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An Agricultural Law Research Article

**Do European Union Non-Tariff Barriers Create  
Economic Nuisances in the United States?**

by

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August, 2005

Originally published in the Journal of Food Law & Policy:  
1 J. FOOD L. & POL'Y 87 (2005)

DO EUROPEAN UNION NON-TARIFF BARRIERS  
CREATE ECONOMIC NUISANCES IN  
THE UNITED STATES?

*Thomas P. Redick & Michael J. Adrian\**

ABSTRACT

*The European Union's new traceability system for biotech crops will lead to the proliferation of non-tariff barriers affecting biotech crops. This, in turn, will lead to economic dislocation and attendant liability in the United States, which is losing billions of dollars in export trade. A chain of complex legal problems will arise for United States-based companies as they strive to trace particular genetically modified (GM) events and avoid commingling. The European Union (E.U.) tracing law for biotech crops applies at each stage of commodity commerce, from grain shippers leading back through elevators, growers, and seed companies. Warranty liability could arise from denial of entry in the ports of the E.U. and any trading partners following a similar "zero tolerance" approach (e.g., China, New Zealand, Japan, etc.) as shippers denied entry use the E.U.-imposed tracing system to trace unapproved-in-E.U. biotech crops back to growers or biotech seed companies. Nuisance liability could arise as growers look to their neighbors for the source of their warranty violation. E.U.-mandated documentation will expedite the process of establishing liability for commingling of the variety of biotech crop.*

*Given the economic impact that the E.U.'s zero tolerance could have upon grain trading and agricultural innovation in the United States, and the legal claims arising from such an impact, United States agribusiness needs legal mechanisms to prevent liability (or allocate it fairly) for those impacted at every stage in the chain of commerce. Without such prevention, growers, seed companies, and grain buyers could become embroiled in claims*

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against one another (i.e., common law claims of warranty, nuisance, trespass, etc.). To prevent liability, businesses need legal tools that could help prevent economic loss and liability claims. These tools include grower or stewardship agreements, grower districts, and industry stewardship (standards for identity preservation).<sup>1</sup>

To reverse E.U. tracing policy and the proliferation of these trade barriers, the United States may need to maintain a “biosafety body count” that measures the human health and ecological impact of E.U. tracing policy. If scientific analysis shows a genuine benefit from biotech crops for human health or the environment, then both regulatory law and products liability law will dictate the increased use of the “best available” technology—biotech crops—as a tool for environmental conservation and avoiding products liability claims arising from impacts to health.

## I. INTRODUCTION

On April 18, 2004, the E.U.’s Directives on Traceability and Labeling went into effect.<sup>2</sup> The laws apply at “each stage” of commodity commerce, from grain shippers leading back through elevators, growers, and seed companies. The practical effect of the E.U. laws is to impose a “zero tolerance” standard for biotech crops that have not received regulatory approval from the E.U., and the Traceability & Labeling (“T & L”) Directives will lead to genetic testing of shipments of United States commodities exports. The E.U. is showing signs of an intent to use genetic tests to trace every kernel, bean, or cottonseed that contains the wrong genes (those lacking regulatory approval in the E.U.), using a “zero tolerance” standard. Even approved biotech crops will be subject to labels, with a 0.9 percent tolerance that will be difficult to meet in United States production without high costs.

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1. “Identity Preservation” is a term for growing crops in a manner that ensures a contractually agreed to level of genetic purity at delivery. The American Soybean Association (“ASA”) has created guidance on Identity Preservation. See American Soybean Association, *Grower Opportunities for Identity Preserved Value-Added Soybeans*, at <http://www.amsoy.org/ipvas/default.htm> (last visited Jan. 20, 2005).

2. Commission Regulation 1829/2003, 2003 O.J. (L 268) 1, 2; Commission Regulation 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Council Directive 2001/18/EEC, 2003 O.J. (L 268) 24, 25. The European Union (“E.U.”) directives on traceability and labeling 1829 and 1830 (9/22/03) are collectively called “T&L Directives” throughout this article. See also Margaret Rosso Grossman, *Traceability and Labeling of GM Crops, Food, and Feed in the European Union*, 1 J. OF FOOD L. & POL’Y 43 (2005).

E.U. officials said these new T&L Directives would be followed by a lifting of the de facto moratorium<sup>3</sup> on regulatory approval of biotech crops,<sup>4</sup> which has created a non-tariff barrier to trade with the United States. In actuality, the new laws appear to be tailored to avoid a legal challenge at the World Trade Organization (“WTO”), while maintaining a regulatory system that denies entry to small traces of biotech crops that have well-documented benefits to the environment or public health.

This “zero tolerance” standard for unapproved biotech crops (most of which are grown in the United States) will persist for years to come, pending a WTO challenge and subsequent E.U. compliance with a pro-U.S. ruling. E.U. trading partners will follow a similar “zero tolerance” approach (e.g., China, New Zealand, Japan, etc.). Liability for the grower could begin with a grower in the United States who unwittingly purchased impure seed and knowingly or unknowingly waived his right to a warranty of merchantability for fitness for the intended purpose of export.

This article is structured to provide the reader with a brief overview, at Part II, of the E.U.’s complex regulatory policy and the United States’ reaction to the new E.U. laws. Over a dozen common forms of crops (e.g., potatoes, tomatoes, etc.) have been dropped to date, in large part due to antibiotech laws in the E.U.; these crops had passed regulatory approval in the United States and had shown no signs of adverse food safety or environmental effects.<sup>5</sup> While there are genu-

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3. See CNN, *Brussels Lifts E.U. Ban on GM Food*, May 14, 2004, at <http://edition.cnn.com/2004/WORLD/europe/05/19/commision.gm/index.html/> (last visited Jan. 20, 2005). The intervening years have featured no new regulatory approvals of U.S.-based companies’ applications for E.U. approval until early 2004, when Syngenta’s sweet corn was approved. See *id.* The European system for approval of genetically modified crops for use in food and feed ground to a virtual halt in late 1997, catching the biotech industry and U.S. trade representatives by surprise. At least two billion dollars in corn trade has been lost due to E.U. policies. See, e.g., *Commission Brings GMO Moratorium to an End*, AGRA EUROPE (May 21, 2004).

4. For purposes of this paper, crops produced using recombinant DNA (“rDNA”) methods will be referred to as “biotech crops.”

5. See, e.g., Lance Gay, *Hope for Biotech Foods Fizzles: Economics, Regulations Blamed, and Market Fails to Materialize*, DETROIT NEWS, May 16, 2004, available at <http://www.detroitnews.com/2004/business/0405/16/a11-153949.htm>.

A decade ago, amid much fanfare, the Food and Drug Administration approved for supermarket sales the first of what promised to be a new generation of genetically modified crops: an ordinary-looking tomato called the Flavr Savr. Now, the Flavr Savr is nowhere to be found on market shelves. Neither are any of the other genetically modified crops (e.g., strawberries, melons, lettuce, potatoes, etc.) that won government approval after millions of dollars spent on research and development. *Id.*

ine concerns that have to be addressed,<sup>6</sup> these risks are manageable and do not justify the worldwide moratorium on biotech crop marketing that E.U. policies will create.

In Part III, the authors review the case law on “nationwide nuisance” class action lawsuits—legal mechanisms that secure compensation for those impacts at stages in the chain of commerce where the growers, seed companies, and grain buyers meet (i.e., common law of warranty, nuisance, trespass, etc.). This article also reviews legal tools available to U.S.-based businesses that could help prevent economic loss and liability claims. These tools include grower agreements, grower districts, and industry standards for “identity preservation.”<sup>7</sup>

After reviewing the tools proposed for preventing liability, in Part IV this article further examines the E.U. policies on biotech crops and briefly outlines the potential implications for the environment and human health in the United States, the E.U., and their trading partners around the world. The authors suggest that the E.U. policy cannot be sustained, given troublesome “relative risks” posed by traditionally-bred counterparts to existing biotech crops (from carcinogen-free corn to soil-conserving biotech soybeans). If scientific analysis shows a genuine benefit from biotech crops for human health or the environment, then both regulatory law and products liability law will dictate the increased use of the “best available” technology (biotech crops) as a tool for avoiding products liability and promoting environmental conservation. History will not look kindly upon our “Biotech Century” if we have banished from the marketplace the best biotech innovations at the cost of countless harms, in terms of lives and species lost.

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*See also* E-mail from Kimball Nill, Technical Issues Director, International Marketing, American Soybean Association to Thomas P. Redick (Sept. 21, 2004) (on file with author) (stating that the following crops had each lost the ability to utilize biotech due to commercial barriers: Flax, Tomato, Sugarbeet, Potato, Lettuce, Rice, Tobacco, Wheat, and Melons). At the time of this article’s publication, such crops are only grown in field trials or tight containment to avoid commingling. *See* Andrew Pollack, *Narrow Path for New Biotech Food Crops*, N.Y. TIMES, May 20, 2004, at C1.

6. For example, there are wild relatives of the squash plant growing in the United States that provide a genetic reservoir of genes of use for future plant breeding. If biotech squash were to become so prevalent that it evolved into a weedy species (particularly one with herbicide resistance), there could be a potential environmental impact to be managed. *See, e.g.*, Jane Rissler of the Union of Concerned Scientists, Comments at a USDA Public Meeting on a Transgenic Virus-Resistant Squash, June 21, 1994, at [http://www.ucsusa.org/food\\_and\\_environment/biotechnology\\_archive/page.cfm?pageID=380](http://www.ucsusa.org/food_and_environment/biotechnology_archive/page.cfm?pageID=380) (last visited Apr. 27, 2005).

7. *See generally supra* note 1.

Voluntary traceability of food is common in certain industry sectors. Many food companies use the voluntary international quality standard ISO 9000 as a form of quality control,<sup>8</sup> and some biotech seed companies use traceability under the same standard.<sup>9</sup> The United States has entered into the realm of mandatory traceability for food products as a counter-terrorism measure,<sup>10</sup> using the “national security exemption” to international trade agreements to justify the costs these measures impose upon importing food products to the United States.

The E.U. does not have a national security justification for tracing and labeling GM products, so it relies upon a combination of food safety and environmental protection concerns. Given the recent history of the regulation of food safety in the E.U., it is easy to understand how the E.U. arrived at its embrace of the “precautionary approach” to biotech crops. The E.U.’s fragmented and inadequate regulatory system for food safety has failed consumers in many different instances. The loss of faith in E.U. regulatory officials began with the E.U.’s inability to prevent the outbreak of mad cow disease (bovine spongiform encephalopathy, or BSE), despite warning signs that many scholars argue appeared all too clear in the harsh light of hindsight.<sup>11</sup> The mad cow disease crisis arose from a protectionist refusal to switch from domestic protein (other cows) to safe foreign soy protein sources, and a refusal to act quickly in response to early signs. E.U. consumers on the mainland also endured other food safety crises, such as toxic dioxin-tainted poultry scandals in Belgium.<sup>12</sup>

Compounding these E.U. food safety failures, the United States biotechnology industry suffered through two widely reported incidents of illegal commingling of biotech crops not approved in the United States for food. These incidents involved StarLink (seed only)

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8. See generally International Organization for Standardization, *Homepage*, at <http://www.iso.org> (last visited Apr. 27, 2005).

9. See, e.g., Pioneer, *ISO 9000 Program at Pioneer*, at [http://www.pioneer.com/pioneer\\_info/corporate/isoprogram.htm](http://www.pioneer.com/pioneer_info/corporate/isoprogram.htm) (last visited Apr. 27, 2005).

10. See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 596 (to be codified in scattered sections of the U.S. Code).

11. See, e.g., Joseph S. Levine, *20/20 Hindsight*, *Nova*, at <http://www.pbs.org/wgbh/nova/madcow/hindsight.html> (last visited Apr. 27, 2005).

12. See, e.g., Kelly Mescher, *U.S. Exports to Europe Remain High; Concern over E.U.’s Traceability Laws Linger*, *SOYBEAN REV.*, Oct. 2002, at 14-15.

corn<sup>13</sup> and ProdiGene corn containing piglet diarrhea vaccine, which was plagued by two unintentional environmental releases in violation of permits.<sup>14</sup> With both the E.U. regulations and the biotech industry suffering from this recent disappointing track record, European consumers are understandably suspicious of biotech crops from the United States.

#### A. Regulation Nos. 1829 and 1830 of the European Parliament

The E.U. T&L Directives are intended to enhance the protection of the health and welfare of humans, animals and the environment.<sup>15</sup> The new regulatory scheme establishes procedures authorizing GM food and feed for distribution within the European Community (E.C.). Biotech crops exported from the United States in shipments of grain (known in the industry as “commodities”)<sup>16</sup> must comply with laws and regulations mandating labeling of both GM food and feed.<sup>17</sup>

#### 1. Regulation 1829—Labeling

Regulation 1829 amends existing E.U. directives on GM labeling of imports, significantly expanding the scope of products that must be labeled.<sup>18</sup> While labeling has been required in the E.U. for some GM food products since 1997 (i.e., those with detectable traces of biotech GM crops), those regulations only required the labeling of GM seeds, plants, and foods derived from GM plants that exhibited DNA or protein of a GM origin. If no trace of GM DNA or protein was present in a final product, no GM label was required.<sup>19</sup> GM animal feed was not covered under the previous GM labeling system.<sup>20</sup> Under the new system, however, all foods and animal feed with ingredients derived from

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13. See *In re Starlink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 834-35 (N.D. Ill. 2002).

