposal.
2. A sufficient price premium (a minimum of $.85 per bushel harvested for soybeans) must be paid to the farmers via the contracts, to ensure delivery by the farmer and to compensate for IP costs.

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81. http://www.soygrowers.com/publications/minrequire-IP.htm (Dec. 11, 2000); *see also* American Soybean Association, Biotechnology & Piracy of Intellectual Properties, http://www.iasoybeans.com/whatnew/relatednewsarchive/asa030403.html (last visited Nov. 26, 2003) ("ASA strongly supports biotechnology and believes the development of biotechnology-enhanced crop varieties and products will benefit farmers, consumers and the environment. Biotechnology is a key tool that will help farmers meet growing world food, health and energy needs.").

82. http://www.soygrowers.com/publications/minrequire-IP.htm (Dec. 11, 2000).

3. Designated delivery points must be facilities that do not deliver any crop into export channels. Transportation costs will be paid by the farmer for deliveries within a 20 driving mile radius of his farm. Additional transportation cots will be paid by the seed company at a rate of $0.30 per bushel for each 10-mile increment beyond the 20-mile radius of applicable farm(s).
4. The contract growing of biotechnology-enhanced varieties that are unapproved for export should be confined to restricted "closed loop" geographic areas, and the number of these separate geographic areas kept to as few as possible, in order to minimize the likelihood for IP system failures.
5. Varietal verification testing of each load delivered by each farmer must be performed at each delivery point, with totals by farmer matched up with the midseason field yield estimates to ensure that each farmer delivered all of the biotechnology-enhanced crop he produces [sic] in that crop year.
6. Before handling or harvesting any other varieties of crops, each farmer must thoroughly clean out all planters, combines, trucks, wagons, augers, storage bins, etc. that were utilized in the planting, harvest, transport, or storage of biotechnology-enhanced crops. All contract transport carriers utilized must have the same clean-out requirement. The seed/biotech company shall be responsible for the proper training of farmers on these requirements.
7. No "test plots" of unapproved for export, biotechnology-derived varieties shall be allowed, other than the above contracted fields.
8. In any publicity about biotechnology-enhanced varieties [e.g., invitations for farmers to view fields at a fall Field Day], seed companies must always state that these crops are being grown under tightly controlled contracts while they are awaiting overseas regulatory approvals.
9. In addition to the aforementioned requirements, the seed company shall adhere to all OECD requirements established for certified seed production.
10. An outside third party will check verification of the establishment of a closed loop system and adherence to these requirements.
11. The seed company shall assume legal and financial liability for any breaches in its closed loop identity preservation system that may result in lost international markets, or cargoes that are denied entry into foreign markets because of detection of the presence of gene(s), protein(s) or DNA identified from the unapproved, biotechnology-enhanced variety. This includes all fines and demurrage charges incurred by U.S. exporters and foreign importers because of presence of unapproved biotechnology-enhanced crops or products.