Biopharming, Biosafety, and Billion Dollar Debacles: Preventing Liability from Biotech Crops

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BIOPHARMING, BIOSAFETY, AND BILLION DOLLAR DEBACLES: PREVENTING LIABILITY FOR BIOTECH CROPS

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I. INTRODUCTION

As the revolution in protein-based drug therapy (also known as "proteomics" or "chemical genomics") follows the mapping of the human genome,

one branch of the agricultural biotechnology industry will likely transform into a system for large-scale pharmaceutical protein production known as biopharming or plant-made pharmaceuticals ("PMPs"). Before the decade is over, thousands of proteins may be grown in corn or other crops in open fields across the United States. It is equally likely that there will be well over one hundred nations overseas who will not consider these PMPs suitable for growth anywhere close to food crops due to the risk of pollen drifting or post-harvest commingling of pharmaceutical proteins with food. If such commingling of PMPs occurs, U.S. grain exports could be banned from the European Union, which continues to cling to a "zero tolerance" policy for biotech crops that have not cleared its high regulatory hurdles, and any nation following the EU's lead. Under a new international environmental agreement, the Cartagena Protocol on Biosafety[1] ("biosafety protocol"), nations will soon be able to turn away any shipment of commodity crops (*e.g.*, corn, soybeans, etc.) that "may contain"[2] traces of biotech altered crops that are not approved for import. As a result, careful measures to contain these PMP crops will need to be implemented.

Loss of export markets for U.S. grain is not the only threat that is posed by commingling of PMPs. At home in the United States, food processors will be concerned that biopharming crops may commingle with the domestic food supply, causing costly recalls and damaging the brands of major food companies. Biopharming could earn the ardor of the drug companies and their patients as the twenty-first century's optimum production system for proteins, while simultaneously causing great concern among U.S. grain exporters, food companies, and

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1. *See* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *opened for signature* June 5, 1992, *available at* http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf (entered into force Dec. 29, 1993) [hereinafter Cartagena Protocol on Biosafety]. The biosafety protocol will probably enter into force at the next Conference of the Parties following the fiftieth ratification. As this article went to press, the forty-eighth nation (Tanzania) had ratified the protocol.

2. *See id.* (stating that under the terms of the biosafety protocol, shipments of commodities must be labeled with "'may contain' living modified organism" designations).

their customers, both at home and overseas, due to the threat of commingling these therapeutic compounds with food or export grains.

The answer to the question of peaceful co-existence for the biopharmer, the overseas biosafety authorities, and food companies may lie in a combination of legal tools. This article will focus on the lessons in "stewardship" of biotech crops that have been provided from two incidents involving losses that have caused, or will eventually have caused, damages estimated in excess of $1 billion: (1) the recall and mass tort litigation, including economic losses, from the *StarLink* corn recall, and (2) the loss of over $1 billion worth of corn exports to the European Union due to commingling of unapproved-in-EU varieties of biotech corn with U.S. corn exports, which may yet lead to liability being imposed upon biotech companies via pending class action litigation.

These multi-billion dollar lessons provide powerful incentives to build detailed, contractually imposed industry standards for the responsible uses of agricultural biotechnology, particularly for the "identity preservation" methods appropriate to particular biopharming applications. Once standards are developed with input from multiple stakeholders, these standards can be imposed via contract upon the entire chain of biopharming commerce. Such identity preservation standards would be quickly adapted from existing systems used for creating certified seed or "non-GMO" crops in response to marketplace pressures. While costly to implement, these systems would greatly reduce the economic and social burdens currently faced by the entire domestic chain of commerce in food production. Moreover, the costs of such systems are largely a product of the immature state of agricultural management of biotech crops in the United States. Demonstrable reductions in costs of identity preservation are possible through the use of "grower districts" or regional moratoria (*e.g.*, no PMPs in the "corn belt") that keep PMPs and food crops in separate geographic areas and production contracts that specify containment measures.

There is scarcely enough time to develop and implement these legislative and contractual options, however, given the accelerating demand for biopharming production capacity in coming years. Federal regulatory programs have shown their limitations in controlling post-harvest commingling. The recent commingling incident involving ProdiGene's PMP corn illustrates this all too well.[3] Indeed, such programs cannot mandate local measures such as grower

3. *Food Industry Alarmed by Biopharm Contamination Incidents*, FOOD TRACEABILITY REP. WKLY., Nov. 18, 2002, *available at* http://www.foodtraceabilityreport.com.

districts, which are creatures of state legislatures, or production contracts, which are generated by parties to a transaction selling seeds.

Even if federal regulatory authority could somehow be extended to mandate better identity preservation methods as a matter of federal law, the attendant public comment delays and limited inspection capacity of the regulatory process leave a gap that industry standards must step in to fill. Given the immediate threat of billion dollar liabilities, and the report of higher premiums being paid to growers of PMPs, there should be adequate incentives to promote better identity preservation. Prompt action should be taken by those who could be targets for liability—biotech seed companies, growers, grain buyers, food processors, and major food companies—to implement industry standards that are appropriately conservative in view of the risks involved.

The entire chain of commerce, in particular food or animal feed products, such as soy or corn products, should pool resources and information and insist that all companies adopt sound stewardship standards. If one competitor cuts corners and competes unfairly with responsible companies, it may become necessary to stop a million or billion dollar liability threat by seeking a civil injunction to restrain that unfair competition.[4] Under some fact patterns, a court that has been made aware of the threat to commerce could be persuaded to enjoin the commercial launch of crops posing excessive economic risks.

II. A SNAPSHOT OF BIOPHARMING AND CORN STEWARDSHIP

Biopharming involves the production of PMPs that enhance plants genetically so that they produce pharmaceutical proteins.[5] Once these proteins are extracted from the plant, purified, and subjected to FDA approval and appropriate clinical trials, they will provide the building blocks for drugs targeting cancer, heart disease, HIV, diabetes, Alzheimer's and other debilitating diseases.[6]

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4. *Cf.* CAL. BUS. & PROF. CODE §§ 17200-17209 (West 1997 & Supp. 2003). Unfair competition and consumer fraud statutes comparable to California's Business and Professional Code Section 17200-17209, can provide the legal grounds for an injunction. However, an easier alternative would be to mandate injunctive relief through a contractual agreement tied to an industry standard.

5. BIOTECHNOLOGY INDUS. ORG., PLANT-MADE PHARMACEUTICAL TERMS (2002), *available at* http://www.bio.org/pmp/pmpterms.pdf.

6. *See* Press Release, Biotechnology Industry Organization, Experts on Plant-Made Pharmaceuticals Available to Media (July 16, 2002), *available at* http://www.bio.org/newsroom/newsitem.asp?id=2002_0716_01.

The extent to which these biopharming compounds can safely be commingled with food is the subject of considerable scientific debate. Since many of these antibodies or vaccines are designed for delivery directly to the bloodstream, the risk of eating them may be minimal, assuming a protein that readily dissolves in the digestive tract. For other compounds, however, there may be characteristics that lead to adverse health effects.[7]

While the real risk to health or environment of particular PMPs may prove to be minimal upon careful inspection, the regulatory approval process for securing a food tolerance for PMPs presents a daunting challenge. While some biotech companies might feel that a food tolerance from the FDA solves their problems, such a food tolerance would only resolve domestic food recall risks for the PMP in question, as well as any grain which has that PMP mixed into it. The overseas authorities for regulatory approval of a food tolerance will need to approve only food or grains that are exported. This includes not only those unapproved varieties of crops, such as PMPs and other non-food biotech crops that are intentionally or knowingly exported, but all exports of food or commodity grains that may contain such a PMP. As a result, a PMP that secures a domestic food tolerance in the United States may create an insoluble problem for grain exporters if overseas regulatory authorities then are required by law to assume that the PMP may be present at some low percentage. At present, the EU's model of zero tolerance for an unapproved variety of biotech crops has not been challenged at the World Trade Organization, and it may be adopted by many other trading partners of the United States.

In sum, PMPs will need to be grown in strict identity preservation systems, even if they have been granted a food tolerance for United States consumption. If they are not carefully contained, they could follow the path of *StarLink* corn. That particular unapproved-in-EU variety of biotech crop has shown up in shipments to major U.S. trading partners, such as Canada and Japan, even after the massive recall of *StarLink* corn was completed.[8]

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7. Bette Hileman, *Drugs from Plants Stir Debate: Technology Promises Huge Benefits but also Raises a Number of New Risks*, CHEM. & ENG'G NEWS, Aug. 12, 2002, at 22.

8. *See* Alex Binkley, *Canada Report Assesses Fallout from StarLink Corn Controversy*, FOOD CHEM. NEWS, Dec. 24, 2001, at 9 (stating Canada has disposed of *StarLink* contaminated feed and foods imported from the United States); Randy Fabi, *Exporters Say Japan Finds StarLink in U.S. Corn Cargo*, TORONTO STAR, Dec. 30, 2002, at D5 (stating that trace amounts of *StarLink* corn was found in a shipment bound for Japan and *StarLink* corn had already been recalled); Guy Hatchard, *U.S. Farmers Reap Heavy Penalty for Sowing GM Crops*, NEW ZEALAND HERALD, Aug. 27, 2002, *available at* http://www.nzherald.co.nz/storyprint.cfm?storyID=2351302

While it appears that industry stewardship is thriving in biopharming,[9] there is not yet a widely disseminated standard operating procedure for identity preservation in biopharming that is subject to regular third party audits. A new report from the National Academy of Science's National Research Council ("NRC") expresses concerns over the level of post-market surveillance that occurs after biotech crops have entered the marketplace.[10] One broad effort at industry stewardship originated with the biotechnology industry's leading trade organization, the Biotechnology Industry Organization ("BIO"), based in Washington, D.C. In recognition of the potential for economic losses arising from the commingling of biopharming compounds with food, BIO announced on October 24, 2002 an initiative that would impose a voluntary moratorium upon biopharming in the corn belt states[11] in the 2003 planting season to come.[12]

BIO's voluntary moratorium went beyond admittedly inconsistent Government requirements.[13] BIO tried to stop biopharming plantings only in 2003

(stating that the European Union will reject any shipment with even a trace of *StarLink* corn).

9. MONSANTO, BIOTECH SAFETY AND BENEFITS INFORMATION (2003), *available at* http://www.monsanto.com/monsanto/layout/sci_tech/ag_biotech/biosafety.asp (stating that Monsanto is committed to research and testing of GE products and disseminating that information to the public).

10. COMM. ON ENVTL. IMPACTS ASSOCIATED WITH COMMERCIALIZATION OF TRANSGENIC PLANTS, NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 192 (2002), *available at* http://www.nap.edu/books/0309082633/html [hereinafter COMM. ON ENVTL. IMPACTS] (stating that precommercialization quality and postcommercialization testing are necessary and essential).

11. *See* ECON. RESEARCH SERV., USDA, HARMONY BETWEEN AGRICULTURE AND THE ENVIRONMENT: CURRENT ISSUES, *available at* http://www.ers.usda.gov/Emphases/Harmony/issues/resourceregions/resourceregions.htm (last updated Apr. 10, 2002) (defining the cornbelt as America's heartland, which includes Iowa and Illinois).

12. *See generally*, BIOTECHNOLOGY INDUS. ORG., STATEMENT REGARDING PLANTS THAT PRODUCE PHARMACEUTICAL AND INDUSTRIAL PRODUCTS, *at* http://www.bio.org/pmp/statement.asp (last visited Apr. 12, 2003) [hereinafter BIOTECH. INDUS. ORG., STATEMENT]. *See also* 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.

13. BIOTECH. INDUS. ORG., STATEMENT, *supra* note 12, *at* http://www.bio.org/pmp/statement.asp. For example, the recommended Animal and Plant Health Inspection Service ("APHIS") regulatory planting distance to avoid biopharming pollen drift to fields containing certified seed corn is one mile, while food/feed corn could be planted within one-quarter mile of the same biopharming corn. ANIMAL & PLANT HEALTH INSPECTION SERV., USDA,

and only in regions where a particular crop—corn—was deemed of considerable economic importance, as measured by the USDA.[14] Corn and the canola plant are considered the "most promiscuous" plants according to press accounts reporting on the BIO initiative.[15]

In the autumn of 2002, the BIO moratorium on biopharming in the corn belt has been subject to significant political pressure from Iowa Senators Charles Grassley and Tom Harkin, and the Governor of Iowa.[16] At a meeting held on January 31, 2003 in Iowa, United States Government officials and BIO's staff members, in cooperation with various food industry stakeholders, urged Iowa growers to refrain from biopharming pending the issuance of new regulations that would provide enhanced federal regulatory oversight.[17]

Everyone in the food chain agrees that the commingling of biopharming compounds with food should be avoided until there is a reasonable consensus among regulators and significant stakeholders about the risks of permitting particular biopharming compounds into the food supply. While the health risks of particular biopharming compound may prove to be minimal with further testing, many food companies were stung by L-tryptophan throughout the 1990s and *StarLink* in this decade, each of which still lacks conclusive scientific proof of

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INFORMATION OF FIELD TESTING OF PHARMACEUTICAL PLANTS IN 2002 (May 21, 2002), *available at* http://www.aphis.usda.gov/ppq/biotech (available under New Information and Announcements). Given a "zero" tolerance that would likely be imposed for many biopharming compounds (which are not approved for use in food or feed, like their predecessor *StarLink*), this gap is nothing short of striking.