14. See Peter Montague, *Bumpy Road for Biotech*, Environmental Research Foundation, at [http://www.rawfoodinfo.com/articles/art\\_bumpyroadforGE.html](http://www.rawfoodinfo.com/articles/art_bumpyroadforGE.html) (last visited Apr. 27, 2005).

15. Commission Regulation 1829/2003, 2003 O.J. (L 268) 1.

16. See, e.g., Army Corps of Engineers, *Navigation Data Information System, Great Lakes Grain Traffic*, at <http://outreach.lrh.usace.army.mil/Industries/Grain/Grain%20GL.htm> (last visited Apr. 27, 2005).

17. Commission Regulation 1829/2003, 2003 O.J. (L 268) 2, 3.

18. See generally Grossman, *supra* note 2, for information on the E.U. regulatory system for biotech crops.

19. See PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, U.S. vs. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD (Aug. 2003), available at <http://pewagbiotech.org/resources/issuebriefs/europe.pdf>.

20. See *id.*

GM crops must be labeled, subject to a tolerance of 0.9 percent for “accidental” (or “adventitious”) presence of approved biotech crops.<sup>21</sup> The Labeling Directive tolerance of 0.9 percent only applies to biotech crops that the E.U. has approved for food use.

Perhaps the most controversial section of Regulation No. 1829 is Paragraph 16, which states that the regulation should cover food and feed produced *from* a genetically modified organism (“GMO”) that has no detectible residue of genetic modification (e.g., soybean oil) but not food and feed produced *with* a GMO.<sup>22</sup> This “distinction by preposition” has vague determining criteria: that which is “from” GMOs, like soybean oil, is subject to labeling and traceability, even if any detectible residues derived “from” the GM source material are not present.<sup>23</sup> That which is made “with” a GMO (e.g., cheeses using rennet enzymes derived from GM bacteria) is not subject to GM labels or traceability, as long as no residue or the microbe remains in the product.

The regulation elaborates upon this by describing a few different scenarios where the regulation would not apply (e.g., products from an animal fed “with” GMO feed).<sup>24</sup> Most notably, the enzymes and processing aids manufactured by major E.U. companies, such as Novo Nordisk,<sup>25</sup> are exempt from regulation under the T&L Directives, while soybean oil produced “from” soybeans grown in the United States will be subject to labeling and tracing. The increased costs led E.U. food manufacturers to switch to alternative sources of vegetable oil, abandoning soybean oil inputs to avoid GM labels. The European Commission officials have attempted to rationalize this distinction by claiming that these are not GM ingredients, but merely processing aids not present in the final product.

The following hypothetical involving beer manufacturers illustrates how the E.U.’s “distinction without a difference” could lead to unfair discrimination against imports. By law, beer made in Germany is subject to restrictions on the use of corn inputs, which is not the case for beer in the United States and Japan. Beer in Germany can use GM yeast, however, and comply with the E.U.’s T&L Directives,

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21. *See id.*

22. *See* Commission Regulation 1829/2003, 2003 O.J. (L 268) 2, 3.

23. *See* Regulation 1829/2003, 2003 O.J. (L 268) at 2, 3.

24. *See* Regulation 1829/2003, 2003 O.J. (L 268) at 2, 3.

25. NOVO NORDISK, NOVO NORDISK ANNUAL REPORT 2004 32-33 (2004), *available at* <http://www.novonordisk.com/investors/reports/reports.asp> (explaining Novo Nordisk is a pharmaceutical company headquartered in the E.U. with offices in seventy-eight countries).

provided no detectable residue of micro-organisms is present. The following chart illustrates this “distinction without a difference.”

PRECAUTIONARY PROTECTIONISM BY PREPOSITION:  
THE E.U.’S “FROM V. WITH” DISTINCTION

Product	Genetically Modified YEAST?	Genetically Modified CORN?	European Union LABEL?	European Union TRACING?
Non-E.U. Beer	No	Yes	Yes	Yes
E.U. Beer	Yes	No	No	No

To the extent that beer from the United States or Japan has corn inputs, it may be forced to apply GM labels and maintain paperwork at each stage of commerce, even if no GM yeast was used in the manufacturing process.

## 2. Regulation 1830—Traceability

As defined by Regulation No. 1830, traceability refers to the ability to trace GMOs and products produced from them (but not products made “with” them, such as cheese and beer) at all stages of their production and distribution.<sup>26</sup> This regulation mandates tracing of GM products from “farm to fork,”<sup>27</sup> or more accurately “seed to shelf.” The grain industry and its suppliers will have to develop systems that can identify to whom and from whom GM products were received. These records of tracing must be made available to E.U. inspectors, and all parties must retain their records for five years.<sup>28</sup>

## 3. “Zero Tolerance” for Unapproved-in-E.U. Varieties

To reach the “zero tolerance” for unapproved-in-E.U. biotech crops at every stage in the seed production, commercial harvest, and

26. See Commission Regulation 1830/2003, 2003 O.J. (L 268) 24, 25.

27. See Douglas Powell, *What’s in a GM Label?*, Mar. 30, 2003, available at <http://www.foodsafetynetwork.ca/gmo/labelgm.htm>.

[Consumers need a] full farm-to-fork tracing and segregation process that can guarantee the origins of even the most minor of ingredients (such as the cornstarch used to thicken the gravy in that frozen meat pie). Although theoretically achievable, such a process is both difficult and enormously expensive. That’s why every country that has implemented a mandatory labeling regime has also included an extensive network of exemptions and loopholes. *Id.*

28. See Ferriere, *infra* note 41 (“Traceability will impose a five-year recordkeeping requirement.”)

distribution process, U.S. producers must completely segregate GM varieties from conventional varieties. The E.U. will allow some unintentional mixing of approved or partially approved varieties at some point in this process (e.g., through pollen drift, commingling in bins that are not completely cleaned of grains, or even dust), if the amount of detectable GM content does not rise above the applicable threshold (0.5 percent or 0.9 percent) tolerances.<sup>29</sup> For biotech crops containing particular genetic events that are not yet approved, the permissible percentage of commingling is zero.

The E.U. regulatory approval system adds an extra layer of complexity by creating a middle ground category for the “partially approved” biotech crop.<sup>30</sup> This category allows a tolerance of 0.5 percent of particular GM genetic events that have not been fully approved by the European Commission but have initial clearance from the European Commission Scientific Committee. That food will not be barred from the European markets.<sup>31</sup> For biotech crops that do not have such clearance, the regulatory tolerance remains at the commercially impossible<sup>32</sup> threshold of zero.

#### 4. E.U. Officials Defend Their Directives

As part of its rationale for the tracing system, the E.U. cited in its regulations the need for consumers to be fully informed as to GMOs and products that contain them.<sup>33</sup> The E.U. believes this will help restore consumer confidence in the food regulatory system, allowing consumers to make better-informed decisions regarding foods that may or may not contain GM ingredients.

Within the past three years, nearly every major official with a position relating to the regulations, including E.U. Health and Consumer Protection Commissioner David Byrne,<sup>34</sup> E.U. Environment Commis-

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29. *Id.* Zero for varieties unapproved in European Union, 0.5 percent for preliminary clearance, 0.9 percent for labeling. Sonja Hillgren, *Biotech and Fortress Europe*, FARM J., July 28, 2003, available at [http://www.agweb.com/get\\_article.asp?pageid=99799&newscat=GN](http://www.agweb.com/get_article.asp?pageid=99799&newscat=GN).

30. See Grossman, *supra* note 2.

31. See Hillgren, *supra* note 29.

32. The legal doctrine of “commercial impossibility” is discussed *infra* at III.D.1. While the European Union was perhaps unaware of this readily foreseeable complication, its traceability system introduces a “zero tolerance” for products that do not pose a wider recognized health risk.

33. Commission Regulation 1830/2003, 2003 O.J. (L 268) 25.

34. News Release, European Union, Authorizations, Consumer Confidence Key to GMO Acceptance in Europe, Feb. 3, 2004, available at <http://www.eurunion.org/news/press/2004/20040013.htm>.

sioner Margot Wallstrom,<sup>35</sup> and the Minister-Counselor for Agriculture, Fisheries and Consumer Affairs of the European Commission, Tony Van der Haegen,<sup>36</sup> have all gone on record as justifying the new rules with similar rhetoric about “consumer confidence” and “collective preferences.” In evocative language, European activist groups have also argued that GM food should not be “crammed down the throats” of E.U. consumers,<sup>37</sup> while also noting that the new regulations will accompany an opening of the closed E.U. approval process for biotech crops.

However, with the ostensible “lifting of the moratorium”<sup>38</sup> that accompanied the passage of the T&L Directives (and the approval E.U.-wide of some biotech corn varieties) the backlash in E.U. member states has begun. As this article was being submitted for publication, the Friends of the Earth activist group announced an initiative that would encourage member states in the E.U. to create “GM free” zones within their borders.<sup>39</sup>

Member of the European Parliament Janusz Wojciechowski, Vice-President of the Agriculture Committee, said:

Poland and other new E.U. Member states want to avoid the errors that the old E.U. Member states made in the past in order to preserve our traditional agriculture. We may produce less than them but our food must be natural and consumer-friendly. Only such a policy can help us to uphold small farms and maintain jobs in rural areas.<sup>40</sup>

## 5. Enforcement Methodologies

In a presentation given at Iowa State University on November 14, 2003, Jean Ferriere of the E.U.’s Trade Directorate informed an audience of United States growers and grain shippers that the E.U.’s new

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35. See *Farming: “Genuine Fear” of GMOs in Europe*, NATIONALIST (CARLOW, IRELAND), July 15, 2002, available at <http://archives.tcm.ie/carlownationalist/2002/07/15/story2310.asp>.

36. Press Release, Pew Initiative, Consumer Trust in Government Is Key to Policies on Genetically Modified Food – on Both Sides of the Atlantic, Oct. 24, 2001, available at <http://pewagbiotech.org/newsroom/releases/102401.php3>.

37. See, e.g., *Commission Brings GMO Moratorium to an End*, AGRA EUROPE (May 21, 2004).

38. See Grossman, *supra* note 2, at 45-46.

39. Barbara Thauront, Independent Media Centre, *Campaign for GM Free Zones and Regions Gathers Force*, Sept. 14, 2004, available at [http://www.indymedia.ie/newswire.php?story\\_id=66573%26print\\_page=true%26include\\_comments=true](http://www.indymedia.ie/newswire.php?story_id=66573%26print_page=true%26include_comments=true); see also *infra* Section III D (discussing the creation of such “GM free” zones).

40. See Thauront, *supra* note 39.

T&L Directives would target non-GMO shipments.<sup>41</sup> When pressed about enforcement capacity, he acknowledged the role that non-governmental organizations would play in conducting independent tests that could find traces of unapproved-in-E.U. varieties in grain shipments arriving at E.U. ports. The E.U. is adding testing centers to help activists currently enforcing its regulatory program track biotech crop content in United States products that were not previously subject to scrutiny for unapproved-in-E.U. biotech content.

Reports of Greenpeace<sup>42</sup> testing commodities, shipments, and food products are fueling concerns that United States commodity shipments may be denied entry.<sup>43</sup> As explained later in this article, the testing of shipments for evidence of unapproved events (each variant of a new trait introduced by biotech methods is a regulated “genetic event”) can lead to liability-triggering events that trace back, via contractual warranties, to a producer who sold an unapproved-in-E.U. variety to a grain buyer. Like a row of dominoes toppling by prior agreement, each seller of the unapproved variety can be held liable under commercial law (breach of warranty) for causing the “contamination” of a large quantity of export soybeans with varieties of biotech crops that lack approval in major overseas markets. In anticipation of such claims, insurers have rewritten policies for grain shippers and growers, excluding liabilities relating to biotech crops (with the risks of unapproved varieties of biotech crops driving the change).<sup>44</sup>

### *B. U.S. Critique: Pretextual Regulations and the Cheese/Beer Loopholes*

The E.U.’s T&L Directives did not arrive without significant advance notice and discussion among United States and E.U. governments and their respective industry leaders. The U.S. government and the E.U. governments have engaged in a “Transatlantic Business

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41. Notes from speech by Jean Ferriere, Presentation to Public Forum on the European Union Traceability and Labeling Regulations, Iowa State University (Nov. 14, 2003) (explaining that “non-GMO” shipments will be periodically tested to verify that non-declarations are true) (on file with authors).

42. See generally Greenpeace, *About Us*, at <http://www.greenpeace.org/usa/aboutus/> (last visited Apr. 27, 2005) (explaining that Greenpeace is a well-known organization that is concerned with environmental issues); Greenpeace, *Global Action for a Global Problem*, at <http://www.greenpeace.org/usa/news/global-action-for-a-global-pro> (last visited Apr. 11, 2005) (“To protect the public’s health and prevent the contamination of the environment, [Greenpeace is] confronting genetic engineering everywhere [they] can, be it along the export routes or along the food chain.”).

43. See Reuters Newswire, *Greenpeace Bars Argentine GMO Soy From Brazil Port* (May 3, 2004) (on file with author).

44. See, e.g., Marc S. Mayerson, *Insurance Recovery for Losses from Contaminated or Genetically Modified Foods*, 39 TORT TRIAL & INS. PRAC. J. 837 (2004).

Dialogue” (“TABD”)<sup>45</sup> for nearly a decade that has discussed various trade issues, including E.U. member nations’ objections to biotech crops.<sup>46</sup> The TABD recommended the formation of an E.U.-U.S. industry and government group that allowed E.U. and U.S. biotechnology and food corporations to meet regularly. The TABD’s biotech initiative, led by Unilever<sup>47</sup> and Monsanto,<sup>48</sup> was formed “to identify potential causes for trade difficulties and propose ways to eliminate them.”<sup>49</sup> In 1998, this process was viewed by the United States as a lever for lifting the E.U. “moratorium” on regulatory approval for biotech crops, such as Bt corn (a category of biotech crop that had several unapproved varieties commingled in U.S. corn supply in 1998).<sup>50</sup> Over time, however, the TABD came to realize that the E.U. vision of biotechnology process-based labels would create barriers to trade.<sup>51</sup>

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45. See, e.g., Trans-Atlantic Business Dialogue U.S. Office, *Trans-Atlantic Business Dialogue Report to the U.S.-E.U. Summit in Ireland, 26 June 2004: Establishing a Barrier-Free Transatlantic Market: Principles and Recommendations*, available at <http://128.121.145.19/tabd/media/TABDReportFINAL22AprilUS.pdf> (mentioning agriculture, including subsidies but not biotech crops). The TABD group provides recommendations and agenda items for U.S.-E.U. economic summits, not exclusive to biotech issues. See, e.g., Transatlantic Business Dialog, *About the TABD*, at [www.tabd.com/about](http://www.tabd.com/about) (last visited Apr. 27, 2005).

46. See generally TABD, *Rome Communiqué*, Nov. 7, 1997, available at <http://128.121.145.19/tabd/media/1997RomeCEOReport.pdf> (forming joint TABD group on biotech issues and indicating “agri-biotechnology” is a particular area for reform); see also Russell Mokhiber and Robert Weissman, *TransAtlantic Business Dialogue: Corporate Conspiracy*, Nov. 20, 2000, available at <http://www.commondreams.org/views/112000-103.htm> (referring to the “top U.S. side concerns: Italian restrictions on genetically modified foods”).

47. E.U.-based Unilever is comprised of various entities that make up one of the world’s largest food and personal care products companies. See generally UNILEVER, UNILEVER ANNUAL REVIEW 2003 (2004), available at [http://www.unilever.com/images/annual\\_review\\_English\\_03\\_tcm3-4018\\_tcm13-5396.pdf](http://www.unilever.com/images/annual_review_English_03_tcm3-4018_tcm13-5396.pdf).

48. U.S.-based Monsanto is a biotech company focused on increasing agricultural productivity through science. See Monsanto Company, *About Us*, at [http://www.monsanto.com/monsanto/layout/about\\_us/default.asp](http://www.monsanto.com/monsanto/layout/about_us/default.asp) (last visited Apr. 27, 2005).

49. *TABD: Tiptoeing Toward a Transatlantic Market*, CORP. EUROPE OBSERVER (CEO Quarterly Newsletter, Amsterdam), May, 1998 at 1, available at <http://www.corporateeurope.org/observer1/tabd.html>.

50. *Id.* (stating that “Franklin Vargo, acting assistant secretary of commerce, is jubilant about this ‘closer and more productive U.S.-European cooperation.’” In particular, Vargo mentions that the NTA process has “solved obstacles that had prevented U.S. exports of genetically engineered ‘BT corn.’”).

51. See, e.g., TABD, *Trans-Atlantic Business Dialogue Report (TABD) 2001 CEO Report*, at 10, available at <http://128.121.145.19/tabd/media/2001DCBrusselsCEOReport.pdf> (noting potential “technical barriers to trade” including “process and production labeling (PPMs) [such as] mandatory biotechnology labeling” that would create trade barriers); see also TABD, *Chicago Conference Report*, at 32, available at <http://128.121.145.19/tabd/media/2001ChicagoConferenceReport.pdf>.

## I. United States Government

When the E.U. proposed its T&L Directives, the Bush Administration asserted that the E.U. labeling scheme was unnecessary and pretextual (i.e., illegal trade discrimination favoring domestic interests). On May 21, 2003, U.S. President George W. Bush referred to the theme of “unfounded, unscientific fears” that allegedly motivated the E.U. in pursuing its biotech agenda.<sup>52</sup> In the same speech, President Bush reiterated the belief that the E.U.’s stance has brought about a secondary problem, as its policy contributed to the hunger problems in Africa.<sup>53</sup> Moreover, this unwarranted focus on a non-existent threat posed by tiny bits of DNA, in a world that happily consumes traces of animal feces, insect parts, and known carcinogens,<sup>54</sup> may distract regulatory agencies from their appointed task of regulating actual risks to health.

U.S. Undersecretary for Economic, Business, and Agricultural Affairs Alan Larson questioned the scientific basis for the E.U.’s requirement of labels on GM foods and called upon the E.U. to utilize rigorous, legitimate scientific risk assessment to dictate policy.<sup>55</sup> Larson cited a European Commission study that reviewed eighty studies on biotech crops, and this study found that classical (i.e., conventional) food safety risks could exceed those posed by biotech crops.<sup>56</sup>

Paragraph 16 of Regulation No. 1829 distinguishes between food and feed produced “from” a GMO and food and feed produced “with” a GMO without a scientific basis.<sup>57</sup> This distinction fails to recognize that the only arguable human injury to be documented in scientific

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145.19/tabd/media/2002ChicagoCEOReport.pdf (stating that “mandatory labeling should be limited to only what is necessary to ensure public and environmental safety”).

52. See, e.g., Dana Milbank, *Bush Lashes Out at Europe on GMO-Ban: President Says Aversion to Biotech Perpetuates African Hunger*, WASH. POST, May 22, 2003, at A01, available at [http://www.nadir.org/nadir/initiativ/agp/free/wto/news/0522bush\\_europe\\_gmo\\_ban.htm](http://www.nadir.org/nadir/initiativ/agp/free/wto/news/0522bush_europe_gmo_ban.htm).

53. Since this speech, new evidence of mycotoxin-related deaths in Kenya adds potential toxicity to the threats faced by Africans.

54. See, e.g., U.S. FOOD AND DRUG ADMINISTRATION, Good Manufacturing Practices (GMPs) for the 21st Century-Food Processing § 2 (“Fruit is usually contaminated by direct or indirect contact with animal feces.”), available at [www.cfsan.fda.gov/~acrobot/gmp-2.pdf](http://www.cfsan.fda.gov/~acrobot/gmp-2.pdf).

55. Undersecretary Alan P. Larson, U.S. Differences with Europe on Plant Biotechnology, Remarks Before the Cato Institute (Sept. 25, 2002), available at <http://www.state.gov/e/rls/rm/2002/13793.htm>.

56. See *id.*

57. Commission Regulation 1829/2003, 2003 O.J. (L 268) 2; see also *supra* notes 24-28 and accompanying text.

literature and associated (however hypothetically) with biotechnology arose from a product made “with” a GM bacterium.<sup>58</sup> The E.U. would place GMOs in a higher-risk category than GM bacteria or other microbes, even if this category has been accused of causing thirty-seven deaths.<sup>59</sup> Since the E.U.’s “from v. with distinction” is based upon hypothetical fears, the “with” exception to GM labeling lacks any scientific basis.<sup>60</sup>

## 2. World Trade Organization Action

To combat the E.U.’s mistaken application of the “precautionary principle” to biotech crops that have proved their worth, the United States has initiated an action at the WTO. The Uruguay Round of multilateral trade negotiations (1986-1993)<sup>61</sup> created the Sanitary and Phytosanitary Agreement. This granted countries the right to regulate food products but required that they be “based on scientific principles.”<sup>62</sup> By this, a product must be scientifically shown to be harmful before a country may restrict imports of it.<sup>63</sup> Under the WTO agreement, the E.U. must prove through scientific principles that biotech crops are inherently less safe than traditionally-bred crops.<sup>64</sup>

In addition to this WTO attack against E.U. policy, the United States also claims that many other trade violations stem from the E.U.’s treatment of GMOs. These arguments were included in the WTO action brought by the United States, Canada, and Argentina on

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58. The activist groups promoting a genetically modified free Europe repeatedly refer to “thirty-seven deaths” caused by L-tryptophan produced in genetically modified bacterium in the late 1980s. See, e.g., Ronnie Cummins, *Exposing Biotech’s Big Lies*, IN MOTION MAGAZINE, May 23, 2002, available at [www.inmotionmagazine.com/ra02/geff14.html](http://www.inmotionmagazine.com/ra02/geff14.html). But see Hong Kong Gov., Food and Envir. Hygiene Dep’t, *Safe Food & Public Health*, at [http://www.fehd.gov.hk/safefood/gmf/gen\\_info3.html](http://www.fehd.gov.hk/safefood/gmf/gen_info3.html) (last visited Apr. 14, 2005) (assuring consumers that the deaths were caused by contaminants rather than by the bacterium itself).

59. See, e.g., Soil Association, *L-Tryptophan: What Made This GM Food Supplement Kill 37 People and Disable 1500?*, available at [http://www.soilassociation.org/web/sa/saweb.nsf/library?openform&cat\\_GMO:\\_technical\\_information](http://www.soilassociation.org/web/sa/saweb.nsf/library?openform&cat_GMO:_technical_information).

60. See, e.g., John Fagan, Ph.D., *The Facts About Genetic Tryptophan: A Summary*, November, 1997, available at <http://www.zmag.org/Bulletins/ptry.htm> (concluding “it is highly likely that genetic engineering was the determining factor in generating this toxin”).

61. Center for Strategic and International Studies, *Genetically Modified Organisms Still Source of US-EU Tension*, July 30, 2003, at [http://www.globalization101.org/news.asp?NEWS\\_ID=55](http://www.globalization101.org/news.asp?NEWS_ID=55) (last visited Jan. 21, 2005).

62. See *id.*

63. See *id.*

64. See generally *id.*

May 13, 2003,<sup>65</sup> which attacked the E.U.'s use of the "precautionary principle" for biotech crop approval on the grounds that it violates trade law.<sup>66</sup>

A five-year "moratorium" on regulatory approval of biotech crops was created by the E.U.'s failure to approve any new GM crops during that time frame.<sup>67</sup> This blocked American exports from entering the E.U. U.S. Speaker of the House of Representatives Dennis Hastert estimated that American farmers experienced a monetary loss during that time of \$300 million per year on corn alone, and that number could exceed \$4 billion by 2005.<sup>68</sup> An academic based in Switzerland reported both soybeans and corn from the United States suffered a combined loss of up to \$1.9 billion per year in lost trade with the E.U.<sup>69</sup>

In March 2003, E.U. Trade Commissioner Pascal Lamy contended that the E.U. would prevail in this trade dispute before the WTO.<sup>70</sup> The WTO allows legislation that addresses the health and welfare of the E.U.'s population if the regulations are based upon "proportional, transparent, scientific advice."<sup>71</sup> The E.U. specifically disclaimed the idea that the regulations were protectionist mea-

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65. BBC NEWS, WORLD EDITION, *WTO to Probe Europe's GMO Policy*, Aug. 29, 2003, available at <http://news.bbc.co.uk/2/hi/business/3191395.stm>.

66. *See id.*

67. *See generally* BBC NEWS, WORLD EDITION, *EU "Regrets" U.S. Action on GM Crops* (Aug. 8, 2003), available at <http://news.bbc.co.uk/1/hi/world/americas/3135763.stm>.

68. *See* PEW INITIATIVE, *supra* note 19.

69. THOMAS BERNAUER, *GENES, TRADE AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY*, 126-28 (2003). Bernauer estimates \$200-400 million annual loss since 1997 in corn and corn byproducts (e.g., gluten). Soybean exports declined from \$2.6 billion in 1996 to \$1.1 billion in 2002 due in large part to labeling and substitution of soy by food producers who purchased Brazilian non-GMO soy instead. Bernauer considers traceability and labeling for all food and feed "more worrying" since "all U.S. corn and soybean exports" to the European Union could collapse.

In the worst case, U.S. producers will find that the cost of forgoing exports to the European Union is smaller than the cost of restructuring the U.S. crop handling system so as to comply with E.U. regulations . . . U.S. farmers are likely to face a disadvantage vis-à-vis countries that opt entirely for non-GE production. For obvious reasons, it will always be cheaper to operate the entire crop-handling system of a country on a non-GE crop basis than to segregate GE and non-GE crops. In brief, the prospects for U.S. corn and soy exports to Europe are rather bleak. *Id.* at 128-29.