14. *See* Gillis, *supra* note 12, at E1, *available at* http://www.washingtonpost.com/wp-dyn/articles/A61908-2002Oct21.html (discussing that corn posed a danger of gene flow due to wide pollination of corn plants).

15. *Id.*

16. Press Release, Senator Chuck Grassley, Grassley Continues Efforts to Support Biotech Crop Production in Iowa (Nov. 4, 2002), *available at* http://www.grassley.sentate.gov (available under "Press Releases" link) (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."); *see also* Response from Stephen H. Howell, Director of the Plant Science Institute at Iowa State University, to the BIO Guidance concerning "Plants Intended Not to Be Used for Food or Feed," *available at* http://www.grassley.senate.gov (link available on Senator Grassley's Nov. 4, 2002 press release) (responding to BIO regulations in conjunction with Senator Grassley).

17. Personal communication from anonymous meeting attendee (February 4, 2003) (notes on file with author).

harm.[18] As a result, these food companies have long memories and a very low tolerance for recall risks.

The recent "near-miss" recall of biopharming compound produced by ProdiGene has provided companies with ample grounds for concern over the ability of one hundred percent of biotech companies to manage their affairs at the level of certainty that both the FDA and food companies require.[19] It should come as no surprise to industry observers to see the Grocery Manufacturers Association ("GMA") taking the position that PMPs should not be grown in food crops (*e.g.*, corn) until better identity preservation has been shown to work.[20]

Neither the NRC nor BIO has invoked the full power of the judicial system to enforce contractual promises to comply with an industry standard, despite looming risks of additional billion dollar food recalls and even larger export losses. Not every potential grower of biopharming crops is currently a member of BIO, nor are all growers contractually bound to follow BIO's lead in this voluntary industry moratorium.[21] Moreover, the overseas regulatory community will be scrutinizing the 2002 harvest looking for "leaks" in the containment protocols for existing growers of biopharming compounds.

The current practice of growing PMPs in the corn belt poses a challenge to the biotech industry to regulate itself better, before liability or industry boycotts drive key members out of business. The current lack of adequate identity preservation systems could set the stage for a complex array of legal barriers to the marketing of U.S. grain commodities overseas if the biosafety protocol enters into force as expected. The biosafety protocol's ripple effect could lead to a complex array of state and federal laws regulating the flow of commodity corn, soybeans, and other commodities to overseas markets.

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18. Press Release, FDA, Recall of L-Tryptophan (Mar. 22, 1990), *available at* http://www.fda.gov//bbs/topics/NEWS/NEW00064.html; *see also* Mark Winston, *Public Loses Food Fight*, VANCOUVER SUN, Sept. 3, 2001, at A15.

19. Press Release, ProdiGene, Inc., ProdiGene, Inc. Reaches Settlement with Agriculture Department (Dec. 6, 2002), *available at* http://www.prodigene.com/0501.htm.

20. Press Release, Grocery Mfrs. of America, GMA Urges the Use of Non-Food Crops for Biotech Drugs: ProdiGene's Errors Raise Serious Concerns, Says GMA (Nov. 14, 2002), *available at* http://www.gmabrands.com/news.

21. BIOTECHNOLOGY INDUS. ORG., BIO MEMBERS (2003), *at* http://www.bio.org/members.asp (listing current BIO members).

III. THE BIOPHARMING PIPELINE BEGINS TO BULGE[22]

According to the extensive report prepared by the environmental activist organization Friends of the Earth ("FOE"), there are over four hundred biopharming products in the research pipeline, and over three hundred have appeared in field trials at locations across the United States.[23] In time, thousands of PMPs may be grown in the corn belt, if growers there are successful in growing such crops without commingling them with food or export crops.

Many unapproved biotech crop varieties are surfacing from the USDA notification system[24] (*e.g.*, ProdiGene's biotech corn varieties containing trypsin, beta-glucuronidase,[25] avidin,[26] TGEV "piglet-vaccine," etc., and Stauffer's various enzymes, vaccines, a protein-based sweetener, a proprietary "therapeutic agent," and other biologically active chemicals[27]). Other companies at the forefront of turning plants into chemical factories include the Virginia-based CropTech, which has produced pharmaceuticals and human enzymes in tobacco, with several products already in clinical trials.[28] San Diego-based Epicyte has part-

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22. This section of the article is drawn from John T. Walsh & Thomas P. Redick, *Managing Agricultural Risks in Biopharming: The Role of Injunctions*, AGRIC. MGMT. COMMITTEE NEWSLETTER (Am. Bar Ass'n), Jan. 2003, *at* http://www.abanet.org/environ/committees/agricult/newsletter/jan03/biopharming.html.

23. *See* BILL FREESE, FRIENDS OF THE EARTH, GENETICALLY ENGINEERED FOOD ALERT, MANUFACTURING DRUGS AND CHEMICALS IN CROPS: BIOPHARMING POSES NEW THREATS TO CONSUMERS, FARMERS, FOOD COMPANIES AND THE ENVIRONMENT, *at* http://www.foe.org/safefood/BIOPHARM_FACTSHEET.doc (last visited Feb. 26, 2003).

24. *See* Brian Tokar, *Biohazards: The Next Generation?*, SYNTHESIS/REGENERATION, Summer 2001, *available at* http://greens.org/s-r/25/25-18.html.

25. *Id.* (stating that "There are contradictory reports as to whether beta-glucuronidase was produced by Stauffer in 2000, but it appears to have been available from them for a number of years. This enzyme reverses a biochemical reaction that helps render irritant molecules soluble.").

26. *Id.* (stating that "Avidin is a protein that naturally occurs in raw egg whites. While Sigma markets it for use in medical diagnostic kits, it is also used as an insect growth inhibitor and is being investigated as a next-generation biopesticide. Avidin binds to biotin, an important B vitamin, and prevents its absorption across the intestinal mucosa. It also causes a type of vitamin B deficiency in some people who consume raw egg whites.").

27. *See* Press Release, Stauffer Seeds, Ultra-High Value Bio Pharming is Becoming a Commercial Reality, *at* http://www.staufferseeds.com/0703ultra.htm (last visited Feb. 18, 2003; site under construction May 12, 2003). Three of Stauffer's products, avidin, beta-glucuronidase, and aprotinin (a protease inhibitor commonly used by surgeons), have been produced in sufficient quantities to be sold through a commercial chemical supplier, St. Louis-based Sigma Aldrich chemical company. *See id.*

28. CROPTECH, EXECUTIVE SUMMARY, *available at*

nered with Dow Chemical to develop and produce experimental human antibodies in plants, as well as a topical contraceptive and a microbiocide against HIV.[29] Monsanto's Integrated Protein Technologies subsidiary is seeking contracts with various clients to produce commercial quantities of various proteins in corn, tobacco, and soybean plants.[30] They hope to produce several metric tons of any appropriate protein within a three-year period. Several other companies in the United States, Canada, and France are also actively exploring these techniques. While the final testing for human therapeutic use has yet to be conducted since corn proteins may vary in some respects, there is optimism that the typical risks introduced by animals (*e.g.*, common viral pathogens) can be avoided through the use of plants.

A. *National Academy of Sciences Expresses Concern*[31]

The National Academy of Sciences, one of the leading scientific organizations in the United States, recently re-examined the risks posed by biotech crops, including PMPs. The report from the National Academy of Science's National Research Council expresses concerns over the USDA's handling of biopharming's environmental risks, finding that the USDA's agency, the Animal and Plant Health Inspection Service ("APHIS"), should more rigorously review the potential environmental effects of novel biotech crops before approving them for commercial use.[32] The report suggested increased public participation on proposed regulatory changes, so that concerns are raised and addressed before open-air field tests occur. In particular, post-market surveillance through ecological testing and monitoring should continue after transgenic plants have entered the marketplace.[33] These academics reporting to the Government found that

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http://www.croptech.com/about/sum.htm (last visited on Apr. 12, 2003).

29. *See* Press Release, Epicyte Pharmaceutical, Inc., Epicyte Pharmaceutical Advances Production of Human HIV Antibodies in Plants (Jan. 28, 2003), *available at* http://www.epicyte.com/fap.epicyte123002HIVplants2.rickvFINAL.pdf.

30. *See* MONSANTO PROTEIN TECHNOLOGIES, MONSANTO, ABOUT OUR BUSINESS, *available at* http://www.mpt.monsanto.com/asp/default.asp?p=business (last visited Apr. 21, 2003).

31. *See supra* note 22.

32. *See* COMM. ON ENVTL. IMPACTS, *supra* note 10, at 1-3, *available at* http://www.nap.edu/books/0309082633/html.

33. *See id.* at 192.

both academia and the Government should be funded to monitor biopharming.[34] The prospect of third party auditing or self-policing by the chain of commerce—not just biotech companies, but their customers and the ever-present activists equipped with genetic test kits—did not appear to enter into the committee's thought process for containment of biopharming operations.

The NRC report suggested that companies using the "confidential business information" protection for information submitted to the agency made it difficult to assess the quality of risk management currently in place for particular biotech crops.[35] In any monitoring program, the decision of whether to disclose information to the public will represent a genuine conundrum. Biotech activists are known for their destruction of test plots, with some activists errantly bombing non-biotech research operations near biotech research facilities. FOE acknowledges in their report the possibility of people stealing biopharming seeds from test plots if the location is publicly known.[36] Ironically enough, they also criticize the secrecy creating a true "Catch 22" for biotech companies, who will encounter criticism for secrecy, but also be blamed for third party actions that cause commingling that may be a risk that increases with public notice. Since these issues relating to theft of test plot seeds have not been resolved, continued secrecy may be necessary to achieve sound risk management. As FOE admits, thefts can readily occur, and apparently have occurred, with publicly listed biopharming products.[37] As a result, a veil of industry secrecy is necessary. There can be ample amounts of information shared, however, about the proper methodologies for maintaining identity preservation of biopharming crops from planting through final use.

B. *Case Study—Biopharming for Cystic Fibrosis*

The current level of industry stewardship for biopharming may be exemplified by the efforts undertaken with regard to "lipase" proteins for cystic fibrosis treatment that are produced in corn. Since this biopharming experiment in corn is taking place in Iowa amid the corn belt, stewardship measures were implemented and widely publicized, in contrast to some of the alleged "secret" and

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34. *See id.* at 60.
35. *See id.*
36. FREESE, *supra* note 23, at 53-54, *at* http://www.foe.org/safefood/BIOPHARM_FACTSHEET.doc.
37. *See id.* at 58.

less careful operations that the Friends of the Earth claims to have uncovered in its report[38].

There are instances of successful production of PMPs that prevent commingling with food. On February 3, 2002, the *Des Moines Register* in Iowa reported that pharmaceutical corn had been grown during 2001 in the middle of the corn belt with one-quarter mile planting distance between the pharmaceutical-containing corn and adjacent cornfields.[39] In May of 2002, the trade journal *Feedstuffs* reported that an Iowa farmer would grow a new seed containing a pharmaceutical protein that will treat cystic fibrosis ("CF corn").[40] This grower reports a one-quarter mile separation distance for this corn, which would appear at first glance to be much shorter than industry standards for safe planting distances to adjacent corn that may be destined for food uses. The American Seed Trade Association, in consultation with APHIS, has stated a minimum planting distance of one mile for growers that seek to avoid problematic commingling of pharmaceutical proteins with the food supply.[41]

The farmer interviewed in *Feedstuffs* reportedly used a separation distance of one-quarter mile around his open fields of a biotech CF corn. This was permissible due to the male sterile hybrids being grown, and the timing of the planting to avoid the open pollination of neighboring fields.[42] He also informed the trade press of plans to inform his neighbors of the biopharming operation he was running.[43] Further inquiries by the author revealed that the farmer undertook a variety of risk management measures, but detailed public confirmation of these measures remains difficult to locate.

CF corn could provide enormous health benefits to cystic fibrosis patients after it is purified and used to treat a symptom of cystic fibrosis, but only if it can be produced without food commingling. As production of this protein

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38. *See* Press Release, Friends of the Earth, Reckless USDA Policy Fails to Keep Biopharmaceuticals Out of Food Supply: Coalition Calls on the USDA for Contamination Information Including Name of Drug or Chemical Being Withheld (Nov. 13, 2002), *available at* http://www.foe.org/new/releases/1102biopharm.html.

39. Anne Fitzgerald, *Iowans Push for Biotech Plant*, DES MOINES REGISTER, Feb. 3, 2002, at 1A.

40. *See* Robert Heuer, *Cooperatives at a Crossroads: Challenge Will Be How to Expand Search for Capital*, FEEDSTUFFS, May 20, 2002, at 1.

41. ANIMAL & PLANT HEALTH INSPECTION SERV., *supra* note 13, *available at* http://www.aphis.usda.gov/ppq/biotech (available under New Information and Announcements) (providing "a summary of confinement measures for organisms being field tested in 2002").

42. *See* Heuer, *supra* note 40, at 21.

43. *See id.*

ramps up to commercial levels and hundreds of acres of this new biotech corn are grown in Iowa or elsewhere in the corn belt, the growers involved will have to be educated to ensure adequate safeguards, including the steps taken by this pioneering grower. In particular, observation of conservative planting distances to reduce the potential for commingling with food is significant. Not every corn grower can make identity preservation work at one-quarter mile distances.