70. Press Conference with Pascal Lamy, E.U. Trade Commissioner, Washington D.C. (Mar. 4, 2003), at <http://www.eurunion.org/news/speeches/2003/030304Pr-Confpl.htm> (last visited Jan. 21, 2005).

71. *See id.*

tures.<sup>72</sup> However, E.U. corn farmers certainly reaped benefits from the exclusion of U.S. corn as the E.U. can easily meet its corn needs with a combination of its own production and non-United States imports.<sup>73</sup> For feed, however, Bernauer suggests that there are not adequate non-GMO supplies of soybeans and that the outlook for United States genetically engineered soy exports to the E.U. is somewhat better than for genetically engineered corn because it appears harder for the E.U. to find substitutes for genetically engineered soy at similar cost.<sup>74</sup>

### 3. United States' Growers React To Economic Impacts of Traceability

One of the biggest stakeholders in the United States is the American Soybean Association (“ASA”), which sold \$9.7 billion in annual exports of U.S. soy products worldwide in 2004.<sup>75</sup> ASA has taken the position that biotech crops approved for food are completely safe for E.U. consumers, but the regulatory scheme established by the E.U. presents a standard that is too burdensome for most companies in the United States to attain.<sup>76</sup> For the seed companies, a one hundred percent guarantee of seed purity is not commercially feasible,<sup>77</sup> yet growers are asked by grain buyers to provide them with a one hundred percent pure warranty due to the grain buyers’ need to meet “zero tolerance” under the E.U. T&L Directives. These growers face the risk of their 99.9 percent pure product being rejected, or even worse, causing an entire ship’s cargo to be lost.

The ASA has repeatedly reiterated its opposition to the T&L Directives, referring to the regulations as non-tariff barriers to trade and

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72. *See id.*

73. *See* BERNAUER, *supra* note 69 at 129. For soy, however, the E.U. has a self-sufficiency level of around 10 percent for whole soybeans, 5 percent for soy meal, and 20 percent for soy oil. Food soy consumption amounts to only one million tons annually which is easily supplied by non-genetically engineered sources. *See id.* at 129.

74. *See id.*

75. *See* American Soybean Association, *Statistics*, at <http://www.asa-europe.org/Statistics/statistics.htm> (last visited Apr. 27, 2005).

76. *See generally* American Soybean Association, *ASA Supports WTO Biotech Case Against European Union*, at <http://www.iasoybeans.com/whatnew/relatednewsarchive/asa051503.html> (last visited Apr. 27, 2005).

77. Kelly Mescher, *U.S. Exports to Europe Remain High; Concern Over E.U.’s Traceability Laws Linger*, SOYBEAN REV., Oct. 2000, at 14-15, available at <http://www.iasoybeans.com/whatnew/eutraceability.pdf>.

violations of the E.U.'s WTO obligations.<sup>78</sup> ASA fears that the E.U. and activist groups would pressure other countries and trading partners to implement similar standards, perpetuating the discrimination.<sup>79</sup>

The United States government and the E.U. government engaged in a dialogue in 2001 that considered lifting the E.U. “moratorium” on regulatory approval in exchange for the United States agreeing to a mandatory “traceability” system to make regulatory approval more palatable for E.U. Member States (and also reversible, in terms of recalling any varieties that were approved in error).<sup>80</sup> While persons within the seed industry made several public statements indicating support for such a trade-off, the ASA, the United Soybean Board, and the National Oilseed Processors Association (ASA/USB/NOPA) disagreed and communicated with the seed industry in 2001 to express the concerns of commodity exporters regarding the potential adverse impact of traceability upon the shipment of commodities worldwide. ASA/USB/NOPA predicted that the E.U. would try to make the traceability system a global standard for managing grain shipments, and the E.U. is currently engaged in doing precisely that via Article 18.2 of the Biosafety Protocol.<sup>81</sup>

Taking the soybean producers as an example, the challenges of E.U.-style tracing can be demonstrated by following the soybeans from harvest to market. Soybeans are first harvested throughout the region of the Midwest United States and transported by wagons or trucks to a common holding bin. They are then taken to a regional center before being loaded onto barges for transport down the Mississippi River. After they reach the Gulf of Mexico, they are transferred onto ocean-going vessels for transport to Europe. At each stage of transport and storage, the soybeans mix and commingle with each other, rendering specific identification and tracing impossible.<sup>82</sup> “Grower districts” have been discussed as a possible option for segregating biotech crops; these are commonly used in Idaho and Washington to

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78. See, e.g., Press Release, American Soybean Association, *ASA Urges USTR to Challenge EU Traceability and Labeling Requirements* (Nov. 25, 2003), available at <http://www.soygrowers.com/newsroom/releases/2003%20releases/r112503.htm>.

79. See *id.* (quoting ASA President Ron Heck).

80. See *supra* notes 47-56 and accompanying text.

81. See E-mail from Kimball Nill, Technical Director of International Marketing, American Soybean Association, to Thomas Redick, author of this article, dated Dec. 13, 2004 (on file with author).

82. See *id.* See also Mescher, *supra* note 77.

avoid commingling of industrial rapeseed with its related food crop, rapeseed used for canola oil.<sup>83</sup>

### C. Global Tracing of Commodity Shipments Via the Biosafety Protocol

The E.U. traceability regime specifically invokes environmental protection as one of the reasons for its passage, singling out biotech crops for scrutiny under a “precautionary approach” due to the potential environmental impacts of biotech products. A new international treaty, the Cartagena Protocol on Biosafety (“Biosafety Protocol”), is designed to address these impacts. The Biosafety Protocol entered into force on September 11, 2003 and will become the law mandating traceability for genetic events for its parties on September 11, 2005.<sup>84</sup> The Biosafety Protocol could provide the E.U. with an argument that customary international law has evolved to recognize the “precautionary principle” (as implemented in a “precautionary approach”) as a legally justified approach to regulatory approval for GMOs (or “living modified organisms” and “LMOs” under the Biosafety Protocol).<sup>85</sup>

The provision of the Biosafety Protocol that mandates tracing of biotech crop inputs in global grain commodity commerce is Article 18.2(a), which reads as follows:

Living modified organisms that are intended for direct use as food or feed, or for processing, *clearly identifies* that they “may contain” living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for fur-

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83. See, e.g., Canola and Rapeseed Production and Development Act, IDAHO CODE § 22-4701. (Michie 2004); Rapeseed Production and Establishment of Districts, WASH. ADMIN. CODE § 16-570-010 (Wash. Dep’t of Agric. 2004) (setting forth the administrative provisions governing the Washington production districts).

84. See SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY & U.N. ENVIRONMENT PROGRAMME, BIOSAFETY AND THE ENVIRONMENT: AN INTRODUCTION TO THE CARTAGENA PROTOCOL ON BIOSAFETY 5 (2003), available at <http://www.biodiv.org/doc/press/presskits/bs/cpbs-unep-cbd-en.pdf>. While the Biosafety Protocol technically entered into force on September 11, 2003, the parties to the protocol needed a meeting to establish the ground rules for implementing the protocol. Biosafety Clearing-House, *Cartagena Protocol on Biosafety*, at <http://bch.biodiv.org/about/protocol.shtml> (last visited Apr. 27, 2005). The first Meeting of the Parties (“MOP”) to the Biosafety Protocol was held February 23-27, 2004, in Kuala Lumpur, Malaysia. Convention on Biological Diversity, *First Meeting of the Conference of the Parties of the Convention Serving as the Meeting of the Parties to the Protocol*, at <http://www.biodiv.org/meetings/mop-01> (last visited Apr. 27, 2005). The seventh meeting of the Conference of the Parties to the Convention on Biological Diversity (COP-7), which provided the terms of reference for the Biosafety Protocol, met in Kuala Lumpur from February 9-20, 2004. *Id.*

85. See BIOSAFETY AND THE ENVIRONMENT, *supra* note 84, at 4 (explaining that “LMOs” is another term for “GMOs”).

ther information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.<sup>86</sup>

As the E.U. enforces “zero tolerance” traceability for unapproved-in-E.U. varieties, other countries could follow its lead. These countries could possibly include nations that do not export to the E.U., but which export to a nation that has trade with the E.U.

The E.U. will use the Biosafety Protocol Article 18.2(a) to establish itself as the Slowest Common Unapproved Denominator (“SCUD”), leading other nations to deny imports of commodities containing any trace of unapproved-in-E.U. biotech crops. Since those nations will then be denied any health benefits or environmental conservation advantages of these biotech crops, they will all share in the E.U.’s lowered levels of protection of environmental and human health.<sup>87</sup> This is the “SCUD” effect, aptly named for the devastating long-range impact that E.U. policy can have;<sup>88</sup> if Article 18.2(a) of the Biosafety Protocol is implemented in a manner that encourages the SCUD effect, this could cause a rapid spread of trade barriers that would be comparable to the long-standing E.U. moratorium on entire U.S. corn shipments.

Indeed, in late 2004, the scientific advisory group appointed to advise the parties to the North American Free Trade Agreement (“NAFTA”) issued a report suggesting that all corn shipments to Mexico from the United States should be milled prior to entry into Mexico.<sup>89</sup> The advisory group, the North American Commission for Environmental Cooperation (“CEC”), made this suggestion to protect

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86. See Council Decision 2002/628, 2002 O.J. (L 201) 48, 55 (emphasis added).

87. See Biotechnology Industry Organization, *Benefits of Agricultural Biotechnology*, at <http://www.bio.org/foodag/background/epabenefits.asp> (last visited Apr. 27, 2005); German Research Foundation, *Statement by the DFG on the Draft Legislation to Reform the Law on Genetic Engineering*, at [http://www.dfg.de/aktuelles\\_presse/reden\\_stellungnahmen/2004/](http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2004/) (stating biotech crops can be specifically adapted to developing nations’ yield needs for food crops) (last visited Apr. 27, 2005).

88. See Nathan A. Canestaro, *Legal and Policy Constraints on the Conduct of Aerial Precision Warfare*, 37 VAND. J. TRANSNAT’L L., 431 n.181 (2005) (describing a scud missile as a “weapon incapable of [the proper] accuracy that would [be needed to] allow the proper selection of military targets over civilian population”).

89. See COMMISSION FOR ENVIRONMENTAL COOPERATION, MAIZE & BIODIVERSITY: THE EFFECTS OF TRANSGENIC MAIZE IN MEXICO: KEY FINDINGS AND RECOMMENDATIONS (“CEC Report”), available at [http://www.cec.org/files/PDF/Maize-and-Biodiversity\\_en.pdf](http://www.cec.org/files/PDF/Maize-and-Biodiversity_en.pdf) (suggesting that Mexico “strengthen the moratorium on commercial planting” by “milling transgenic grain at the point of entry”).

Mexico's corn production from unwanted commingling with unapproved genetic events that may be present in United States corn shipments and are not approved for environmental release in Mexico. Fourteen industry associations including corn, soy, cotton, and wheat growers, as well as the Biotechnology Industry Organization, promptly forwarded a letter objecting to the suggestion that milling of corn shipments from the United States be required to protect biodiversity.<sup>90</sup>

The CEC's report will rightfully endure intense scrutiny because it appears to have ignored the potential health effects of forced milling, which leads to transportation and storage methods that may allow the formation of harmful mold and other mycotoxins (which are known to cause health problems in Mexico).<sup>91</sup> It also appears to have ignored the less burdensome alternatives to milling, including the measures used to contain certain weed seeds present within commodities under the International Plant Protection Convention,<sup>92</sup> which mandates the use of tarps, mowing of areas adjacent to rail lines, and other related measures to prevent the release of certain weed seeds into the environment that are already present within commodities shipments.

Even if drastic measures such as the "mill at the border" are averted, United States grain shippers will still face a serious dilemma under the emerging traceability regimes mandated by the E.U. and the Biosafety Protocol. If grain shippers from major grain-exporting, biotech-growing nations (e.g., United States, Canada, Argentina, Brazil, etc.) ship unapproved varieties into a nation and successfully off-load all product, the shipper could still be liable for traces of unapproved varieties under a warranty obligation (applying international commercial law) and possibly a regulatory violation under the domestic law of the importing nation. At its logical extreme, even a nation receiving food aid could set up trade barriers because it hopes to ex-

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90. See Letter from American Farm Bureau Federation, et al. to Michael Leavitt, Administrator, Environmental Protection Agency (Oct.18, 2004), available at <http://www.nopa.org/content/newsroom>.

91. See, e.g., Margorie A. Peraza et al., *Modulation of Chemical Toxicity and Risk Assessment*, ENVTL. HEALTH PERSPECTIVES, Aug. 1997, available at <http://ehp.niehs.nih.gov/members/1997/105-8/peraza-full.html> ("Mycotoxins are by-products of fungal contamination of food crops, most common in corn, peanuts and cottonseed . . . in Mexico [ ] the rural, tropical conditions often result in contamination of corn, a major agricultural product and food source.").

92. The International Plant Protection Convention is an international treaty related to plant health that has been signed by over 135 countries. See The International Plant Protection Convention, at <http://www.ippc.int> (last visited May 16, 2005).

port to the E.U., which Zambia has already done, citing the Biosafety Protocol as its legal support.<sup>93</sup>

The Biosafety Protocol also has a specific “liability and redress” element (Article 27) still under negotiation that would create liability for biotech crops under an international liability protocol.<sup>94</sup> In the future, as a result of Article 27 of the Biosafety Protocol or national laws on liability, businesses in the United States may see strict liability applied to require “remediation” of biotech crops growing in places where they are not wanted (comparable to the *StarLink* testing, recall and remediation process)<sup>95</sup> via United States court claims filed for “harm” to biodiversity that occurs abroad.

### III. LIABILITY FOR BIOTECH CROPS UNDER UNITED STATES COMMON LAW TORTS

The primary United States liability events that may be triggered by this regulatory regime include: (1) shipments that are turned away at foreign ports for unapproved-overseas biotech content, (2) food product recalls, and (3) environmental remediation costs. The latter two would arise from shipments of unapproved-overseas varieties that are not detected and turned away, leading to the spread of crops within a food supply or ecosystem long after they are released into commerce or the environment.

The legal claims that would arise from these factual settings would include: (1) nuisance liability claims for neighbors who are sued for breach of warranty and are left looking for someone to blame, (2) contractual breaches of warranty obligations to customers, and (3) various regulatory-based liability theories that arise when import controls are violated and a regulatory recall is ordered (as occurred with *StarLink* corn in the United States and *Pringles* potato chips, which were recalled from the Japanese food supply when an unapproved-in-Japan GM potato event was discovered in *Pringles* pul-

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93. M.M. Lewanika, *Establishing Acceptance: Biosafety Regulation in Zambia*, 47 *BIO-TECHNOLOGY AND DEV. MONITOR*, Sept. 2001, available at <http://www.biotech-monitor.nl/4706.htm>.

94. Compare the Biosafety Protocol to what emerged ten years after the Basel Convention on Hazardous Waste, which passed a non-retroactive, joint and several liability protocol, *see generally* Secretariat of the Basel Convention, United Nations Environment Programme, *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal Adopted by the Conference of the Plenipotentiaries on 22 March 1989*, available at <http://www.basel.int/text/con-e.htm>.

95. *See, e.g., In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

led from the shelves of a grocery store in Japan).<sup>96</sup> This article will confine itself to a discussion of nuisance and warranty liability scenarios, and leave the international regulatory enforcement scenario for another author.

Since grain shippers will want to avoid these liability issues, suppliers (such as elevators growers) who sell their grain may be asked to warrant the genetic purity of their product. For any liabilities that arise in the future, grain shippers in the United States may seek to enforce the typical “pass-through” warranties going back to the growers. These grain suppliers may be asked at some point in the future to contribute toward the cost of recalling unapproved varieties that were released in small amounts but are technically illegal due to “zero tolerance” standards. Growers may encounter seed companies who successfully disclaim liability for warranty. In the end the liability may be contractually allocated to growers, who are not insured or adequately capitalized to handle this level of commercial risk.

#### A. *The StarLink Decision*

Biotech crops lacking regulatory approval in major overseas markets are potentially an “economic nuisance,” which is a relatively new invention of the common law when applied to biotech crops. This can include “private” nuisance (such as neighbor to neighbor, through pollen flow or other commingling)<sup>97</sup> and “public” nuisance (such as public harms caused by a biotech seed company). Commingling of an unapproved-in-E.U. variety may be found analogous to blocking a public road, contaminating a river or an air purifier, or rendering an entire county’s corn crop unfit for its intended market.

While the boundary between nuisance and trespass is not well defined doctrinally,<sup>98</sup> the modern trend in trespass recognizes airborne

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96. See generally JUAN LÓPEZ VILLAR, FRIENDS OF THE EARTH INTERNATIONAL, GMO CONTAMINATION AROUND THE WORLD, Oct. 2001, available at <http://www.foe.org/camps/comm/safefood/gefood/foodaid/contamination.pdf>. On June 21, 2001, Japan’s Calbee Foods Co. Ltd. voluntarily recalled some of its snack products after traces of illegal genetically modified NewLeaf Plus Potato were found. The same type of GM potato was found in “Pringles” chips manufactured by Procter and Gamble, which was forced to pull 800,000 packets off the Japanese market. *Id.* at 15.

97. See E. Ann Clark, *The Implications of the Schmeiser Decision*, available at <http://www.percyschmeiser.com/crime.htm> (discussing the farmer Percy Schmeiser, who made headlines with his alleged theft of Monsanto’s intellectual property which he claimed was a nuisance); see also *Monsanto Canada, Inc. v. Schmeiser and Schmeiser*, [2001] F.C. 256.

98. See, e.g., ENVIRONMENTAL LAW PRACTICE GUIDE § 16.03[1] (“It is practical to consider a trespass cause of action along with nuisance where appropriate, although

pollution as a trespass where the plaintiff can demonstrate physical damage to his property (including loss of marketability).<sup>99</sup> The *Star-Link* case extended this to include economic loss caused by a biotech crop's pollen drift or post harvest commingling, recognizing claims for both trespass and nuisance.<sup>100</sup>

On July 11, 2002, a federal district court judge in Chicago denied a motion to dismiss a “novel” claim whereby growers injured by the FDA-mandated recall of StarLink corn sought compensatory damages and an injunction for a public and private nuisance.<sup>101</sup> This decision was a groundbreaking and fairly comprehensive precedent suggesting liability standards for biotech crops in a variety of states.<sup>102</sup> U.S. District Judge James B. Moran denied a motion to dismiss farmers’ claims for strict product liability, consumer fraud, negligence, and public and private nuisance alleging economic loss<sup>103</sup> in twenty-seven consol-

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some courts differentiate between the two . . . Some courts do not differentiate but just treat nuisance and trespass as identical, with the same evidence requirements.”).

99. See, e.g., *Born v. Exxon Corp.*, 388 So. 2d 933, 934 (Ala. 1980) (quoting *Borland v. Sanders Lead Co.*, 369 So. 2d 523, 529 (Ala. 1979)); *Wilson v. Interlake Steel Co.*, 649 P.2d 922 (Cal. 1982); *Bradley v. Am. Smelting & Ref. Co.*, 709 P.2d 782, 786 (Wash. 1985); see Larry D. Scheafer, Annotation, *Recovery in Trespass for Injury to Land Caused by Airborne Pollutants*, 2 A.L.R.4th 1054 (1980).

100. See *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002); see also *Sample v. Monsanto*, 283 F. Supp. 2d 1088, 1093 (E.D. Mo. 2003) (discussing “physical injury” and granting summary judgment in favor of Monsanto on tort claims alleging economic loss from unapproved-in-E.U. crops but alleging no actual commingling or “physical injury”).

101. See *In re StarLink*, 212 F. Supp. 2d at 835.

102. See, e.g., *id.* As previously noted, StarLink corn was approved for feed by the EPA, but not for food uses. As a condition of approval, Aventis was required to maintain an adequate identity preservation program to keep StarLink out of the food supply. Aventis apparently thought that commingling problems, should they arise, would be worked out with food regulators to allow some percentage of unapproved StarLink in food. *Id.*

103. See *id.* While the “economic loss” doctrine is a matter for strict products liability analysis beyond the scope of this article, it could represent a barrier to recovery in some settings arising from environmental releases of biotech crops causing economic loss. See *East 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); *Cf. Sherman v. Johnson & Towers Balt., Inc.*, 760 F. Supp. 499, 501-02 (D. Md. 1990) (holding that *East River* is not applicable to consumer losses) and Margaret Rosso Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 237 (2002) (stating that “[i]n some states, mere economic loss from defendant’s negligence will not be compensated; plaintiff must also prove physical harm to property”).

idated actions<sup>104</sup> in multidistrict litigation (“MDL”).<sup>105</sup>

Plaintiff farmers had filed consolidated class actions on behalf of a nationwide class of corn farmers alleging common law claims for: (1) negligence, (2) strict liability, (3) private nuisance, (4) public nuisance, and (5) conversion, as well as statutory claims under (6) the Tennessee Consumer Protection Act of 1997 and (7) the North Carolina Unfair Trade Practices Act. Plaintiffs sued the seed developer and seed companies. The seed companies moved to dismiss, and the court denied the motion, recognizing claims for negligence, strict product liability, private nuisance, public nuisance, and consumer fraud.<sup>106</sup> Within months of the denial of the motion to dismiss, the plaintiffs settled for up to \$110 million, with notice given to thousands of corn growers who lost money due to depressed corn prices.<sup>107</sup>

Future cases filed by organic or non-GM crop growers may cite this decision to support claims for nuisance arising from the sale and production of unapproved-in-E.U. varieties of biotech crops. If commingling occurs through pollen drift, or a “volunteer” emerging from grain left on the ground in a prior harvest or through post-harvest commingling, growers suffering economic loss from commingling can claim the economic loss under resurgence, issuance or trespass arising from the negligent or unreasonable marketing of a particular biotech crop, and thousands of growers similarly situated may recover for their economic loss. As the law evolves to encompass the “physical injury” of economic loss caused by commingling of an unapproved-in-E.U. variety of biotech crops, the *StarLink* decision, combined with overseas trade barriers, could create another multi-million dollar precedent.

A majority of states have some form of the “economic loss doctrine” that bars purchasers of goods from asserting negligence claims

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104. See, e.g., News Release, Iowa Department of Justice & Attorney General Tom Miller, Miller: Aventis Signs Formal Agreement to Mitigate Losses from StarLink Corn (Jan. 23, 2001), available at [www.state.ia.us/government/ag/StarLink\\_binding\\_agt\\_rel.htm](http://www.state.ia.us/government/ag/StarLink_binding_agt_rel.htm) (quoting Iowa Attorney General Tom Miller as saying that it was “irresponsible” for Aventis to market the StarLink seed corn with unrealistic restrictions, such as 660-foot “buffer strips” between StarLink and other planted corn and segregating StarLink grain from other corn, and saying that his office believes most growers were not aware of the restrictions).

105. See *In re StarLink*, 212 F. Supp. 2d at 852.

106. See *id.*

107. See Notice of Pendency of Class Action, Settlement Class for Certification, Proposed Settlement and Fairness Hearing, Starlink Corn Prods. Liability Litigation, MDL No. 1403 (N.D. Ill. Feb. 14, 2003), available at [www.non-starlinkfarmerssettlement.com/notice.pdf](http://www.non-starlinkfarmerssettlement.com/notice.pdf).

with damages for economic losses.<sup>108</sup> Economic loss in some states is defined as constituting qualitative defects in the goods themselves (e.g., where there is no claim of personal injury or property damage other than a qualitative defect in the goods at issue). The *StarLink* court applied Illinois law<sup>109</sup> to hold that a “physical injury” to property occurred when StarLink commingled with other corn bound for food uses or export.

Not every state will be receptive to such claims. For example, nuisance law as a tool to recover economic losses in the “stream of commerce” was criticized in *City of San Diego v. U.S. Gypsum Co.*<sup>110</sup> While the *StarLink* decision is a novel extension of nuisance doctrine, this extension was not entirely unpredictable. Various courts preceding the *StarLink* decision struggled to define the boundaries of nuisance law when products cause environmental harm.<sup>111</sup>

Lawyers representing Aventis<sup>112</sup> and other biotech companies have called this “public nuisance” claim unprecedented because it sought compensation for interference with corn markets, including export markets that refused *all* United States corn due to the presumed commingling of *StarLink* corn (and other “unapproved” varieties of biotech corn).<sup>113</sup> Legal commentators have analyzed the

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108. See, e.g., Thomas P. Redick, *Symposium: Stewardship for Biotech Crops: Strategies for Improving Global Consumer Confidence*, 44 JURIMETRICS J. 5 (2003).

109. See, e.g., *Moorman Mfg. Co. v. National Tank Co.*, 435 N.E.2d 443, 448-49 (Ill. 1982) (finding that the economic loss doctrine applies to the sale of inferior or defective goods and that cases without accompanying personal injury or property damage are more appropriately handled by existing warranty laws).

110. 35 Cal. Rptr. 2d 876, 883 (1994) (awarding summary judgment to the defendants, stating that manufacturers of asbestos containing building materials did not create nuisance on city property and rejecting the idea that “the stream of commerce can carry pollutants every bit as effectively as a stream of water” and holding the nuisance law would “become a monster that would devour in one gulp the entire law of tort”).

111. See, e.g., *Arcade Water Dist. v. U.S.*, 940 F.2d 1265, 1266 (9th Cir. 1991); *Selma Pressure Treating Co. v. Osmose Wood Preserving Inc.*, 271 Cal. Rptr. 596 (Cal. Ct. App. 1990) (holding a chemical vendor liable for failure to warn of proper disposal); *Shurpin v. Elmhirst*, 195 Cal. Rptr. 737 (Cal. Ct. App. 1983); *Cf. Town of Hooksett Sch. Dist. v. W.R. Grace Co.*, 617 F. Supp. 126 (D. N.H. 1984); *County of Johnson v. U.S. Gypsum*, 580 F. Supp. 284, 294 (D. Tenn. 1984) (stating that plaintiffs cannot “convert almost every product liability action into a nuisance claim”).