The reason for this caution is partially due to the potential for misunderstanding by less-informed overseas agencies. Those overseas regulatory authorities might read this press and see a one-quarter mile planting distance, and then assume that commingling with nearby corn was occurring, because they were not apprised of other stewardship measures. As a result, barriers to trade might be erected whenever the APHIS one mile planting distance for corn is not followed to the letter. This "LMO event"[44] might even have to be reported someday soon on commodities shipping documentation under the biosafety protocol's "may contain LMO" standard for all commodities shipments from the United States that "may contain" that LMO, including non-corn shipments that may contain corn as foreign material.[45] Moreover, if the pattern from *StarLink* corn were to repeat itself, there would most likely be an FDA-mandated recall of any food products that are produced from corn that cross-pollinated with CF corn.

C. StarLink *and its Ensuing Mass Tort Litigation*[46]

The PMPs discussed above are necessarily being grown under the looming shadow of the *StarLink* corn recall, which sets the standard for how to commingle non-food biotech crops. *StarLink* corn was genetically engineered by Aventis Crop Science, Inc. ("Aventis") to resist pests and a proprietary herbicide. It was not approved anywhere—United States or overseas—for commingling with food in any amount (*i.e.*, it faced a "zero tolerance" for commingling with

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44. Under the biosafety protocol, an LMO is a "Living Modified Organism." *See* Cartagena Protocol on Biosafety, *supra* note 1, *available at* http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf.

45. *Report of the Meeting of Technical Experts on the Requirements of Paragraph 2(a) of Article 18 of the Cartagena Protocol on Biosafety*, Intergovernmental Committee for the Cartagena Protocol on Biosafety, 3d Meeting, Provisional Agenda Item 4.1.5, UNEP/CBD/ICCP/3/7/Add.1 (Apr. 22-26, 2002), *available at* http://www.biodiv.org/doc/meetings.asp?wg=BSTE182A-01 (see Final Report).

46. Portions of this section of the article are drawn from Walsh & Redick, *supra* note 22.

food). In one controversial legal ruling issued on July 11, 2002, the federal court handling the multi-district litigation ("MDL") lawsuit denied a motion to dismiss claims for negligence and both public and private nuisance arising from the commingling of *StarLink* corn with other neighboring farmers.[47] The discovery of *StarLink* "contamination" led to at least twenty-seven class action lawsuits in six states against Aventis CropScience USA, Research Triangle Park, North Carolina. These suits were consolidated, using MDL procedures, before U.S. District Court Judge James B. Moran in Chicago.[48] These claims survived a motion to dismiss the farmers' claims for negligence and public and private nuisance alleging economic loss from airborne *StarLink* pollen.[49] The court held that the economic damage to the farmers' corn could be a compensable injury,[50] even if the growers in question never experienced direct commingling.[51]

Aventis apparently thought that commingling problems, should they ever arise, would be worked out with food regulators to allow some small percentage of unapproved *StarLink* in the U.S. food supply. After the stewardship program designed to channel the *StarLink* corn was found to have failed in tests conducted upon taco shells by the Friends of the Earth activist group, the EPA did not grant a reasonable food tolerance.[52]

After the 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. The Advisory Panel appears to have adopted a precautionary approach of its own to allergy risks, finding no proven safe threshold for allergenicity because the human immune system is acutely sensitive. The economic impact of this regulatory mistake in allowing the careless marketing practices of Aventis was further compounded by the EPA Advisory Board's decision to impose "zero tolerance" for the recall from food supplies. Any amount of detectable *StarLink* merited destruction of the food in-

47. *See In re* StarLink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828, 834, 852 (N.D. Ill. 2002).

48. *See id.* at 833.

49. *Id.* at 852.

50. *Id.* at 842-43 (stating that to the extent that corn was commingled or contaminated, plaintiffs have properly alleged a claim upon which relief may be granted).

51. *Id.* at 848 (public nuisance alleged allowing recovery for decline in corn prices triggered by export market losses).

52. Press Release, Friends of the Earth, Genetically Engineering Contaminants Found in Safeway Brand Taco Shells: Recall by FDA and Safeway Company Demanded by Coalition (Oct. 12, 2000), available at http://www.foe.org/safefood/moreoncorn.html.

volved. The result was a recall of *StarLink* that reportedly will exceed hundreds of millions of dollars by many estimates.[53]

The EPA later admitted that it made a huge mistake when it approved *StarLink* for "feed only" without requiring adequate identity preservation measures to keep this corn from entering the food supply.[54] The litigation will continue to work its way through the courts, and new claims may continue to rise if new *StarLink* corn plants sprout from stray kernels that fell to the ground in the preceding harvest, potentially commingling with successive harvests each growing season.

The health risks of *StarLink* are still being assessed by regulators, who have not identified any actual cases of personal injuries. Allegations abound, including cases of anaphylactic shock allegedly caused by *StarLink* in California.[55] Consumers sued in putative class actions in various courts,[56] many consolidated in Chicago under federal Multidistrict Litigation Rules, and some sued for a refund of their money spent in buying food tainted with *StarLink*.[57] These cases delved into the health effects of *StarLink* while farmers pursued the economic impacts with nuisance and consumer fraud cases.

StarLink serves as confirmation that both personal injuries and economic loss will be compensated, even when the Centers for Disease Control ("CDC") says no one could prove to have been hurt, and even though economic losses are very difficult to prove. Aventis also proved that biotech companies will compensate economic losses of customers, to a point, both voluntarily and through class action settlements. Before *StarLink* has wound down, however, the costs paid by Aventis could exceed one billion dollars.

StarLink corn, while not providing any unique consumer benefits, is one of many biotech varieties of common crops grown in the United States. Many of these crops lack regulatory approval in major markets overseas. On June 5, 2002, activists reported that unapproved corn was present in some U.S. food aid

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53. Press Release, Inst. for Agric. and Trade Policy, Institute Calls on State Attorneys General to Investigate StarLink Corn Disaster (Nov. 9, 2000), *available at* http://www.biotech-info.net/IATP_PR1.html.

54. Anthony Shadid, *EPA: Altered Animal Feed Must Pass Human Standard*, BOSTON GLOBE, Mar. 8, 2001, at E3.

55. Marc Kaufman, *Biotech Corn Is Test Case for Industry*, WASH. POST, Mar. 19, 2001, *available at* http://www.organicconsumers.org/ge/doom.cfm.

56. Mike Robinson, Associated Press, *Judge Approves $9 Million Settlement in Bioengineered – Corn Suit* (Mar. 8, 2002), *available at* http://www.biotech-info.net/settlement.html.

57. *Id.*

in Central America[58] and are raising a public outcry, causing the United States Government to again affirm its zero tolerance for Cry9c in the U.S. food supply. A grain industry official reported at a 2002 meeting in Sri Lanka that USDA grain industry tests show *StarLink* corn showing up at higher levels recently in United States corn exports. [59] This discovery was repeated in Japan in December 2002.[60]

In the final analysis, *StarLink*'s biggest economic impact may not be the billion dollar recall of food and grain or the continuing costs of testing and destruction of contaminated inputs that are still ongoing, but keeping residual *StarLink* out of food.[61] *StarLink* has effectively turned the corn belt and chains of commerce leading toward human food or export into "*StarLink*-free" identity-preserved chains of commerce. This will be required for several years until *StarLink* is eliminated from the system (*i.e.*, farmers must rotate crops and herbicides to stop herbicide-resistant *StarLink* "volunteers" from cropping up each planting season).

The biggest economic impact from *StarLink* may lay in the future course of regulatory approval and tolerances imposed for unapproved biotech crops, in overseas markets. *StarLink* may be the "precedent" that protects precautionary regimes like the EU and New Zealand. The federal decision in the United States to impose zero tolerance for the *StarLink* food recall could become the "bad facts" that make "bad law" in nations around the globe. In addition, for the next few years, *StarLink* may be presumed by overseas authorities to be present somewhere in massive cargoes of U.S. grain commodities as a matter of law, through the presumption of legal precautionary approaches, under the may contain standard that leads to "less than zero" tolerance for unapproved biotech crops. The legacy of *StarLink* could linger for years to come in the precautionary approach of nations banning biotech crops overseas. By 2050, *StarLink*'s impact

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58. *See* GENETIC ID, INC., GMO ANALYSIS REPORT (2002), *available at* http://www.foe.org/foodaid/Nicaragua_test_results.pdf (discussing laboratory analysis performed for Friends of the Earth stating that samples of World Food Program taken from Nicaragua tested positive for Monsanto Roundup Ready DNA).

59. E-mail from Kim Nill, American Soybean Association, to Kirk Miller, Special Assistant, North American Export Grain Association (June 13, 2002) (on file with author).

60. Randy Fabi, *Japan Got Trace of Biotech Corn, U.S. Exporters* Say, TORONTO STAR, Dec. 30, 2002, a D5.

61. *See* K. T. Arasu, Reuters, *U.S. Firm Clueless Over Starlink Slip Despite Test* (Jan. 2, 2003), *available at* http://131.104.232.9/agnet/2003/1-2003/agnet_january_3.htm (stating that *StarLink* contaminated corn slipped through testing).

could be measured in trillions of dollars and millions of hungry peoples' lives lost or needlessly placed at risk.[62]

D. *Biotech's Prodigal Son—ProdiGene*[63]

In late 2002, the USDA reported ProdiGene's compliance violations.[64] After a corn crop failed, ProdiGene destroyed the plants, plowed the field, and allowed food grade soybeans to be grown in the same field.[65] Over 500,000 bushels of soybeans in Nebraska were commingled with about 500 bushels of ProdiGene's corn.[66] USDA inspectors acted quickly and kept these commingled soybeans with traces of PMP corn away from the U.S. food supply.[67] ProdiGene purchased the PMP-contaminated soybeans, currently under quarantine, because these soybeans were grown in a field that ProdiGene had used for growing biotech corn that encoded pharmaceutical proteins.[68]

To anyone who has ever rotated crops, it should come as no surprise to hear that a few volunteer corn plants grew up among the soybeans. The USDA investigation of the incident led to heavy fines, due to the explicit warning about the corn plants that was reportedly delivered to ProdiGene during a walk-through USDA inspection. After ProdiGene settled with the USDA, however, it took an interest-free loan from the USDA to pay its fine.[69] ProdiGene remains an operating business that is addressing "compliance challenges" according to Prodi-

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62. Andrew S. Natsios, Director of the United States Agency for International Development (US AID), has taken the position that the EU's precautionary approach is contributing to South African nations' decision to deny food aid from the U.S., despite thirteen million lives at risk from hunger. *See* Jim Fuller, *Natsios Says Disinformation Campaign Is Slowing African Famine Relief: Remarks Follow Visit to Zambia and Malawi* (Aug. 29, 2002), *available at* http://usinfo.state.gov/topical/global/develop/02082903.htm.

63. *See supra* note 22.

64. *See* Brenda Cassidy & Douglas Powell, *Pharmaceuticals from Plants: The ProdiGene Affair*, Food Safety Network, *at* http://www.foodsafetynetwork.ca/gmo/prodigene.htm (Dec. 3, 2002).

65. *See id.*

66. *See id.*

67. *See id.*

68. *See id.*

69. Justin Gillis, *U.S. Will Subsidize Cleanup of Altered Corn*, WASHINGTON POST, Mar. 26, 2003, at E1, *available at* http://www.washingtonpost.com (available using search under "Archives" link).

Gene's president, Anthony Laos.[70] "As with any new industry and new regulatory program, we can always do better," added Laos.[71] "Working together with USDA, we intend to, now and in the future."[72]

This incident drove the GMA to demand that biopharming crops never be grown again in food crops.[73] The leading growers' associations—the National Corn Growers Association ("NCGA"), American Soybean Association ("ASA"), and American Farm Bureau Federation ("AFBF")—"reaffirmed their support for developing pharmaceutical and industrial crops through agricultural biotechnology," issuing a more moderate statement than GMA, advocating sound stewardship but not a complete moratorium on the use of food crops for biopharming.[74]

About six weeks before the ProdiGene commingling incident hit the press, BIO had announced a controversial initiative in late September that would have its members suspend biopharming operations in the corn belt in crops used for food.[75] Upon arrival, this policy was questioned by the Governor of Iowa and Senators Charles Grassley and Thomas Harkin, who have been promoting Iowa as the logical epicenter for biopharming in corn.[76] It remains to be seen whether this voluntary BIO moratorium will dominate PMP practices. Compliance could be enforced by BIO members exercising their influence, or by potentially offended members of the chain of commerce who may see a need to enjoin any biopharming operations taking place in the corn belt.[77]

While the ProdiGene commingling incident appears to validate the concerns that BIO raised in announcing its voluntary moratorium, BIO has left

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70. *The ProdiGene Episode: What Happened,* FARMWEEK, Nov. 22, 2002, *available at* http://www.ilfb.org/viewdocument.asp?did=4409&r=2.465457E-02&r=2713587&r=0.9559442.

71. *Id.*

72. *Id.*

73. *See* Press Release, Grocery Mfrs. of America, *supra* note 20, *available at* http://www.gmabrands.com/news.

74. Press Release, Am. Farm Bureau Fed'n, AFBF, Farm Groups Concerned About Compliance Infractions (Nov. 14, 2002), *available at* http://www.fb.org/news/nr/nr2002/nr1114.html.