112. Aventis is an E.U.-based pharmaceutical company with a strong presence in the United States. Aventis Pharmaceuticals, *Aventis in the United States: At a Glance*, at <http://www.aventis-us.com/newsroom/presskit/index.jsp> (last visited Apr. 27, 2005).

113. Andrew Harris, *Danger Uncertain, But Suits Multiply*, NAT’L L. J., Sept. 9, 2002 (stating that Aventis attorney Sheila Birnbaum thinks that “suits are not based on personal injuries, but instead on ‘very novel tort theories’” and quoting her as saying, “It’s our tort system running wild again”); Rachel G. Lattimore & Raquel Whiting, *Genetically Enhanced Seed Suits Not Rooted in Law or Logic*, WASH. LEGAL FOUND. LEGAL

*StarLink* precedent in some detail, however, and in context it appears to represent a logical progression from past cases.<sup>114</sup>

*StarLink* established a precedent for agricultural biotechnology,<sup>115</sup> but its legal impact may be minimized in future actions. Other plaintiffs have tried and failed to make a case for damages arising from other varieties of biotech crops that lack overseas approval. In *Sample v. Monsanto Co.*,<sup>116</sup> farmer plaintiffs tacked public nuisance and negligence theories onto an antitrust action against Monsanto for GM corn and soybean seeds that caused a nationwide decline in corn prices (i.e., economic loss). Plaintiffs claimed that Monsanto failed to take the appropriate measures to prevent the GM corn from entering the “chain of grain marketing”<sup>117</sup> and that, as a result, the plaintiffs lost significant domestic and foreign commodity corn markets.

The court held that plaintiffs had abandoned or failed to prove the physical injury allegations that survived a motion to dismiss<sup>118</sup> (i.e., actual commingling via pollen drift). The court also held that it could not apply state law other than Illinois and Iowa (where each of the two class plaintiffs resided) even though a “potential unnamed class member might live in a state where nuisance claims are actiona-

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BACKGROUND, July 27, 2001, available at [www.arentfox.com/legal\\_updates/content592.htm](http://www.arentfox.com/legal_updates/content592.htm).

114. See, e.g., Margaret Rosso Grossman, *Genetically Modified Crops in the United States: Federal Regulation and State Tort Liability*, 5 ENVTL. L. REV. 86, 93 (2003) (stating that *ex post* liability allocates fault to those who cause harm that *ex ante* regulation fails to prevent).

115. Amelia P. Nelson, *Legal Liability in the Wake of Starlink: Who Pays in the End?*, 7 DRAKE J. AGRIC. L. 241 (Spring 2002).

116. 283 F. Supp. 2d 1088 (E.D. Mo. 2003).

117. See *id.* at 1091 (quoting counsel for the plaintiffs as stating, “The claims of this tort class are based on *commingling*, our word ‘*contamination*,’ in the U.S. marketing channel, not where the wind blows in Iowa and where and if it blows over the fence of a particular farmer’s property”). The court then explained the plaintiffs’ position and incorrectly stated the European Union had banned U.S. soybeans, as well as corn:

Counsel explained that the term “contamination” did not refer to physical injury to the person or property of the plaintiffs, but to the “U.S. marketing channel.” Plaintiffs allege that non-GM farmers lost revenue because the European community rejected Monsanto’s genetically modified products and boycotted all American corn and soy as a result. *Id.*

118. Plaintiffs alleged that genetically modified seeds caused environmental problems, such as “toxicity to soil microorganisms and non-target insects such as butterflies” and “contamination caused by cross-pollination and commingling.” See *id.* Plaintiffs also asked the Court “to enter an injunction requiring Monsanto to control and/or prevent contamination of non-GM crops, soil and farming, storage and transportation equipment; to implement and monitor an effective Insect Resistance Management Plan; and to adequately test GM seeds for human health and environmental safety.” *Id.*

ble absence of physical injury.”<sup>119</sup> As a result, the court granted summary judgment on claims alleging economic loss from unapproved-in-E.U. crops, finding that “no evidence of physical injury to the person or property of the named plaintiffs or any proposed class member was offered by plaintiffs.”<sup>120</sup>

Given the *Sample* decision, it may be difficult for plaintiffs to prove actual commingling in the chain of grain marketing sufficient to establish the “physical injury” contemplated by the *StarLink* decision.<sup>121</sup> However, while a nuisance is incapable of any exact or precise definition,<sup>122</sup> nuisance law may be flexible enough to encompass economic loss caused by a biotech crop that lacks regulatory approval in a major overseas market.

### B. Warranty Liability and Industry Stewardship

The United States’ life sciences industry should contain the *StarLink* precedent to its unique fact pattern by avoiding the creation of new “bad facts” that might reinforce the *StarLink* decision allowing compensatory damages. Unfortunately, the current use of form contracts that shift risk to growers and impose warranty disclaimers could lead to increased risk under the *StarLink* precedent, while doing little to prevent the allocation of liability to a negligent biotech company that fails to warn of the potentially cataclysmic economic risks of commingling.

For example, Monsanto asks its growers to sign a Stewardship Agreement with them that contains requirements and procedures that growers must agree to follow.<sup>123</sup> The seed company liability disclaimers appear in various places in the agreement, including: (1) the fine print of Stewardship Agreements, (2) the separate guide for farmer practices delivered with the seed, and (3) the logo on the bag. Ac-

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119. *Sample*, 283 F. Supp. 2d at 1092 n.1.

120. *Id.* at 1091.

121. Monsanto used its controversial forum selection clause to get venue in its home district, the Eastern District of Missouri. Monsanto succeeded in having claims for negligence and nuisance dismissed because the farmers did not allege facts supporting actual commingling of their grain with Monsanto’s unapproved-in-E.U. variety of corn. *Id.*

122. W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS, 616-17 (5th ed. 1984) (stating that “[f]ew terms have afforded so excellent an illustration of the familiar tendency of the courts to seize upon a catchword as a substitute for any analysis of the problem; the defendant’s interference with the plaintiff’s interests is characterized as a ‘nuisance,’ and there is nothing more to be said”).

123. See, e.g., 2005 Monsanto Technology Stewardship Agreement, in David R. Moeller and Michael Sligh, Farmers’ Guide to GMOs, available at [http://www.nationalaglawcenter.org/assets/articles/moeller\\_gmos.pdf](http://www.nationalaglawcenter.org/assets/articles/moeller_gmos.pdf).

ording to the Stewardship Agreement, the grower is bound to assume the risk of liability and agrees not to save seed upon ripping open the bag. Such a “bag rip” agreement would ostensibly bind growers in a fashion similar to “click-wrap” website contracts or “Shrink-Wrap” software licenses,<sup>124</sup> but this novel theory of contract law remains untested in the context of stewardship agreements.

According to the Stewardship Agreement, growers are bound to “channel grain produced to appropriate markets as necessary to prevent movement to markets when the grain has not yet received regulatory approval for import.” Under a separate section entitled “You Understand,” the channeling obligation is clarified by stating that not all of Monsanto’s products have been approved in certain export markets and, as a result, crops generated with the aid of those products must be segregated. This document requires growers to confine biotech crops to approved uses and markets. Such efforts should help appease European fears concerning the co-mingling of approved and non-approved GM crops and other products.

While Monsanto provides extensive disclosures, if it were to fail to inform growers of the risk that they run by commingling their unapproved variety with a neighbor’s crop then the combined effect of this uniform non-disclosure, paired with a form contract common to all growers, could create the “commonality” required to certify a nationwide class action. And if the “physical injury” of commingling is alleged by the neighbor (whose crop is no longer fit for its intended purposes), then a compensation claim for a decline in grain prices could be recoverable. While it is not possible to predict Monsanto’s future legal policies and positions with certainty, Monsanto appears to have plans to market unapproved-overseas soybeans and corn in the coming era of traceability.<sup>125</sup> Monsanto may need to change the approach it takes to protect itself from claims by growers for the biotech soybean, which could be commercially launched in the next few years,

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124. See, e.g., Mark A. Lemley, *Intellectual Property and Shrinkwrap Licenses*, 68 S. CAL. L. REV. 1239, 1241 (1995) (explaining that shrinkwrap licensing agreements are designed to bind the customers who use the product by the terms of the vendor in exchange for use).

125. Monsanto has also withdrawn Roundup Ready Wheat, which is a variety of biotech crop that lacks E.U. approval and carries commingling risks comparable to self-pollinating soybeans. Press Release, Monsanto Company, Monsanto to Realign Research Portfolio, Development of Roundup Ready Wheat Deferred (May 10, 2004), available at <http://www.monsanto.com/monsanto/layout/media/04/05-10-04.asp>.

and threaten several billion dollars per year in annual soybean exports to the E.U.<sup>126</sup>

### C. *Grower Insurance for Biotech Crops*

Given *StarLink's* massive liability, which included nearly all economic loss without any proven human injury, the insurance industry is writing this risk of economic loss from biotech crops out of policies.<sup>127</sup> Insurers now demand premiums for specific GMO endorsements, just as they have done with other novel environmental liabilities. Many carriers are now writing “GMO exclusions” applicable in farm insurance, grain shipping, and other industry sectors.

In early 2000, a major Swiss insurer issued a report stating that it would be hesitant to provide insurance for the liability risks arising from biotech crops.<sup>128</sup> This re-insurance company, Swiss Re,<sup>129</sup> was widely reported as taking the position that insurers had inadequate data available on the relevant loss scenarios.<sup>130</sup> Swiss Re and other insurers expect that biotech crop risks will become more calculable over time, as data is accumulated, and will eventually become easier to fit into traditional insurance models.<sup>131</sup> Swiss Re was quoted as stating: “today we must assume that the one-sided acceptance of incalculable risks means that any participants in this insurance market run the risk not only of suffering heavy losses, but also of losing control over their exposure.”<sup>132</sup>

Thus growers concerned about being left uninsured for the risks of commingling (which are increasingly being shifted contractually to the grower) should carefully review their farm liability policies with their agent and/or legal counsel. If a policy contains an exclusion for particular liability risks of biotech crops, the grower should determine

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126. See MONSANTO COMPANY, 2004 ANNUAL REPORT: SETTING THE STANDARD IN THE FIELD 7 (2004), available at [http://www.monsanto.com/monsanto/content/media/pubs/2004/2004\\_annual\\_report.pdf](http://www.monsanto.com/monsanto/content/media/pubs/2004/2004_annual_report.pdf) (explaining Monsanto's hopes to launch a new soybean in 2005).

127. See generally Mayerson, *supra* note 44.

128. See Tom Lowe, *Insuring the GM Industry*, THE JACKSON PROGRESSIVE, May 25, 2000, at [www.jacksonprogressive.com/issues/foodtech/insuringgm052500.html](http://www.jacksonprogressive.com/issues/foodtech/insuringgm052500.html) (last visited Apr. 27, 2005).

129. Swiss Re is one of the largest insurers in the world. See *Need to Know*, TIMES (London), Feb. 15, 2005, at 38.

130. See *id.*

131. See generally Mayerson, *supra* note 44.

132. Peter Montague, *If You're Not Concerned About GM Foods You Will Be After You Read This: What the National Academy of Science Says About Genetically Engineered Crops*, TOM PAINE, COMMON SENSE, May 19, 2000, at <http://www.tompaine.com/feature2.cfm/ID/3153> (last visited Apr. 27, 2005).

the range of liability for damages. The covered perils should include pollen drift from neighboring farms growing an unapproved-in-E.U. genetic event, commingling at harvest through shared combines, or commingling through post-harvest mixing in transports, grain elevators, and so on through the chain of commerce.

Given the retreat of insurers from the risks posed by unapproved-in-E.U. varieties, biotech companies should fund or support a nationwide legal strategy that: (a) manages the class action exposure generated by these dangerous disclaimers and (b) seeks to prevent “bad facts” from making bad case law (i.e., prevent large scale commingling of any unapproved-in-European biotech variety) as they have done with other foreseeable billion dollar liability risks. Some form of joint self-insurance and risk management could also be considered as an option for this shared risk.

#### *D. Grower’s Response to Traceability Risks*

It is obvious that the E.U.’s various tracing-related directives will change United States grain handling into a more document-intensive process. Producers may have to provide proof to buyers that they have maintained records of the varieties of biotech events. Cautious growers have already begun saving receipts and documenting use of particular seeds in order to be prepared to show that they did not grow a variety barred from entry into the E.U.

At a minimum, E.U. traceability will probably increase costs of U.S. production by forcing a transformation of markets via contractual requirements that impose a higher level of “process standard” upon agricultural production. The difficulty of complying with the E.U. T&L Directives has been the subject of studies commissioned by the feed industry.<sup>133</sup>

The sale in the United States of a biotech crop that cannot be exported to the E.U. represents an economic threat to crops bound for export. The economic risks of these crops are largely left to the states to manage, via various methodologies.<sup>134</sup> These crops cannot reach their intended market if the unapproved biotech crop mixes with it in the field, through pollen drift, a “volunteer” emerging from

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133. See, e.g., Tim Herrman, *White Paper on Traceability in the U.S. Grain and Plant Protein Feed Ingredient Industries*, July 2, 2002, available at <http://www.oznet.ksu.edu/grsiext/white%20paper%20CVM.pdf> (explaining the results of a Kansas State University study commissioned by the American Feed Industry Association).