75. *See* BIOTECHNOLOGY INDUSTRY ORGANIZATION, STATEMENT, *supra* note 12, *at* http://www.bio.org/pmp/statement.asp.

76. *See, e.g.,* Press Release, Senator Tom Harkin, Harkin Urges Review of Biotech Crop Ban (Nov. 1, 2002), *at* http://harkin.senate.gov/news.cfm?id=188229; Press Release, Senator Chuck Grassley, *supra* note 16, *available at* http://www.grassley.sentate.gov (available under "Press Releases" link).

77. *See* Gillis, *supra* note 12, at E1, *available at* http://www.washingtonpost.com/wp-dyn/articles/A61908-2002Oct21.html.

avoidance of the next commingling problem to individual members and federal regulatory oversight.[78] It remains to be seen whether future commingling incidents will be uncovered in the corn belt.

IV. WELCOME TO WAFFLE WORLD: THREE-DIMENSIONAL REGULATORY CHESS

To gain a better understanding of the challenges facing agricultural producers in the emerging market for biopharming, this article attempts to define the fast-evolving regulatory trends at three levels of legal authority. First, the Federal Government in the United States has asserted control over the approval and commercial release of biotech crops, while appropriately hesitating at the prospect of regulating their commercial impact. That policy-making function is left to states and plaintiffs' class action counsel. Second, regulation is emerging at the state level to regulate commercial impact, both the fifty states in the United States and overseas "states" in federalized systems, such as the European Union and Brazil. Third, regulation of biotech crops is rapidly proliferating at the international level. Nations around the world are adopting the Cartagena Protocol on Biosafety, creating adverse commercial impacts in the United States. Stacked atop one another, these layers of regulation force the entire food chain to find ways to market products without triggering regulatory bans or liability at some level. Any PMP that commingles with food products or grain borne for export will trigger a complex, multi-level legal reaction.

This article can only provide a partial overview of the myriad of state, federal, and international regulatory standards that regulate biopharming. These standards are undergoing rapid evolution. The emergence of new parallel grids of state and international regulation create a "waffle world" phenomenon in the regulation of agricultural biotechnology. After nearly fifteen years of coordinated federal policy on agricultural biotechnology in the United States, many new biotech crops are entering the commercial marketplace with full federal regulatory approval, only to be greeted with hostility due to state and international regulation. After *StarLink*, however, the legal framework for regulating the commercial impact of agricultural biotechnology is rapidly expanding to include farming states and international regulations. Barriers to trade are emerging at the international level, which create the need for regulation at the state level (*e.g.*, the California rice market looks east to Asia, and bans biotech rice).

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78. Ann Thayer, *USDA Fines ProdiGene; Industry Reacts to Farm Interests*, CHEM. & ENG'G NEWS, Dec. 16, 2002, at 12.

These barriers create conditions for potential billion dollar losses in export markets in addition to food recalls. With the expertise of state-level agricultural managers and the development of contractual industry standards, farming states can detect and prevent the threat of commingling liability that can arise from various scenarios.[79] Once the liability threat is identified, potentially responsible parties can act upon it without waiting for regulatory guidance that may never be forthcoming.

At the international level, a global grid of emerging international regulatory requirements will increasingly force exporters of grain to segregate out "unapproved" biotech crops, particularly those involving biopharming. Each nation that ratifies the biosafety protocol will be intent on imposing its own arcane system of approval and labeling of biotech crops, with no uniform tolerance for commingling or labeling.[80] Biopharming is entering the arena of international biotechnology regulation at a moment when chaos reigns (one industry observer likened the atmosphere to an "elementary school cafeteria at lunch hour"). Adding the potential for commingling of biopharming compounds makes stewardship more complex and increases the liability risks associated with shipping commodities overseas where the costs associated with a shipment being turned away will be allocated according to contract and to business necessity, which sometimes overrides the explicit terms of a contract.

As a result, the steady stream of waffle batter—United States "deregulated" biotech crop approvals—is going to be met, as the twenty-first century unfolds, with the regulatory equivalent of a waffle iron. The regulatory grids formed by various differing state and international requirements—none singing in "harmony"—could lead to increased segregation of U.S. agricultural products, such as grain and even the animals that eat biotech crops. The result will transform shipments of commodities into more compartmentalization than is economically justified by the risks of the biotech crops. On the bottom side of the

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79. *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. (Envtl. L. Inst.) 10,328, 10,329 (May 2000) (stating that liability for the economic losses incurred through commingling of 'unapproved-in-EU' varieties of crops with grain bound for exports has yet to be established through court precedents). *But cf.* Robert Schubert, *Monsanto Still Suing Nelsons, Other Growers*, CROPCHOICE, May 21, 2001, *available at* http://www.cropchoice.com/leadstry.asp?recid=326 (stating that litigation is reportedly pending in the Eastern District of Missouri alleging economic losses from corn that was not approved for export to the European Union and was sold without full disclosure of this material fact).

80. *See infra* Appendix A, at p. 151.

waffle iron, at the level of U.S. state law measures, a nationwide grid emerges as a steady stream of state and local laws and begins to force segregation of biotech crops in various ways.

The first example arises in California, where the legislature quietly banned biotech rice due to fears over the "commercial impact" on exports of rice to markets where the new Aventis "Liberty Link" rice had not yet been approved for import.[81] Illinois and Iowa are trying to sort unapproved-in-EU biotech corn through localized industry standards.[82]

Increasingly irrelevant federal standards occupy the middle ground between two grids of regulation (state and international), which will compress the entire United States corn, soybean, and other biotech crops into increasingly compartmentalized chains of commerce.

For agricultural lawyers and their clients, there are two urgent areas of legal work to undertake. First, those involved in food production will need to monitor and, if possible, influence each and every state, federal, and international regulatory requirement for food traceability. Second, new regulatory requirements and commercial processing will transform agricultural chains of commerce into careful paper trails of legal agreements, monitoring and testing records, and other assorted paper protections. The attorney that helps allocate and manage the risks of commingling biotech crops will be doing his clients an enormous favor in an era when billion dollar losses are so easily created.

In the final analysis, these risks that are not managed well may lead to litigation. With class actions pending in the wake of the billion dollar losses arising from both *StarLink* and the broader unapproved-in-EU corn litigation, there are ample grounds for pursuing, where appropriate, a civil injunction to restrain the marketing of a biopharming variety that lacks adequate measures for prevention of commingling with food or export-bound crops.

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81. A.B. 2622, 1999-2000 Leg., Reg. Sess. (Cal. 2000) (codified at CAL. FOOD & AGRIC. CODE §§ 55,000-55,108), *available at* http://www.leginfo.ca.gov/billinfo.html (search by bill number A.B. 2622).

82. Press Release, Iowa Corn, Iowa, Illinois Corn Growers Launch Farmer-Owned Quality Assurance Program (Apr. 15, 2002), *available at* http://www.iowacorn.org/archives/release_novecta%20introduction.htm.

V. LIABILITY RISKS FOR CROPS NOT APPROVED FOR EXPORT

Biopharming presents risks of food recalls similar to the *StarLink* debacle. Even if the FDA was to grant a food tolerance, however, for certain biopharming compounds, there is still a significant risk that these compounds will not be approved for export to major markets overseas. These economic impacts are also part of the *StarLink* saga, and farmers are seeking compensation for decreased corn prices caused by the *StarLink* commingling. While the Iowa Senators and even food companies may be satisfied if biopharming compounds are believed to be segregated from the food supply, there are overseas customers for grain exports who must also be satisfied. They may revise extensive testing or paperwork detailing the source of grain. As a result, a complete picture of proper biotech company stewardship cannot be provided unless exports are protected as well.

A. *The Liberty Link™ Soybean—Nipping the Billion Dollar Debacle in the Bud*[83]

Fortunately, certain sectors of the U.S. grain system have been adapting to the overseas demands of customers. The American Soybean Association ("ASA") realized in late 1997 that the EU had no present intention of approving new varieties of genetically enhanced crops for import. Corn shipments to the EU were being channeled away from export shipments in the hope of preserving the flow of corn exports to the EU. To prevent commingling of unapproved-in-EU varieties of GE soybeans, ASA called upon eleven biotech seed companies to refrain from marketing any new variety of GE soybean that lacked approval in major overseas markets, in particular the lucrative EU market.

Aventis disregarded this request at first, proceeding with plans to market the Liberty Link™ soybean, which had no approval for export to the EU after harvest. ASA entered into several months of negotiations to educate Aventis (its corporate predecessor AgrEvo USA) 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 market (a potential public nuisance). ASA asked Aventis to follow a detailed identity preservation system, including the contested items of a high premium for growers, dedicated domestic facilities to divert the biotech soybeans away from export channels, and an assumption of

83. *See supra* note 22.

liability for any nuisances or other liability that growers and Aventis might jointly cause.

Aventis did not market the Liberty Link™ soybean, announcing in press releases that it was serving the public interest by acting to protect export markets. ASA agreed in its own public statements that Aventis had acted responsibly and commended Aventis publicly for its discretion. The business press reported that Aventis had invested millions of dollars in developing its Liberty Link™ soybean, an investment it is still trying to recoup.

If companies and growers fail in their joint stewardship efforts, growers involved in the program may end up on the receiving end of a nuisance lawsuit. This could lead to a claim for comparative fault against the seed company.[84]

B. *Unapproved-in-EU Corn Enters the Litigation Arena*

In a putative class action filed on behalf of thousands of corn and soybean farmers against Monsanto in the U.S. District Court, Eastern District of Missouri, attorney Richard Lewis has alleged antitrust and environmental claims under the nuisance and consumer fraud laws applicable to the class, based upon price fixing and other anti-competitive conduct.[85] The case seeks economic damages for farmers suffering losses from "regulatory and consumer rejection of genetically modified crops."[86] The case also seeks improvements in "environmental and human health testing of [biotech] crops."[87] Corn prices are alleged by anti-biotech activists to have dropped precipitously since the introduction of biotech corn, in part due to factors involving the refusal of the EU and many food manufacturers to purchase biotech corn for human consumption, a trend that was accelerated considerably by the *StarLink* corn recall.[88]

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84. *See generally* Selma Pressure Treating Co. v. Osmose Wood Preserving, Inc., 221 Cal. App. 3d 1601 (1990) (discussing a chemical spill which led to comparative fault for chemical supplier's failure to warn of improper disposal).

85. Schubert, *supra* note 79.

86. *See id.*

87. *See id.*

88. Hatchard, *supra* note 8, *available at* http://www.nzherald.co.nz/storyprint.cfm?storyID=2351302 (discussing Genetic ID employee allegation that "the U.S. food industry has lost billions of dollars in exports since introducing GM crops. US maize prices are at their lowest for 30 years - down from US$3 ($6.43) to $1.30 ($2.79) a bushel. In 1996, before GM crops were introduced, US maize farmers made a profit of US$1.4 billion. Last year, they lost US$12 billion.").

The question of recovery for economic losses in the context of property damage for product liability continues to create a mish-mash of case law. For economic losses of growers arising from biotech company marketing practices, the courts may have to resolve whether the "economic loss" doctrine bars recovery.[89] While this article will not delve into this issue in detail, the case law is sufficiently mixed so that each particular jurisdiction should be scrutinized for its current approach.[90] The case law barring recovery for economic loss is a confusing muddle of mixed holdings, particularly in light of cases finding "severe pecuniary loss" supports a nuisance claim.[91] As a result, growers alleging pollen drift, which could be grounds for trespass or nuisance, may find that the economic loss doctrine does not bar recovery. They also may find that courts of equity, which are empowered to manage nuisances, are inclined to grant injunctive relief to nip a nuisance in the bud.

Given the potential impact on exports from the sale of unapproved-in-EU varieties of corn, state-level groups are calling for biotech companies to stop selling varieties of corn that cannot be exported to the EU. The Illinois Farm Bureau recently took a stand on unapproved-in-EU varieties of corn, echoing ASA's call for restraint in marketing unapproved-in-EU varieties of soybeans.[92] This action recognizes that up to a $1 billion in corn trade could be lost if these unapproved-in-EU varieties of corn were to be commingled with corn or corn gluten bound for export. While the National Corn Growers Association and others were will-

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89. *See* Margaret Rosso Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 237 (Supp. 2002) ("In some states, mere economic loss from defendant's negligence will not be compensated; plaintiff must also prove physical harm to property.").

90. *See* E. River S.S. Corp. v. Transamerica Delaval, Inc., 476 U.S. 858, 866-75 (1986). Some federal courts have applied the *East River* economic loss doctrine to consumer, as well as commercial, purchasers of vessels. *See, e.g.*, Somerset Marine, Inc. v. Forespar Prods. Corp., 876 F. Supp. 1114, 1116 (C.D. Cal. 1994) (holding that *East River* applies in consumer as well as commercial transactions); Karshan v. Mattituck Inlet Marina & Shipyard, Inc., 785 F.Supp. 363, 366 (E.D.N.Y. 1992); Paquette v. Deere & Co., 719 A.2d 410, 413 (Vt. 1998); Cont'l Ins. v. Page Eng'g Co., 783 P.2d 641, 647-48 (Wyo. 1989) (following *East River* in denying economic losses resulting from failure of dragline pulley used in mining operation); *but see* Sherman v. Johnson & Towers Balt., Inc., 760 F. Supp. 499, 501-502 (D. Md. 1990) (suggesting that *East River* holding is not controlling in cases involving consumer transactions).