134. See, e.g., MICHAEL R. TAYLOR ET AL., *TENDING THE FIELDS: STATE AND FEDERAL ROLES IN THE OVERSIGHT OF GENETICALLY MODIFIED CROPS* (Dec. 2004), available at <http://pewagbiotech.org/research/fields/report.pdf>.

grain left on the ground in a prior harvest, or through post-harvest commingling.<sup>135</sup>

## 1. Organic Growers

Organic growers may agree to “zero tolerance” for biotech crops in their harvest in an effort to meet the E.U.’s “zero tolerance” standard for unapproved varieties in food or feed. Given the problems of commingling from various steps in production, such growers are likely to incur problems in delivering the goods promised.<sup>136</sup> Farmers are increasingly asked to certify that their crop is non-GM or is free from unapproved-in-E.U. varieties when there are no assurances that seed sold to them was pure (i.e., free from unwanted genetic events).<sup>137</sup>

However, contracts to deliver grain to demanding grain buyers who expect growers to meet this strict “zero tolerance” standard may fail to be enforced in certain courts, due to the commercial “impossibility” or “impracticability” of both a grower and a seed company achieving “zero tolerance” for unapproved-in-E.U. genetic events in today’s marketplace.<sup>138</sup> If the grower failed to assume a particular risk (e.g., he stated in his warranty that he could not warrant the purity of the seed he purchased), then the grain buyer may be assuming the risk of impure seed containing an unapproved-in-E.U. variety, which triggers specific economic loss to a customer in Europe.

Section 2-615 of the Uniform Commercial Code echoes the common law impossibility defense, providing a defense to contract enforcement where the determination of whether the risk of the given contingency was so unusual or unforeseen and would have such severe consequences that performance would give the promisee an advan-

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135. See Redick, *supra* note 108.

136. Erik Stokstad, *A Little Pollen Goes a Long Way*, 296 SCI. 2314, June 28, 2002, available at <http://www.sciencemag.org/cgi/reprint/296/5577/2314a.pdf> (predicting difficulty in growing “a truly GM-free crop” in the United States and suggesting “[z]ero tolerance is not going to work”).

137. Farmers should state a “pass-through” warranty (i.e., “the seed company represented the seed was X variety and did not represent it as genetically modified organism seed”). If the seed company represented it as non-genetically modified seed, the growers should repeat that warranty. Growers should use care to avoid contamination in bins, augers, combines, transports, etc., and save all seed invoices for at least five years.

138. The Uniform Commercial Code provision governing excuse of performance has replaced the common law requirement of impossibility of performance by a less stringent standard of commercial impracticability. See, e.g., MINN. STAT. ANN. § 336.2-615, cmt. 3 (West 1966); *Nora Springs Coop. Co. v. Brandau*, 247 N.W.2d 744, 748 (Iowa 1976).

tage that he did not bargain for in making the contract.<sup>139</sup> If an organic grower promises “zero tolerance” in an era when seed purity as to unapproved biotech events is not guaranteed to zero,<sup>140</sup> that grower could be seen as assuming the risk of impure seed. While some commentators have suggested neighboring biotech growers could be liable to organic growers,<sup>141</sup> the balance of authority generally would not favor an organic grower whose agreement to deliver to a certain standard imposes upon his land a restriction of his own choosing, an agreement made after years of allowing pollen to freely flow across his property.<sup>142</sup> Commingling with a trace of increasingly common biotech crops is arguably foreseeable in today’s marketplace.

As a result, organic growers are not likely to succeed in asserting liability claims from GM contamination if they agree to deliver one hundred percent non-GM crops (assuming their seed does not carry a one hundred percent guarantee). If certifying organizations and organic customers insist on organic crops that contain no “genetically engineered-contamination” then organic growers will have few remedies other than formation of strictly enforced exclusionary grower districts.<sup>143</sup>

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139. See, e.g., *Mishara Constr. Co., Inc. v. Transit-Mixed Concrete Corp.*, 310 N.E.2d 363 (Mass. 1974); Comment, *Contractual Excuse Based on a Failure of Presupposed Conditions*, 14 DUQ. L. REV. 235, 249 (1976) (stating that the test under UCC § 2-615 is whether an unforeseen, unrecorded contingency was one that the parties could reasonably have foreseen as a real possibility affecting performance, making it a risk that the parties were “tacitly assigning to the promisor by their failure to provide for it explicitly”). Compare *Neal-Cooper Grain Co. v. Texas Gulf Sulphur Co.*, 508 F.2d 283, 293 (7th Cir. 1974); *Center Garment Co. Inc. v. United Refrigerator Co.*, 3341 N.E.2d 669, 673 (Mass. 1976); *Olson v. Spitzer*, 257 N.W.2d 459, 463 (S.D. 1977). For older cases defining and applying a similar common-law test of impossibility of performance, see *Village of Minnesota v. Fairbanks, Morse & Co.*, 31 N.W.2d 920, 926 (Minn. 1948); *Canadian Indus. Alcohol Co. v. Dunbar Molasses Co.*, 179 N.E. 383, 384 (N.Y. 1932).

140. Biotechnology Industry Organization, *Standards Need to Be Developed for Adventitious Presence of Biotech Products*, at <http://www.bio.org/foodag/background/adventitious.asp> (last visited Apr. 27, 2005).

141. See A. Bryan Endres, “GMO:” *Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union*, 22 LOY. L.A. INT’L & COMP. L. REV. 453, 484 (2000).

142. See Drew L. Kershen, *Legal Liability Issues in Agricultural Biotechnology*, NAT’L AGRIC. L. RES. CTR., Nov. 2002, available at [http://www.nationalaglawcenter.org/assets/articles/kershen\\_biotech.pdf](http://www.nationalaglawcenter.org/assets/articles/kershen_biotech.pdf), reprinted in 10 ENVTL. LIABILITY 203-16 (Dec. 2002) (discussing general tort theories related to pollen drift and litigation such as *Starlink*).

143. Cf. Edie Lau and Mike Lee, *Biotech Ban May Sprout Others: Mendocino County’s Action Rattles Genetic Engineering Industry*, SACRAMENTO BEE, Mar. 5, 2004, available at <http://www.sacbee.com/static/live/news/projects/biotech/archive/030504.html> (stating that “the 14,839 voters who this week banned genetically modified organisms

## 2. Corn Growers “Channeling”

Since about twenty percent of the United States corn harvest is exported, and only a fraction of that would be bound for the E.U., the National Corn Growers Association (“NCGA”) acknowledges the challenge of segregating crops and informs growers to “Know Before You Grow” so that they are aware of post-harvest limitations on marketing.<sup>144</sup> As we noted above, the lost corn trade to the E.U. since 1997 has been estimated by various sources in the United States and Europe to exceed, in total, as much as \$1.5 billion (at a conservative estimate of \$200 million per year for seven years).<sup>145</sup>

NCGA warns growers in explicit detail regarding the economic risks posed by unapproved-in-E.U. varieties, stating:

You should select hybrids with the full knowledge of whether it is conventional, approved for E.U. export or not yet approved for E.U. export. Growers should read their grower agreements before planting and be fully aware of the requirements of those agreements. It is vital that hybrids awaiting E.U. approval are kept out of export and processing channels. Growers must also “Know Where to Go” when they sell their harvest: NCGA urges you to funnel hybrids not approved for E.U. export into one of three markets. Those markets are: (1) your own livestock rations, (2) domestic livestock feeding channels or (3) elevators accepting grain not yet approved for E.U. export. Visit the American Seed Trade Association web site and look up information about the grain facilities accepting hybrids not yet approved for export to the E.U.<sup>146</sup>

NCGA has been heavily involved in the controversy over Mexico’s perceived threat from biotech corn.<sup>147</sup> A letter sent to EPA Administrator Michael Levitt<sup>148</sup> pointed out that all non-indigenous corn carries some potential for replacing local varieties or commingling its DNA with related corn or teosinte plants. Among the corn seed industry, Dupont-Pioneer has long led an industry effort to conserve ge-

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in Mendocino County have shaken the establishment far beyond their small North Coast Community”).

144. See National Corn Growers Association, *Know Before You Grow*, at [http://www.ncga.com/biotechnology/know\\_where](http://www.ncga.com/biotechnology/know_where) (last visited Apr. 27, 2005); see also American Seed Trade Association, Grain Handlers Database, at <http://asta.farmprogress.com> (last visited Apr. 27, 2005).

145. See CNN, *EU Defends Biotech Crop Rules*, Aug. 18, 2003, available at <http://www.cnn.com/2003/WORLD/europe/08/18/us.europe.gm.ap> (stating that “American farmers estimate the EU restrictions have cost them nearly \$300 million a year (267 million euros) in lost corn exports alone.”).

146. See *Know Before You Grow*, at *supra* note 144.

147. See *supra* notes 95-99 and accompanying text.

148. Letter to Michael Leavitt, *supra* note 90.

netic resources in corn around the world, and particularly in Mexico.<sup>149</sup> The company recently renewed that commitment with a pledge of \$1 million to the Global Crop Diversity Trust, an international fund charged with funding genebanks (storage facilities for plant germplasm) and crop diversity collections around the world.<sup>150</sup>

### 3. Soybean Growers “Identity Preservation”

In late 1997, the American Soybean Association (“ASA”) made a strategic decision to safeguard United States exports of soybeans to the E.U. To address the role of commingling export soybeans with unapproved-in-E.U. soybeans, ASA sent a letter to eleven companies involved in producing seeds for biotech crops. In this letter, ASA asked each company to refrain from the unrestricted commercial marketing of unapproved-in-E.U. soybeans.<sup>151</sup>

In 1998, ASA asked AgrEvo USA to restrict marketing of seed to United States farmers of the Liberty Link Soybean seed, which lacked approval in the E.U., to ensure that growers and grain handlers would keep it out of United States soybean exports.<sup>152</sup> AgrEvo eventually agreed that its “Liberty Link Stewardship Program” needed improvement to ensure that the Liberty Link Soybean did not commingle with soybeans bound for export.<sup>153</sup> AgrEvo first proposed narrowing the geographical scope of its launch of Liberty Link soybean and eventually abandoned the product launch altogether.<sup>154</sup>

The second test of ASA’s policy requiring complete segregation of unapproved varieties came in 1999 with the launch of Dupont’s

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149. See, e.g., Press Release, Pioneer Hi-Bred International, Inc., Pioneer Hi-Bred International, Inc., Contributes Funds to SIUE National Corn-to-Ethanol Research Center (Nov. 8, 2004), available at [http://www.pioneer.com/pioneer\\_news/press\\_releases/corporate/siue.htm](http://www.pioneer.com/pioneer_news/press_releases/corporate/siue.htm).

150. Press Release, Pioneer Hi-Bred International, Inc., DuPont Announces \$1 Million Commitment to Global Crop Diversity Trust: Pledge Will Help Sustain Endangered Global Plant Genetic Resources, Biodiversity (Mar. 3, 2004), available at [http://www.pioneer.com/pioneer\\_news/press\\_releases/corporate/global.htm](http://www.pioneer.com/pioneer_news/press_releases/corporate/global.htm) (“As part of DuPont’s commitment to conserving and promoting biodiversity, the company recently sent a message to seed industry leaders specifically outlining the importance of and benefits derived from preserving crop genetic diversity.”).

151. See Thomas P. Redick, *Biopharming, Biosafety, and Billion Dollar Debacles*, 8 DRAKE J. AGRIC. L. 136-37 (2003).

152. See Press Release, American Soybean Assoc., ASA Applauds AgrEvo Effort to Protect U.S. Soybean Export Markets (Apr. 14, 1998), available at <http://www.soygrowers.com/newsroom/releases/documents/agrevodl.htm>.

153. See *id.*

154. See Redick, *supra* note 151.

high-oleic soybean.<sup>155</sup> This commercial launch featured strict adherence to the identity preservation plan proposed by ASA (as adapted in confidential negotiations). As a result of these negotiations, an industry standard for “identity preservation” began to emerge.<sup>156</sup> The eleven-point plan adopted by ASA/USB/NOPA for ensuring that biotech companies practice sound stewardship for “unapproved-overseas” varieties is a useful tool in managing liability risks.<sup>157</sup> Through the use of crop-specific isolation, machinery and bin cleanout procedures, and third party oversight of every step, ASA has attempted to establish a system minimizing the likelihood of commingling. To the extent that biotech companies follow this standard, they will avoid significant threats of class action liability and will also assist growers in meeting contractual obligations to their buyers.