91. *See, e.g.*, Neb. Innkeepers, Inc. v. Pittsburgh-Des Moines Corp., 345 N.W.2d 124, 129-30 (Iowa 1984) ("The question becomes whether so many businesses have suffered the same economic harm that the plaintiff's damages are no longer special.") (quoting Stop & Shop Companies, Inc. v. Fisher, 444 N.E.2d 368, 373 (Mass. 1983)).

92. Martin Ross, *'No' Before You Grow?*, FARMWEEK, Jan. 16, 2003, *available at* http://www.ilfb.org/viewdocument.asp?did=4731.

ing to write off the $200 million in whole corn exports to the EU,[93] the threat of losing corn gluten exports—$400 million or more annually—has upped the ante, causing certain states to begin creating their own segregation systems. As will be discussed below, there are legislative initiatives addressing unapproved varieties, including a California law making the entire state non-biotech for rice.

There would appear to be an imminent need for developing standards for identity preservation for: (1) varieties of GE crops that lack overseas approvals; and (2) the few varieties of industrial and pharmaceutical crop production systems that are entering the marketplace. The latter, in particular, appear to present a risk of repeating the food-commingling debacle that led to the *StarLink* recall.

The threat of injunctive relief was used to restrain the sale of Liberty Link™ soybeans, and it could have easily been used to prevent the sale of *StarLink*.[94] While there are many claims now being made to seek compensation for the losses caused by *StarLink*, those predictable losses might also have created sufficient threat of irreparable harm to merit an injunction against *StarLink* prior to sale. *StarLink* corn was allegedly sold without a full disclosure to growers of the risks of commingling, creating a consumer fraud that could be actionable under statutes protecting consumers.

Given the magnitude of the economic harm that could be caused by an unapproved-in-EU variety, an attorney general seeking to apply public nuisance law could persuade a sympathetic state or federal court judge to declare the sale 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 consumer fraud statutes are on the books, the law of nuisance can adapt to encompass a fraud in progress, if it is filed on behalf of a large enough group, to constitute a public nuisance or fraud upon consumers.

The lessons learned from *StarLink* and Liberty Link™ for biotech companies are clear. While these seeds were state of the art and would have promoted sustainable reductions in soil loss through herbicide resistance and "no till" production, they posed a threat to other crops the marketability of other crops because they lacked regulatory approval. In the coming age of "precau-

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93. Letter from AgBiotech Planning Committee to United States Senators (Dec. 18, 2001), *available at* http://www.ncga.com/public_policy/letters/2001/biotechnolgy/section_333.htm (indicating that the EU's "moratorium on approval of new biotech varieties has resulted in a reduction of U.S. corn exports valued at more than $200 million," but the NCGA's bigger concern is the EU's new traceability and labeling proposals that could further limit exports to Europe).

94. The draft complaint for injunctive relief against sales of Liberty Link would have applied, with minor changes, to *Starlink* corn (copy of complaint on file with author).

tion" (where Waffle World is forged), these concerns for overseas regulatory approval will increase for the foreseeable future.

VI. THE CARTAGENA PROTOCOL ON BIOSAFETY: A GLOBAL BIOTECH BAN?

For U.S. exporters of grain (*i.e.*, commodities such as corn, soybeans, rice and canola), the Cartagena Protocol of Biosafety[95] stands as an unprecedented legal tool for erecting trade barriers to exports of commodities. The biosafety protocol has a long and complex history and is a complex law containing seemingly conflicting provisions regarding the standard for judging a nation's refusal to accept biotech crops. As a result, it is a commodity trader's worst nightmare. The matrix of national trade barriers being erected to biotech crops in some nations is attached hereto as Appendix A.[96]

The problems raised by the commingling of biopharming compounds are not simply economic. In some parts of the world, the delivery of the wrong kernel of unapproved corn (*e.g., StarLink*) could lead to criminal liability. The U.S. regulatory system is not equipped to inspect every grower and grain handler to ensure that commercial standards for identity preservation are followed to the last detail. The White House has issued a request for "voluntary field-testing" for cross-pollination risks,[97] but the realm of post-harvest commingling is controlled through contractually imposed standards for identity preservation or "channeling"—the term used in the corn industry. Industry efforts at containment of post-harvest commingling are driven by the need to comply with overseas regulatory agencies that will ban grain exports from the United States.

In particular, the mischievous and misinformed parties to the Cartagena Protocol on Biosafety, an international treaty that will regulate biotech crops once it is ratified in 2003, are preparing to lower the boom on any U.S. commodity crops that cannot document zero tolerance containment for all biopharming crops or any other unapproved varieties grown in the United States.[98] Indeed,

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95. *See generally supra* note 1, *available at* http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf.

96. *See infra* Appendix A, at p. 151.

97. *See* Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and to Establish Early Food Safety Assessments for New Proteins Produced by Such Plants, 67 Fed. Reg. 50,578 (Aug. 2, 2002).

98. DREW L. KERSHEN, LEGAL LIABILITY ISSUES IN AGRICULTURAL BIOTECHNOLOGY 21 (Nat'l Ag Law Ctr. Publ'ns ed., 2002), *available at* http://www.nationalaglawcenter.org/publications/articles/kershen.pdf.

many observers predict that the future will hold a *less than zero* tolerance system for grain being shipped from the United States. Under this less than zero tolerance system, each importing nation may require a grain shipper to state to a moral and legal certainty that there could not possibly be any unapproved varieties, in particular, these new bio-pharming varieties that everyone agrees must be kept out of the food chain.

For those wondering how such a system could devastate U.S. grain exports, one need only look "down under" at trade between Australia and New Zealand. In turning away Australian cotton seed, New Zealand turned away a shipment of seed that might have contained unapproved biotech content, without conducting genetic testing, because it knew that Australians were growing a fairly small percentage of biotech cotton.[99] Using a similar approach, the EU has refused shipments of U.S. whole corn for several years running, which some U.S. trade experts say now adds up to $1 billion trade loss. Under the impending biosafety protocol, grain traders might have to state that shipments of grain from the United States "may contain" certain biotech crops that lack regulatory approval overseas, including every biopharming crop that does not have a well-documented identity preservation system behind it.

Given this global trend toward this precautionary approach to biotech crops, the stakes for building generally accepted identity preservation systems for biopharming could not be higher. In addition to billions of dollars in trade from the United States, which directly affects the continued economic viability of many U.S. growers, there will be life or death impacts overseas from misguided precautionary policies and the corresponding inability of the U.S. chain of commerce to segregate certain biotech crops. As this article went to press, forty million starving Africans were at risk of being denied food aid from the United States due to fear of "toxic" biotech crops.[100] African leaders, like growers of food crops in the United States, have legitimate concerns that food aid would end up being diverted as seed to be planted, leading to permanent genetic "contamination" that could preclude future trade with precautionary nations like the EU or domestic recalls of food containing *StarLink* or other unapproved biotech corn

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99. *See, e.g.*, Press Release, Life Sciences Network, Australia's Cotton Crop Could Be All GE-Farmers (Sept. 18, 2002), *available at* http://www.lifesciencesnetwork.com/printpage-news.asp?ID=2478.

100. David Hegwood, Prepared Remarks Before the Biotechnology Forum at the United States Chamber of Commerce, Biotechnology: Following the Rules (Dec. 15, 2002), *available at* http://usinfo.state.gov/topical/global/biotech/02121701.htm.

varieties. As U.S. corn growers know after $2 billion of losses—the *StarLink* billion domestically, and the unapproved-in-EU billion lost in corn trade with the EU—biotech crops need not be toxic to cause economic harm to growers and food companies.

It is a sad irony that these same impoverished African populations could also be the populations that reap the most benefit from innovation in biopharming. Vaccines placed in staple crops could control the infant illnesses that create high mortality rates, and may even help manage the African AIDS epidemic one day. Unfortunately, the EU's precautionary approach to biotech crops appears to be well entrenched in Europe and it is spreading to adjacent nations (e.g., the Slovakian and Croatian dominoes are falling). Asia-Pacific trading partners of the United States are also growing leery of biotech crops.

This deadlock could be resolved someday by the health benefits that biopharmed compounds could bring. These benefits would open markets overseas, as consumer benefits are shown through life-saving innovation and high premiums for growers. Sharing the benefits of biopharming overseas, as has been actively initiated for golden "vitamin A rice"—rice that would prevent blindness in thousands of undernourished consumers overseas—should help to improve consumer attitudes toward biotech crops.

In the face of standards for national approval of biotech crops that allow indefinite waffling about regulatory approval for biotech crops, however, making any laws that emerge a grid of varying requirements, grain traders will have to be alert to the threat of large ocean-going vessels being turned away in particular ports.[101]

Corn exports from the United States to the EU have declined over the past several years, and *StarLink* is estimated to have caused $1 billion in domestic economic impact from the massive recall triggered by the commingling of *StarLink* corn with food.[102] Experts in the identity preservation process for exports of grain have expressed grave concerns for many more billions in grain

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101. *See* Reuters, *Brazil Turns Away GM Argentine Corn* (June 9, 2000), *available at* http://www.safe-food.org/-news/2000-06-18.html (noting Brazilian port authorities turned away two shipments of genetically altered Argentine corn).

102. *See* Phillip Brasher, Associated Press, *Biotech Corn Hurting U.S. Exports* (Nov. 17, 2000), *available at* http://www.connectotel.com/gmfood/ap171100.txt (discussing the economic effects of the *StarLink* corn recall on the United States); Alan Guebert, *Europe's Biotech Battle vs. U.S. Reaches Zenith*, PEORIA J. STAR, Dec. 10, 2002, at C2 (discussing the impact on U.S. corn prices due to decreased exports because of biotech corn concerns).

trade[103] as well as domestic economic impact,[104] if the biosafety protocol continued to lead nations around the world to create trade barriers to biotech crops and any shipments of grain commodities that may contain traces of biotech crops.

Under this looming threat of billion dollar impacts, attorneys for parties with significant capital at stake are scrambling to properly allocate and contain the risks. Mass tort liability can be prevented in some cases by careful use of legal tools, the first of which is the simple contract. If the entire chain of commerce is properly and fairly documented with comprehensive written agreements, then the necessary segregation process can be specified and, one hopes, followed to the last detail throughout the chain of commerce.

VII. THE STATES BEGIN TO REGULATE THE "COMMERCIAL IMPACT" OF BIOTECH CROPS

The Pew Foundation has summarized state law activity relating to agricultural biotechnology for the 2001 legislative year on its website.[105] Almost half of all state legislatures passed bills in 2001 addressing some aspect of agricultural biotechnology, according to new research released by the Pew Initiative on Food and Biotechnology.[106] One hundred and thirty pieces of legislation—112 bills and 18 resolutions—were introduced in thirty-six states, with twenty-two states passing those bills into law.[107] About thirty percent of the bills focused on protecting genetically modified ("GM") crops from willful destruction by radical anti-biotechnology activists.

This state level legislative activity is nothing new. Each successive year has seen a variety of legislative proposals, many of which attempt to direct policy on communicating risks to growers from commingling of biotech crops.[108] In 2000, there was a horde of state law proposals pending, making it nearly impos-

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103. Val Giddings, Presentation to the Biotechnology Industry Organization (Sept. 21, 1995) (stating that "the biosafety protocol is a train headed for a Volkswagen filled with $50 million in U.S. agricultural assets") (presentation personally attended by author).

104. Stephen Censky, *Improving Communication from Seed Production Through Retail, available at* http://www.soygrowers.com/newsroom/releases/documents/aba-rtp2.html (last visited May 12, 2003) (predicting a "cataclysm of lost export trade with the European Union" if identity preservation methods were not carefully implemented – one year before the *StarLink* news broke).

105. *See infra* Appendix B, p. 155.

106. *See id.*

107. *See id.*

108. *See id.*

sible for the biotech industry to effectively lobby each state to ensure its concerns were addressed.[109]

The states have traditionally been left with largely unfettered powers to regulate agriculture within their borders, and "stop sale" of seed at the border if it contains any unwanted living organism, usually weed seed, but any foreign material can come within this regulatory power. In the future, we can expect to see state-level governments continue to take steps to protect U.S. exports.

State and local governments around the world can exercise police power to keep out noxious weeds, including biotech crops that are not approved for export to key export markets.[110] This power includes the abatement of public nuisances, including specific threats that come to the attention of the legislature. As an adjunct to this broad power, state legislatures may create agricultural districts with various powers defined by statute.[111]

Cross-pollination of varieties that would be better off separated is not a new problem—grower districts in various jurisdictions across the United States could emerge as tools to control agricultural nuisances from GMOs.[112] Districts can be declared off-limits to certain varieties that are likely to render the dominant crops in a region less marketable and can also provide a protective function in preventing private nuisance lawsuits.[113] The public entity responsible will have broad discretion to take measures necessary to abate a living threat to agriculture and will be exempted from the law of trespass for actions taken to protect life, health, or property.[114]

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109. *See id.*

110. *See, e.g.*, Press Release, Natural Law Party Wessex, Dorset Farmers Advised to Watch Brazil as GM Crops Decision Sits in Balance (Oct. 13, 1999), *at* http://www.btinternet.com/~nlpwessex/Documents/brasilgmconf.htm.

111. *See, e.g.*, CAL. FOOD & AGRIC. CODE §§ 52,851, 52,901-52,923 (West 2001) (stating nonapproved varieties of cotton require permit to protect "integrity of approved Acala or Pima cotton" in single variety cotton districts).

112. Farmland Info. Library, *State Farmland Protection Database: Agricultural Districts*, *available at* http://www.farmlandifo.org/fic/laws/kwagdis.html (last updated June 6, 2001) (listing districts and statutes affecting farmland). Various states take differing approaches to districting and internet data. *See, e.g.*, OHIO REV. CODE ANN. §§ 929.01-929.03 (West 1999); N.C. DEP'T OF AGRIC. & CONSUMER SERVS., SUMMARY OF COMMODITIES BY COUNTY (2003), *available at* http://www.agr.state.nc.us/stats/cntysumm/index.htm.

113. Farmland Info. Library, *supra* note 112, *available at* http://www.farmlandifo.org/fic/laws/kwagdis.html.

114. Irvine v. Citrus Pest Dist., 144 P.2d 857, 861 (Cal. Ct. App. 1944).

As was previously noted during the 1999-2000 session, the California legislature took steps to create a non-biotech grower district—for rice only—in the entire state of California.[115] Assembly Bill 2622 established California-specific standards for keeping different varieties of rice separate from each other while imposing fees on the sale of rice seeds that pose economic risks.[116] This law was dubbed the "Trojan horse" or "yellow submarine" for its cowardly, underground approach to regulating biotech by some avid biotech supporters who felt blind-sided by the fact that the bill did not specifically mention biotechnology or genetic engineering.

The stated purpose of the bill is to avoid the economic impacts of rice that cannot be exported,[117] which currently means biotech rice, but might also mean rice that harbors diseases. It provides a special committee and its scientific advisors with the power to require identity preservation as a condition of marketing the rice.[118] Various restrictions and fees will be imposed upon any rice deemed to have "commercial impact" so that the identity preservation programs are well-funded. California rice growers market their products worldwide, some in the biotech industry believe the measure is targeted at them.

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115. *See* A.B. 2622, 1999-2000 Leg., Reg. Sess. (Cal. 2000) (codified at CAL. FOOD & AGRIC. CODE §§ 55,000-55,108), *available at* http://www.leginfo.ca.gov (under "Bill Information" link).

116. CAL. FOOD & AGRIC. CODE §§ 55,050-55,052, 55,060-55,063; *see also* A.B. 2622.

117. CAL. FOOD & AGRIC. CODE §§ 55,000-55,003; *see also* A.B. 2622.

118. CAL. FOOD & AGRIC. CODE § 55,040. Powers include:

> (a) Identifying rices that have characteristics of commercial impact. (b) Recommending to the secretary proposed regulations establishing terms and conditions for planting, producing, harvesting, transporting, drying, storing, or otherwise handling rice identified pursuant to subdivision (a), including, but not limited to, seed application requirements, field buffer zones, handling requirements, and identity preservation requirements. All rice identified pursuant to subdivision (a) shall be subject to an identity preservation program. (c) Reviewing the efficacy of terms, conditions, and identity preservation programs imposed on the planting, producing, harvesting, transporting, drying, storing, or otherwise handling of rice identified pursuant to subdivision (a) using the most current industry standards and generally accepted scientific principles.

Id. The law also limits the number of petitions for new rice that are permissible to a given petitioner, which could severely limit the usual practice of submitting many different choices and traits in seeds for biotech crops. *Id.* § 55,040(e); *see also id.* § 55,020 (discussing the establishment of the special committee).

The California Rice Commission, a trade group representing growers and millers, led the crusade to pass this bill.[119] Nearly forty percent of California rice crop is exported[120], over $320 million annually. Japan takes delivery of most of this, and its laws on biotech approvals are strict, with "zero tolerance" for unapproved varieties of biotech crops.[121] Aventis had no approval in Japan for Liberty Link™ rice when the bill was passed. Rice industry experts appointed by the California Secretary of Food and Agriculture will appoint experts, with input from the rice commission, and will use all available legal mechanisms to enforce the standards. Biotech rice will have to be separated from conventional rice during production, distribution, and particularly export.

Special fees apply to rice seed that is deemed to have "characteristics of commercial impact."[122] Statutory fees range as high as five dollars for every hundred pounds of seed, leading to eight dollars per acre planted.[123] The California Rice Commission believes these fees will cover the costs of enforcing identity preservation standards, but will not prevent seed buyers from using the latest innovations in agricultural biotechnology.

These programs for segregation are also evolving in the corn belt, despite strong political influences of life sciences companies. Long before the USDA began exploring its own program for keeping unapproved-in-EU varieties out of corn, the Iowa and Illinois Corn Grower Associations initiated an "IP certification program" named Novecta that sought to ensure that corn grown in those states followed segregation policies keeping unapproved-in-EU corn varieties (*e.g.*, Roundup Ready corn) out of the supply of export corn.[124] This allowed for increased sales to corn processors who ship product to Europe and have to follow EU law.

A voluntary federal program is being proposed by the USDA.[125] The program is designed "to ensure grains, oilseeds, rice, and seed products were not

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119. Dale Kasler, *Biotech Backers Feel Targeted by Rice Bill*, SACRAMENTO BEE, Sept. 2, 2000, *available at* http://www.biotech-info.net/rice_bill.html.

120. *Id.*

121. Jae Hur, Reuters, *Japan Food Recall Revives StarLink Biotech Scare* (May 25, 2001), *available at* http://www.organicconsumers.org/gefood/japanrecall.cfm.

122. Kasler, *supra* note 119, *available at* http://www.biotech-info.net/rice_bill.html.

123. *Id.*

124. *See* NOVECTA, A JOINT PROJECT OF THE ILLINOIS AND IOWA CORN GROWERS ASSOCIATION, *at* http://www.novecta.com/About_Us/about_us.html (last visited Mar. 3, 2003).

125. Randy Fabi, Reuters, *USDA Mulls Voluntary Scheme for GE Crop Segregation* (Aug. 6, 2002), *available at* http://www.organicconsumers.org/gefood/segregation080802.cfm.

inadvertently exposed to genetically modified crops."[126] USDA stated in a Federal Register notice that "the emergence of value-enhanced commodities and a niche market for non-biotechnology-derived commodities have created a greater need to differentiate products in the handling system,"[127] an implicit recognition of the threat posed by commingling of biopharming crops and other unapproved-in-EU varieties of biotech crops. As Reuters reported:

> A USDA spokesman said the industry-funded program would be similar to the federal inspection system for the meat industry. Meat companies create their own food safety program, which is approved and monitored by federal inspectors. The new system "will be flexible enough to incorporate, where appropriate, already existing standards and procedures such as those developed by private organizations," USDA said.[128]

VIII. WILL THE FOOD PROCESSORS REVOLT AGAINST BIOPHARMING?

The concerns of food processors in the aftermath of *StarLink*, as Jeffrey T. Barach, Vice President of Special Projects at the National Food Processors Association, recently informed the trade press, include the following economic impacts should biopharming products ever commingle with food products:

> 1. Claims for illness and injury[129]—the associated costs of resolving illness and injury claims can be quite large, even when the scientific evidence of injury is not particularly sound (*e.g.*, the $9 million settlement of the personnel trying punitive class action arising from the *StarLink* recall,[130] despite the CDC finding that no one claiming allergic injury had the physical evidence to prove it).[131]
>
> 2. Food recalls[132]—probably the largest economic component of *StarLink* legacy. Finished food is costly to recall.

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126. *Id.*
127. *Id.*
128. *Id.*
129. Hileman, *supra* note 7, at 25.
130. Robinson, *supra* note 56, *available at* http://www.biotech-info.net/settlement.html.
131. Michael Howie, *CDC Reports StarLink Not Cause of Allergic Reactions*, FEEDSTUFFS, June 18, 2001, at 1.
132. Hileman, *supra* note 7, at 25.

3. Damage to brand names from future avoidance by consumers[133]—while this is perhaps the most difficult impact to quantify, it could be the largest and longest-lasting impact in some cases. As a result, owners of large-scale national brands will be very sensitive to the commingling threat posed by biopharming.

4. Loss of food processor goodwill[134]—taking one step back in the chain of commerce, food processors who sell to owners of national brands must stake their reputations and goodwill on their quality control methodology.

In an era when biopharming is blooming faster than the regulatory and industry standards needed to contain it, food processors' policies mandating particular containment methodology will weed out successful food processors from those who cannot survive in a zero tolerance environment for certain unapproved biotech crops.

Given the lack of existing U.S. regulations mandating containment measures for bio-pharming and other unapproved varieties, the task of managing these crops will fall to those with capital at stake and lawyers on retainer ready to protect that capital. Companies in the food chain will not stand idly by waiting for another *StarLink* to happen. Grain exporters, in particular, are potentially at risk for losing billions of dollars in overseas markets if there is a bio-pharming commingling episode comparable to *StarLink* corn.

If the plans for containment or stewardship of biopharming are not adequate, then proteins not intended for human consumption could end up in the food supply. At the first sign of such a threat, the entire chain of commerce of potentially responsible companies should join together and seek an injunction stopping the sale or harvest of any rogue biotech crop that is being grown without meeting strict containment protocols. The threat of injunctive relief should be placed in front of those who would market the seed without sound stewardship, and negotiations over proper containment initiated in earnest while there is ample time to implement good management practices. This "second wave" of biotech crops may require an extra layer of stewardship beyond that voluntarily provided to date by biotech companies in their marketing programs. Indeed, the leaders of this effort to contain the occasional inexperienced or sloppy biotech company should be those experienced, careful biotech companies that are practicing sound stewardship. This sharing of stewardship knowledge is a form of self-defense against the common enemy of burgeoning biotech bans. Another economic dis-

133. *Id.*
134. *Id.*

aster on the scale of *StarLink* could banish biopharming to greenhouse containment in perpetuity.

Unlike the United States, where alert grower associations can keep unapproved varieties of biotech crops from commercial use, including a possible court order enjoining the sale, African nations appear to lack the rule of law needed to manage agricultural biotechnology. South America is ahead of Africa, perhaps, but still struggling to manage biotech crops. Brazil imposed a standing injunction against biotech soybeans pending regulatory approval, albeit with porous borders that have allowed smuggling of biotech soybeans. In the United States and Canada, similar injunctions have been sought, but none of the threats of injunctive relief has matured into an actual injunction at this point in time, to the author's knowledge.

A system that is this hostile to biotech crops is clearly in need of fixing so that biotech benefits can be reaped. While U.S. trade lawyers challenge the EU's biotech ban as trade barriers under the World Trade Organization, the Cartagena Protocol on Biosafety is being touted as an international validation of such a precautionary approach to biotech crops. In any challenge to such regulation, however, the United States will surely hear about its own treatment of *StarLink* corn, in which a zero tolerance standard was imposed that mandated a broad recall and extreme measures to contain further spread. If the United States had been alert to the risks that *StarLink* posed, the sale of *StarLink* had been enjoined, or the threat of such an injunction had forced one hundred percent containment, the United States would not be in this untenable position now. If an injunction had been threatened against *StarLink* back in 1998, *StarLink* would not currently impede the United States plan to declare EU policy illegal at the World Trade Organization.

IX. CONCLUSION

Industrial and pharmaceutical applications of agricultural biotechnology require identity preservation methodologies. To maintain identity preservation at the level of zero tolerance for unapproved DNA molecules, a level the EPA panel endorsed for *StarLink*, strict measures should be maintained. Eventually, the USDA could set standards for identity preservation for (1) varieties of GE crops that lack overseas approvals, and (2) the few varieties of industrial and pharmaceutical crop production systems that are entering the marketplace. The latter, in particular, appears to present a risk of repeated food-commingling debacles like the *StarLink* recall. A necessary adjunct to any regulatory regime would be the

use of industry standards and civil injunctive relief to enforce those standards against any maverick whose careless use of agricultural biotechnology would pose a threat of another billion dollar debacle.

APPENDIX A[135]

This chart lists major trading partners of the U.S., but does not include every nation that is signatory to the Cartagena Protocol on Biosafety or the Codex Alimentarius.

KEY:

U = Unclear, N = No, Y = Yes, Y? = Probable Yes by 2003

A = Available, D = Draft, E = Exemption Exists, NA = Not available at this time, UD = Under Development

Country	Biosafety protocol ratified?	Is planting approval required?	Is food approval required?	Is labeling required for GM food?	Is there a required label text?	Must processed foods be labeled?	Must animal feed be labeled?	Must GM food additives/ processing aids be labeled?	Are retail /food service products regulated?
Argentina	U	Y	N	N, UD	N	N, UD	NA	NA	NA
Australia & New Zealand	N	Y	Y	Y	Y, A	Y, E	NA	Y, E	Y, E
Brazil	U	Y	Y	Y, E	Y, A	Y	NA	Y, E	NA
Canada	U	Y	Y	N	N	N	N	N	NA
Chile	U	NA	NA	Y, E	Y	Y	NA	UD	NA
China	Y?	Y	Y	Y	Y, A	UD	NA	NA	Y
Croatia	Y	Y, D	Y, D	UD	N	UD	NA	UD, E	NA

135. This chart is primarily the work of Mark Mansour, Keller & Heckman, LLP, Washington, D.C., and his associates. The data should not be construed as being sufficiently up-to-date so as to justify reliance by grain traders. Mr. Mansour should be contacted for country specific questions at mansour@Khlaw.com.

Country	Bio-safety proto-col rati-fied?	Is planting approval required?	Is food approval required?	Is label-ing re-quired for GM food?	Is there a re-quired label text?	Must proc-essed foods be la-beled?	Must animal feed be la-beled?	Must GM food addi-tives/ process-ing aids be labeled?	Are retail /food service prod-ucts regu-lated?
Czech Republic	Y	Y	Y	Y	NA	Y	NA	NA	NA
Hong Kong	U	NA	NA	UD	UD	UD	NA	NA	NA
India	Y	Y	NA	NA	NA	NA	NA	NA	NA
Indone-sia	U	NA	Y	UD	UD, A	UD	NA	NA	NA
Japan	U	Y	Y	Y, E	Y, A	Y, E	UD	N	NA
Malaysia	Y?	Y	UD	N	N	N	N	N	NA
Mexico	Y	UD	NA	UD	D, A	UD	NA	NA	NA
Nicara-gua	Y	NA	Y	Y	N	Y	NA	NA	NA
Norway	Y	NA	Y	Y, E	Y, A	Y, E	NA	N	NA
Paraguay	U	Y	N	N	NA	N	NA	NA	NA
Philip-pines	U	UD	UD	UD	UD, A	UD	NA	NA	NA
Russia	U	NA	Y	Y, E	Y, A	Y, E	NA	NA	NA
Saudi Arabia	U	NA	Y	Y	Y	Y	NA	Y	NA
Singa-pore	U	NA	UD	UD	NA	NA	NA	NA	NA
South Africa	U	Y	NA	Y, E	Y, A	Y, E	NA	Y	NA
South Korea	Y?	Y	Y	Y, E	Y, A	Y, E	NA	NA	NA
Sri Lanka	U	NA	NA	NA	NA	NA	NA	NA	NA

Country	Bio-safety proto-col rati-fied?	Is planting approval required?	Is food approval required?	Is label-ing re-quired for GM food?	Is there a re-quired label text?	Must proc-essed foods be la-beled?	Must animal feed be la-beled?	Must GM food addi-tives/ process-ing aids be labeled?	Are retail /food service prod-ucts regu-lated?
Switzer-land	Y	NA	Y	Y	Y, A	Y, E	NA	Y, E	Y
Taiwan	U	NA	UD	UD, E	Y, A	Y	NA	NA	NA
Thailand	U	Y	Y	Y, UD	UD	UD	NA	UD	NA
United States	N	Y, E	Y	N	N	N	NA	N	NA

European community	Y	Y	Y	Y, E	Y, A	Y	Y	Y (food additives)	NA
Austria	Y	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
Belgium	U	Y	Y	Y, E	Y, A	Y	Y	Y (food additives)	NA
Denmark	Y	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
France	U	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
Germany	U	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	Y
Greece	U	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
Ireland	U	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
Italy	U	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
Luxembourg	Y	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
Netherlands	U	Y	Y	Y, E	Y, A	Y, E	NA	Y (food additives)	NA
Portugal	U	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
Sweden	Y	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
Spain	Y	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	NA
U.K.	U	Y	Y	Y, E	Y, A	Y	NA	Y (food additives)	Y
Codex	NA	N	UD	UD	UD	NA	NA	NA	NA

APPENDIX B: LEGISLATIVE PROPOSALS CIRCA 2001

Part I

The following chart is a sampling of state legislation during 2001 related to agricultural biotechnology.[136]

Key:

Passed: Bill was passed by state legislatures and (where indicated) by Governor.
Defeated: Bill was brought to a vote and did not pass.
Carryover: Bill was not voted on and there are plans to reintroduce it.
Postponed: Decision to vote on bill has been held for another date (yet to be determined).
Referred: Bill has been sent for review by a committee with jurisdiction over the issue. (Wherever possible, body and date of referral are noted.)
Other: see note

GA HB308

- Topic: Agricultural Contracts
- Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. An agricultural contract, for example, must be accompanied by a disclosure statement explaining the material risks faced by the producer; it must be written in a way that is understandable to a person of average intelligence; and it must indicate that the producer may recover damages caused by a violation of these requirements.
- Status: Referred (Referred to House Committee on Agriculture & Consumer Affairs) on 1/31/2001.

136. The sampling is reprinted with permission granted by the Pew Initiative on Food and Biotechnology. A complete version of the chart may be accessed at http://pewagbiotech.org/resources/factsheets/bills/.

GA SB227

- Topic: Agricultural Contracts
- Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. An agricultural contract, for example, must be accompanied by a disclosure statement explaining the material risks faced by the producer; it must be written in a way that is understandable to a person of average intelligence; and it must indicate that the producer may recover damages caused by a violation of these requirements.
- Status: Referred (Referred to Senate Committee on Judiciary) on 2/21/01.

IA SF254

- Topic: Agricultural Contracts
- Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. The legislation, for example, requires that an agricultural contract must: i) be accompanied by a disclosure statement explaining the material risks faced by the producer; ii) be written in a manner that is understandable by a person of average intelligence; iii) permit the producer to recover damages caused by a violation of these requirements; and iv) prohibit provisions stating that information contained in an agricultural contract is confidential.
- Status: Referred (Reassigned to Committee on Agriculture) on 1/23/02.

IA HF147

- Topic: Regulation
- Description: Requires that GM seed be labeled and prohibits it from being sold in bulk.
- Status: Carryover (Agriculture Committee 1/31/01. No action in 2002).

IA HF257

- Topic: Regulation
- Description: Requires that GM seed be labeled and that the label include recommended planting and management practices required to minimize the risk of other plants being affected by GM pollen.
- Status: Referred to Agriculture Committee on 1/31/01. No action in 2002.

IA HF734

- Topic: Regulation
- Description: Requires GM seed to be labeled and to include information regarding possible environmental consequences of genetic modification as well as sound management practices for minimizing impact to non-GM crops. This legislation also seeks: i) to include -- on GM seed labels -- a notice regarding any financial risks associated with marketing the crop; and ii) to make the entity required to place the label on the seed (e.g. the seed producer) liable for damages caused to non-GM crops if the person who uses the seed (e.g. the crop producer) complies with the management practices outlined on the label.
- Status: Carryover (Referred to Agriculture Committee on 4/24/01).

IA HF741

- Topic: Regulation
- Description: Requires that developers of certain GM seed provide crop producers with a security plan approved by the Department of Agriculture and Land Stewardship. According to this legislation, the plan must include a closed system that provides minimal risk to non-GM crops of GM crop exposure. This legislation also seeks to absolve GM crop producers from liability for possible environmental damages caused GM crops.
- Status: Carryover (Referred to Agriculture Committee on 4/27/01. No action in 2002).

IA SF431

- Topic: Regulation
- Description: Requires that GM seed be labeled and seeks to absolve GM crop producers of liability for environmental damages potentially caused by GM crops. This legislation also requires the Iowa Crop Improvement Association to study several GM seed issues including sound management practices, the segregation of grain produced from GM and non-GM crops, liability and the marketability of GM crops.
- Status: Referred (Referred to Agriculture Committee 4/5/01. No action in 2002).

IA SF454

- Topic: Regulation
- Description: Requires that GM seed be labeled and include information regarding possible environmental consequences of genetic modification as well as sound management practices for minimizing impact to non-GM crops. This legislation also seeks: i) to include -- on GM seed labels -- a notice regarding any financial risks associated with marketing the crop; and ii) to make the entity required to place the label on the seed (e.g. the seed producer) liable for damages caused to non-GM crops if the person who uses the seed (e.g. the crop producer) complies with the management practices outlined on the label.
- Status: Referred (Referred to Agriculture Committee. Reassigned to Agriculture Subcommittee on 1/23/02).

IA SF539

- Topic: Regulation
- Description: Requires that GM seed be labeled and seeks to absolve GM crop producers of liability for environmental damages potentially caused by GM crops. This legislation also requires the Iowa Crop Improvement Association to study several GM seed issues including sound management practices, the segregation of grain produced from GM and non-GM crops, liability and the marketability of GM crops.

• Status: Carryover (Referred to Agriculture Subcommittee on 4/27/01. No action in 2002).

IA SF80

• Topic: Regulation

• Description: Requires that GM seed be labeled and that seed producers develop practices for minimizing exposure of GM crops to non-GM crops. This legislation also seeks to hold the entity that labels the seed liable for any damages caused by such exposure.

• Status: Carryover (Referred to Agriculture Committee on 4/5/01. No action in 2002.)

ID HB272

• Topic: Agricultural Contracts

• Description: Makes provisions for farmers and/or producers to recuperate damages due to failure of a seed manufacturing facility.

• Status: Defeated.

KS HB2278

• Topic: Agricultural Contracts

• Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. This legislation, for example, determines it unlawful for a contractor to discriminate against any producer (i.e. in terms of price paid for a commodity), as well as to provide false information to a producer.

• Status: Carryover (Died in Agriculture Committee on 5/31/02).

KS HB2280

• Topic: Agricultural Contracts

• Description: Provides that an agricultural contract imposes an obligation of good faith.

• Status: Carryover (Died in Agriculture Committee on 5/31/02).

KS HB2281

• Topic: Agricultural Contracts

• Description: Provides for the regulation of agricultural production contracts intended to protect farmers and producers. This legislation, for example, states that a provision which is part of an agricultural contract is void if the provision states that the information contained in the agricultural contract is confidential.

• Status: Carryover (Died in Agriculture Committee on 5/31/02).

KS SB308

• Topic: Agricultural Contracts

• Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. This legislation, for example, requires that an agricultural contract: i) impose an obligation of good faith; ii) be accompanied by a disclosure statement that sets forth the nature of the material risks faced by the producer; iii) indicate that the producer may cancel a contract within three business days after the contract is executed; iv) contain no provisions stating that information contained in the contract is confidential; and v) indicate that if the contractor ends the contract, the contractor may have to reimburse the producer for damages.

• Status: Carryover (Died in Agriculture Committee on 5/31/02).

MA HB3385

• Topic: Regulation

• Description: Places the burden of ensuring environmental and human health safety related to GM crops on biotechnology companies. This legislation states that any entity that genetically engineers organisms for use in the food

supply shall be liable for damages caused by their products unless the harm done was a result of another person violating reasonable safety precautions outlined in a signed agreement by both persons.

• Status: Referred (Referred to the Committee on Natural Resources and Agriculture on 4/23/01) (Accompanying Study ordered 11/7/01).

MA SB1789

• Topic: Regulation

• Description: Places the burden of ensuring environmental and human health safety related to GM crops on biotechnology companies. This legislation states that any entity that genetically engineers organisms for use in the food supply shall be liable for damages caused by their products unless the harm done was a result of another person violating reasonable safety precautions outlined in a signed agreement by both persons.

• Status: Referred (Referred to the Senate Committee on Science and Technology on 1/3/01).

ME LD1266

• Topic: Regulation

• Description: Requires that a manufacturer of GM plants, plant parts or seed shall provide written instructions to all growers on how to plant these items and how to grow and harvest the crop to avoid cross-contamination of a non-GM crop or wild plant populations.

As passed: Same

• Status: Passed (Passed by Governor on 5/31/01)

MN HF150

• Topic: Regulation

• Description: States that a manufacturer of GM seed must provide written instructions about how to plant the seeds as well as grow and harvest the crop to avoid cross-contamination with non-GM crops. This legislation also asserts that GM seed manufacturers: i) must notify agricultural growers using

that GM seed manufacturers: i) must notify agricultural growers using nearby land when GM seed will be planted in the vicinity; and ii) are liable to agricultural growers who suffer damage due to cross-contamination of pollen from GM crops. Lastly, this legislation states that products derived from non-GM crops may be labeled as "free of genetically modified organisms."

- Status: Carryover (Referred to Agriculture Policy on 1/16/01).

MN HF807

- Topic: Regulation
- Description: Eliminates exemptions which permit certain genetically modified agricultural products to be released into the environment without first undergoing an environmental assessment.
- Status: Referred (Referred to Agriculture Committee on 2/12/01.

MN SF1203

- Topic: Regulation
- Description: States that a manufacturer of GM seed must provide written instructions about how to plant the seeds as well as grow and harvest the crop to avoid cross-contamination with non-GM crops. This legislation also asserts that GM seed manufacturers: i) must notify agricultural growers using nearby land when GM seed will be planted in the vicinity; and ii) are liable to agricultural growers who suffer damage due to cross-contamination of pollen from GM crops. Lastly, this legislation states that products derived from non-GM crops may be labeled as "free of genetically modified organisms."
- Status: Defeated (Referred to Agriculture Committee on 3/1/01).

MO HB306

- Topic: Agricultural Contracts
- Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. This legislation, for example, requires that an agricultural contract: i) impose an obligation of good

faith; ii) be accompanied by a disclosure statement that sets forth the nature of the material risks faced by the producer; iii) indicate that the producer may cancel a contract within three business days after the contract is executed; iv) contain no provisions stating that information contained in the contract is confidential; and v) indicate that if the contractor ends the contract, the contractor may have to reimburse the producer for damages.

• Status: Referred (Referred to Agriculture Committee on 2/1/01). No Action 4/4/01.

MS HB1336

• Topic: Agricultural Contracts

• Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. This legislation, for example, requires that an agricultural contract: i) impose an obligation of good faith; ii) be accompanied by a disclosure statement that sets forth the nature of the material risks faced by the producer; iii) indicate that the producer may cancel a contract within three business days after the contract is executed; iv) contain no provisions stating that information contained in the contract is confidential; and v) indicate that if the contractor ends the contract, the contractor may have to reimburse the producer for damages.

• Status: Defeated.

MS SB2865

• Topic: Agricultural Contracts

• Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. This legislation, for example, requires that an agricultural contract: i) impose an obligation of good faith; ii) be accompanied by a disclosure statement that sets forth the nature of the material risks faced by the producer; iii) indicate that the producer may cancel a contract within three business days after the contract is executed; iv) contain no provisions stating that information contained in the contract is confidential; and v) indicate that if the contractor ends the contract, the contractor may have to reimburse the producer for damages.

• Status: Defeated.

NC SB1086

• Topic: Agricultural Contracts

• Description: Seeks to enhance fairness in agricultural contracts by protecting producers of vegetables and other crops from loss caused by unfair, harmful or unethical trade practices of handlers. This legislation, for example, requires that contracts for the production of fruits, vegetable or other crops must be written in plain English and contain a provision that the producer may cancel the contract within three days of its execution.

• Status: Referred (Referred to Committee on Rules and Operations on 4/25/01).

NC HB1426

• Topic: Regulation

• Description: Requires that any person who intends to grow, process, store, sell, transport or otherwise possess experimental (i.e. GM) tobacco must obtain a license from the state Commissioner. The application for such license must be accompanied by a bond in the amount of one million dollars.

• Status: Referred (Referred to House Committee on Agriculture on 5/7/01).

ND SB2145

• Topic: Agricultural Contracts

• Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. An agricultural contract, for example, must: i) be accompanied by a disclosure statement explaining the material risks faced by the producer; ii) be written in a way that is understandable to a person of average intelligence; iii) not contain provisions that state information in the contract is confidential; and iv) permit the producer to recover damages caused by a violation of these requirements.

• Status: Defeated.

ND SB2413

• Topic: Agricultural Contracts

• Description: Requires that if a written contract for the sale of grain does not contain provisions to settle disagreements then the parties shall attempt to resolve those disagreements through mediation or arbitration.

As passed: Same

• Status: Passed (Passed by Governor)

ND SB2280

• Topic: Anti-Crop Destruction

• Description: States that a person who willfully and knowingly damages or destroys any crop, livestock, or commodity produced for personal, commercial, testing or research purposes is liable for twice the costs.

As passed: Same

• Status: Passed (Passed by Governor)

ND HB1338

• Topic: Moratorium

• Description: Bans the sale or planting of transgenic wheat for a period of two years.

As passed: Requests a study of issues related to genetic modification. [Note: The bill originally introduced sought to ban the sale or planting of transgenic wheat for a period of two years.]

• Status: Passed (Passed a revised bill requesting a study of issues related to genetic modification).

ND HB1442

- Topic: Regulation
- Description: Requires that a person holding a patent on a GM seed shall notify a farmer in writing and obtain written permission from the farmer before collecting crop samples to determine whether patent infringement has occurred.

As passed: Same

- Status: Passed (Passed by Governor)

NE LB587

- Topic: Agricultural Contracts
- Description: Provides for the regulation of agricultural production contracts intended to protect farmers and producers. This legislation, for example, determines that it would be unlawful for a contractor to engage in unfair practices against any producer in terms of price paid for a commodity.
- Status: Referred (Referred to Agriculture Committee on 1/18/01). Postponed 4/19/02.

NE LB592

- Topic: Agricultural Contracts
- Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. This legislation, for example, requires that an agricultural contract: i) impose an obligation of good faith; ii) be accompanied by a disclosure statement that sets forth the nature of the material risks faced by the producer; iii) indicate that the producer may cancel a contract within three business days after the contract is executed; iv) contain no provisions stating that information contained in the contract is confidential; and v) indicate that if the contractor ends the contract, the contractor may have to reimburse the producer for damages.
- Status: Referred (Referred to Agriculture Committee on 1/18/01). Postponed 4/19/02.

OK SB162

- Topic: Agricultural Contracts
- Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. An agricultural contract, for example, must: i) be accompanied by a disclosure statement explaining the material risks faced by the producer; ii) be written in a way that is understandable to a person of average intelligence; and iii) permit the producer to recover damages caused by a violation of these requirements.
- Status: Referred (Referred to Judiciary Committee on 3/14/01).

SD HB1136

- Topic: Agricultural Contracts
- Description: Provides for the regulation of certain agricultural production contracts intended to protect farmers and producers. This legislation, for example, requires that an agricultural contract: i) be accompanied by a disclosure statement that sets forth the nature of the material risks faced by the producer; ii) indicate that the producer may cancel a contract within three business days after the contract is executed; and iii) indicate that if the contractor ends the contract, the contractor may have to reimburse the producer for damages.
- Status: Defeated.

VT HB247

- Topic: Moratorium
- Description: Proposes to establish a moratorium on the planting of seeds or plants that are genetically modified. This legislation also seeks: i) to establish a registration process for the sale or distribution of such seeds or plants; ii) to create a commission on the use of genetically engineered seeds or plants in Vermont; and iii) to require food products containing ingredients from genetically engineered plants to have that information on the label.

- Status: Carryover (Referred to Agriculture Committee on 2/9/01).

VT SB79

- Topic: Moratorium
- Description: Proposes to establish a moratorium on the planting of seeds or plants that are genetically modified. This legislation also seeks: i) to establish a registration process for the sale or distribution of such seeds or plants; ii) to create a commission on the use of genetically engineered seeds or plants in Vermont; and iii) to require food products containing ingredients from genetically engineered plants to have that information on the label.
- Status: Carryover (Referred to Agriculture Committee on 2/9/01)

Part II

The following are several examples of various city and state legislative proposals[137]

California:

Active Legislation

1. Vandals that destroy Genetically Modified crops must pay twice the amount of the cost of the damage.
2. Mandatory labeling of packaged food containing at least 1% genetically engineered material.

137. The information contained in this portion Appendix B is reprinted with the permission of the Organic Consumers Association. The list was compiled as of November 2001 and may be accessed on the Organic Consumers website at http://www.organicconsumers.org/ge/usgeleg.cfm.

3. Task force to decide whether genetically modified foods should be served in public schools.

4. Resolution passed through San Francisco Commission on the Environment encouraging support of federal level bills as well as granting preference to organic in city purchasing, awaits full vote by city council.

New York:

Active Legislation

1. Mandatory labeling for milk that is produced by cows that are fed growth hormones. Introduced March 16, 1999. Contact State Assemblyman Clarence Norman, Jr. (518) 455-5262.

2. Five-year moratorium on the sale and planting of genetically engineered seeds. Contact Sarah Johnston, Executive Director, NOFA New York, (518)922-7937.

Minnesota:

Active Legislation

1. Five-year moratorium on the sale and cultivation of genetically engineered seeds.

2. Bill placing liability on seed companies in the event of the contamination of non-GM crops. Past Legislation

3. H.B. 3973 prohibiting the sale of genetically engineered food unless labeled, and providing for penalties and remedies. Not carried over after adjournment, May 17, 2000.

4. S.B. 3638 prohibiting the sale of genetically engineered food unless labeled, and providing for penalties and remedies. Not carried over after

adjournment, May 17, 2000.

5. H.B. 2614 regulating the use of genetically modified organisms. Not carried over after adjournment, May 17, 2000.

6. H.B. 3820 establishing liability for the spread of certain genetically modified organisms; specifies damages. Not carried over after adjournment, May 17, 2000.

7. City Council resolution passed in Minneapolis encouraging support of the federal level bills on safety testing and mandatory labeling; encourages sourcing of organic products in city purchasing and public schools.

Hawaii:

Active Legislation

1. Resolutions mandating that all genetic engineering be reported to the state, and ensuring its responsible use based on the success of the technology for the papaya industry.

Past Legislation

1. H.B. 540 Making an appropriation for the study of the spread of genetically modified organisms or their genes during field testing. Passed February 17, 1989.

2. S.B. 726 Requiring an environmental assessment for the proposal to release within the state a genetically modified organism that has been altered at the molecular or single cell level. Passed March 11, 1993.

Maine:

Active Legislation

1. Labeling for genetically engineered food. Introduced January 26, 1999.

Contact Representative Martha Bagley, (207) 225-6567.

2. Statewide referendum on labeling slated for November 2001.

Past Legislation

1. Labeling for genetically engineered food. Not carried over after adjournment, October 24, 1997. Contact Representative Chartrand.

2. Labeling for genetically engineered food. Voted down in committee, March 30, 1995. Contact former Representatives Heeschen and Ault.

3. Labeling for genetically engineered food. Voted down in committee, March 24, 1994. Contact former Representative Titcomb.

Maryland:

Active Legislation

1. Ban of Terminator Technology.

Past Legislation

1. Prohibits use of rGBH and other growth hormones; requires labeling of genetically engineered foods. Voted down in committee, March 22, 1999. Contact Del. Tony Fulton, (401) 366-5133.

Nebraska:

Active Legislation

1. Seed company liability in the event of the contamination of non-GM crops.

Past Legislation

1. Labeling for genetically engineered food. Not carried over after

adjournment, April 14, 1998. Contact Senator Jennie Robak, (402) 471-2715.

2. L.B. 959 Relating to crop damage and genetic engineering. Defines terms; provides a cause of action for certain crop damage; repeals the original sections; and declares an emergency. Not carried over after adjournment, April 12, 2000.

Michigan:

Active Legislation

1. H.B. 5399 Mandatory labeling of packaged food containing at least 1% genetically engineered material. Referred to House Committee on Agriculture and Resource Management.

Mississippi:

Active Legislation

1. Institution of a system to track all sales of non-GM seeds.

Vermont:

Active Legislation

1. Mandatory labeling of agricultural inputs produced with the use of genetic engineering, including seeds. Introduced January 5, 2000. Contact Senator Cheryl P. Rivers, (802) 234-5803.

2. Planting moratorium bill was reduced to farmer notification, passed by Senate Agriculture Committee 2000, and subsequently held up by Senate Finance Committee. Contact Ellen Taggert, ruralvt@sover.net.

3. H.B. 382 Directing the University of Vermont to study the consequences of genetically engineered crops and livestock on Vermont agriculture.

Carried over to Adjourned Session of 1999-2000 Biennium.

4. H.B. 567 Requesting the University of Vermont study the impact of genetically
engineered crops and livestock on Vermont agriculture.

Past Legislation

1. Labeling for genetically engineered food. Introduced February 26, 1993. Contact former Representative Christiansen.

Iowa:

Past Legislation

1. S.B. 2189 Prohibiting a person from selling or offering to sell genetically modified crop seed if the person includes in the sale price any charges associated with genetically engineering the seed; provides exceptions; sets violation code and punishment for violation. No carryover after adjournment, April 26, 2000.

Oklahoma:

Active Legislation

1. Task force to decide whether genetically modified food should be served in public schools.

West Virginia:

Past Legislation

1. S.B. 605 Requiring foods free from genetically modified components and pesticides served in schools. Not carried over after adjournment, March 19, 2000.

2. S.B. 150 Relating to Plant Pest Act; permits compliance agreements; includes genetically modified organisms within the definition of plant pest since technological changes mandate the capability of the Department to protect public health. Passed April 3, 1991.

New Hampshire:

Active Legislation

1. H.R. 291 proposing a statewide ban on the importation or sale of Seed Sterilization, or "terminator," technology. Sent to three-year study committee. Contact Christina Grimm, NH Health Freedom Coalition, (603) 472-2233.

Past Legislation

1. H.R. 1209 proposing mandatory labeling for foods that contain ingredients derived from plant seeds that have been treated resulting in artificially heightened immunity to any pesticides or herbicides. Failed to pass House. Contact Representative Harold V. Lynde (603) 635-7215.

2. H.R. 221 proposing mandatory labeling for milk products known to contain genetically engineered growth hormone. Failed to pass full vote March 25, 1999. Contact Representative Sandra B. Keans (603) 332-3472.

3. Mandatory labeling for milk products known to contain genetically engineered growth hormone. Not carried over after adjournment, June 25, 1997. Contact former Representative McCarley.

4. Mandatory labeling for milk products known to contain genetically engineered growth hormone. Failed to pass full vote, March 15, 1995. Contact Representative Pamela Coughlin (603) 673-0998.

Pennsylvania:

Active Legislation

1. H.R. 453 urges Congress to enact legislation requiring the labeling of genetically engineered food. Introduced April 11, 2000. Referred to House Committee on Intergovernmental Affairs.

Texas:

Past Legislation

1. H.B. 55 Relating to the release of genetically modified organisms. Prohibits the release of a genetically modified organism unless the person prepares and files an environmental impact assessment. Defines a "genetically modified organism" as an organism that has been altered at the molecular or single-cell level, including an organism changed or created through recombinant DNA techniques or other similar genetic engineering techniques. Passed January 30, 1995.

2. City Council of Austin passed a resolution in support of the federal level bills encouraging mandatory labeling and safety testing.