This raises the question of whether all soybean seed production should be conducted in accordance with most of the technical requirements of ASA’s eleven-point plan, to ensure delivery of seed that is nearly one hundred percent free from unapproved-overseas varieties of biotech soybeans. At present, the warranty of purity provided for seed is not within the low levels mandated by the E.U. The American Seed Trade Association has shown a willingness to adapt to customer needs but is concerned about the high cost of meeting “zero tolerance” in seed.<sup>158</sup> Industry websites explain the difficulties inherent in assuring one hundred percent genetic purity of seed.<sup>159</sup>

Seed company liability disclaimers that shift the risk of commingling to the grower without an adequate disclosure of the risks of commingling and the methodology for preventing it, may encounter judges that are unwilling to enforce the disclaimer.<sup>160</sup> These clauses,

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155. See, e.g., J.L. Glancey et al., *Development of High Oleic Soybean Oil-Seed Hydraulic Fluid*, FEEDSTOCKS, Mar. 1999, at 1.

156. See, e.g., Presentation by Stephen Censky, ASA President, Improving Communication from Seed Production Through Retail, available at <http://www.soygrowers.com/newsroom/releases/documents/aba-rtp2.html> (predicting a “cataclysm of lost export trade with the European Union” if identity preservation methods were not carefully implemented; this prediction was made in 1999, the year it was revealed that StarLink corn had been used for unapproved purposes).

157. See *infra* note 185.

158. See News Release, American Seed Trade Association, A Seed Industry Response to Issues Raised By the Presence of Biotech Seed in Conventional Seed Lots (July 8, 2004), available at <http://www.amseed.com/newsDetail.asp?id=95>.

159. See, e.g., DuPont, *Gene Flow Via Pollination and Crops Derived Through Biotechnology*, at [http://www.dupont.com/biotech/science\\_knowledge/gene\\_flow/scientific\\_narrative.htm](http://www.dupont.com/biotech/science_knowledge/gene_flow/scientific_narrative.htm) (last visited Apr. 27, 2005).

160. See generally J.W. Looney, *Warranties in Livestock, Feed, Seed, and Pesticide Transactions*, 25 U. MEM. L. REV. 1123 (1995).

along with forum selection in the seed company's home jurisdiction, are often challenged as unconscionable contracts of adhesion.<sup>161</sup> Despite this, many companies in the industry continue to make use of these disclaimers, accompanied by detailed stewardship programs.<sup>162</sup>

#### 4. Rice Growers' Legislative Approach

To date California has protected its commodity export markets from the sale of biotech varieties that lack overseas approval. The California legislature took steps to control the marketing of new varieties of unapproved rice, in part to protect export markets from the impacts of commingling. California has a long history of legislative management of agriculture, including the establishment of zones for certain varieties of cotton, rice, or other commercially important crops requiring genetic purity to meet market demands. These zones limit the opportunity for pollen to cause an economic nuisance moving across boundary lines. Agricultural Districts have various powers defined by statute,<sup>163</sup> including the abatement of public nuisances or other specific threats that come to the attention of the legislature.<sup>164</sup> The public entity responsible takes all measures necessary to abate a living threat to agriculture. Once abated, the entity often has a lien for the costs of doing so on the affected owner.<sup>165</sup>

However, the advisory commission on rice, which is made up in part of California Rice Commission members, recently recommended growing Ventria's<sup>166</sup> field trial of rice with a plant-made pharmaceutical ("PMP") to the California Secretary for the Department of Food and Agriculture.<sup>167</sup> The California Department of Food and Agricul-

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161. See, e.g., *Monsanto v. Homan McFarling*, 302 F.3d 1291, 1306 (Fed. Cir. 2002) (Clevenger, J. dissenting) (chastising the court's upholding of the Monsanto forum selection clause by stating, "My colleagues have the honor of making this court the first to enforce a forum selection clause in a contract of adhesion against a defendant in derogation of his constitutional rights").

162. See generally *id.* at note 29. The Monsanto program for grower stewardship includes instructions on "channeling" requirements, and solicits contact information from the grower to allow notifications to go to them regarding "regulatory status" and other issues. See *id.*

163. See, e.g., CAL. FOOD AND AGRIC. CODE §§ 59081-59088 (2004).

164. See CAL. FOOD & AGRIC. CODE § 59081 (2004).

165. CAL. FOOD AND AGRIC. CODE §§ 5401, 5462, 5428, 5430, 7305 (2004).

166. Ventria is a U.S.-based biotech company that focuses its efforts on products in the biopharmaceutical and nutrition fields. See Ventria Bioscience, *About Us*, at <http://www.ventria.com/aboutus> (last visited Apr. 27, 2005).

167. Paul Elias, Biotech Firm Wants to Grow Rice for Medicinal Supplements, USA TODAY, Apr. 7, 2004, available at [http://www.usatoday.com/tech/news/techpolicy/2004-04-07-genmod-rice\\_x.htm](http://www.usatoday.com/tech/news/techpolicy/2004-04-07-genmod-rice_x.htm).

ture expressed a need for public hearings. Ventria has reacted, however, by committing to moving the majority of its operations to Maryville, Missouri, where it hopes to find a more welcoming environment than California.<sup>168</sup> After Riceland Foods and Anheuser Busch questioned the wisdom of growing this rice near the Southeast boarder of Missouri, which is close to the Arkansas-Missouri \$100-million rice market, Ventria agreed to stay at least 120 miles from that rice-growing region.<sup>169</sup>

## 5. Wheat Growers

The Executive Board of the National Association of Wheat Growers (“NAWG”) approved a biotechnology Principles of Commercialization setting out a roadmap for commercializing biotechnology traits in wheat. This was prepared by the joint Biotechnology Committee of NAWG, U.S. Wheat Associates, and the Wheat Export Trade Education Committee (“WETEC”).<sup>170</sup>

The Principles of Commercialization state that United States wheat producers recognize the benefits of biotech wheat chain and generally support commercialization of transgenic wheat trait, provided that there is a commercialization plan that “facilitates commercialization with minimal market disruption,” and allows customers to make purchases based on their preferences for specific traits, classes, qualities, and characteristics.<sup>171</sup> Wheat growers will vigorously oppose commercialization of transgenic wheat traits that do not meet all of the aforementioned principles. While the WETEC board approved this draft plan in October 2004, the U.S. Wheat Associates Board (“USWAB”) rejected the draft plan in October 2004 in a closed executive session. According to NAWG’s report of that decision, no alternative plan was proposed by USWAB, and no direction was given to the Biotechnology Committee for amendments. The action leaves the

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168. See *University Draws California Biotech Firm to Maryville*, COLUMBIA DAILY TRIB. (Columbia, MO), Nov. 21, 2004, (stating that Ventria will move to Maryville, home to Northwest Missouri State University, where a new building will be constructed using \$5 million from anonymous donors for it and other emerging biotech companies to use), available at <http://www.showmenews.com/2004/Nov/20041121News021.asp>.

169. See, e.g., *Anheuser-Busch, Ventria Strike Deal on Rice*, COLUMBIA DAILY TRIB. (Columbia, Mo.), Apr. 16, 2005, available at <http://www.showmenews.com/2005/Apr/20050416News016.asp>.

170. See National Assoc. of Wheat Growers, 2005 Policy Resolutions 26, available at [www.wheatworld.org/pdf/NAWG%202005%20Resolutions.pdf](http://www.wheatworld.org/pdf/NAWG%202005%20Resolutions.pdf).

171. See *id.*

wheat industry without a coordinated plan to move forward on this critical issue of acceptance of biotech crops.<sup>172</sup>

### *E. The Biosafety Body Count*

Historically, trade agreements and the WTO have been accused of promoting environmental degradation, forcing nations to compete for commercial success at the expense of the environment, and rushing toward a “lowest common denominator” of minimal environmental protection.<sup>173</sup> With the advent of biotech crops, however, there is a role reversal underway. The WTO can enhance environmental protection by reigning in the E.U. and its member states’ mistaken moratorium on biotech crops, reversing the trend toward worldwide rejection of biotech crops that provide the best available control technology for managing significant threats to ecological and human health.

While the “precautionary approach” mandating increased regulatory scrutiny and traceability of biotech crops is based upon fears of future harm, it appears to be a system that could lead to unintended consequences including loss of human lives. It could be argued that the E.U. system of traceability has already led to adverse effects upon the health of consumers in both the E.U. member nations and nations who hope to export to the E.U.

In the E.U. food manufacturers are so wary of triggering consumer fears about traces of GMOs that they will suspend the sale of products that are below the one percent GM label threshold, but nevertheless test positive for traces of GM content. On April 12, 2001, Italian authorities seized and tested a sample of soy-based biscuits made by Plada, an Italian subsidiary of H.J. Heinz, the multinational United States-based food company. While tests showed GM levels were well under one percent (0.08 percent), Heinz recalled the biscuits, asserting that it used only conventional, non-GM ingredients.<sup>174</sup> This was unfortunate for many consumers, because the Heinz biscuits

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172. Press Release, National Association of Wheat Growers, *Biotech Action Plan Falls One Step Short* (Jan. 21, 2005), available at <http://www.wheatworld.org/html/news.cfm?ID=667>.

173. See, e.g., Donella Meadows, *Free Trade Can Work Against the Environment—Or For It*, available at [http://www.sustainer.org/dhm\\_archive/search.php?display\\_article=VN506nafta-iiid](http://www.sustainer.org/dhm_archive/search.php?display_article=VN506nafta-iiid).

174. Reuters, *Italy Authorities Seized Biscuits for GMO Tests*, Apr. 12, 2001, available at <http://www.connectotel.com/gmfood/rel20401.txt>.

were one of the very few baked goods products which sufferers of Celiac disease<sup>175</sup> are allowed to consume.

As noted earlier in this article, President Bush has accused the E.U. of hindering the fight against famine in Africa.<sup>176</sup> During a drought in 2002, the United States attempted to alleviate some of the suffering by offering food aid, but their offer was rejected by Zambia based upon fears that seeds of GMO-containing foods might intermingle with the domestic agricultural systems, rendering their exports ineligible for entry into the E.U.<sup>177</sup> The Zambian government initially accepted GM foods when offered by the United States.<sup>178</sup> Zambian Vice President Enoch Kavindele said, “if Americans can eat GM, Zambians should be able to eat GM.” Two months later, however, President Levy Mwanawasa declared the food “poisonous” and ordered that it be shipped to neighboring Malawi, which possessed no GM restrictions.<sup>179</sup> The Zambians claimed that public concern prompted the change, but *Time* magazine learned through a senior government official that at least two diplomats from European countries “leaned on the Zambians in private discussions” in order to affect their decision.<sup>180</sup> This issue remains relevant today, as the world press recently criticized the United States for placing “relentless pressure” on Sudan and Angola to accept gene-altered food aid.<sup>181</sup>

If the E.U.’s T&L Directives continue to dominate world trade, driving its trading partners to reject all biotech crops lacking E.U. approval, this global rejection will have measurable adverse effects in the form of health effects from mycotoxins and environmental effects of soil run-off. These adverse consequences will be measured in floating fish and loss of habitat for endangered species, leading to nutritionally distressed children, lost species, and lost lives. In an ironic twist, the E.U.’s effort to avoid having biotech food “forced down its throat” could lead to the force-feeding of mycotoxins or pesticides in nations

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175. Due to their genetics, Europeans have a relatively high rate of Celiac disease. *See id.*; *see also* Celiac Disease Foundation, Celiac Disease, at [www.celiac.org/cd-main.html](http://www.celiac.org/cd-main.html) (last visited Apr. 27, 2005) (explaining that celiac disease is a life long digestive disorder that interferes with the digestion of nutrients and can also cause damage to muscle tissue and the small intestine).

176. *See supra* note 52 and accompanying text.

177. Pew Initiative, *supra* note 36.

178. *See* Simon Robinson, *To Eat or Not to Eat*, TIME ONLINE EDITION, NOV. 24, 2002, at <http://www.time.com/time/nation/article/0,8599,393605,00.html> (last visited Jan. 21, 2005).

179. *See id.*

180. *Id.*

181. Reuters, *African Groups Criticise US Over GMO Food Aid*, May 4, 2004, available at <http://www.forbes.com/business/newswire/2004/05/04/rtr1358095.html>.

lacking the risk management tools to detect and remove such contaminants. Over time, direct loss of life and species that is attributable to E.U. biotech policy could be tracked using a “biosafety body count” that links deaths to various adverse effects of this tampering with the global food supply. As the “biosafety body count” rises, the world will slowly be forced to come to grips with the benefits that biotech crops now on the market could have offered earlier, if they had been widely accepted.

#### IV. CONCLUSION

The agricultural biotechnology industry in the United States will only have a thriving future if the entire agbiotech industry implements adequate measures for “containment” of biotech crops that are not approved for export. To maintain the flow of commodities to export markets, biotech companies can work closely with growers associations armed with crop-specific “standards of care” that the E.U. could accept.

A heightened level of industry-wide stewardship could be established immediately with a standard stewardship clause incorporated into signed agreements with growers. The contracts could be enforced by the threat of contractually stipulated injunctive relief against those who fail to comply with stewardship standards. This industry-wide mandatory stewardship program would simultaneously stem a looming tide of frivolous nuisance cases and also isolate the public nuisance precedent established in the *StarLink* case<sup>182</sup> by preventing another set of bad facts from reaching appellate courts and making bad law for biotech companies.

A coordinated strategy between growers and biotech companies is needed to prevent both economically cataclysmic impacts to international trade and devastating legal precedents that could cede some control over the biotech industry’s future to plaintiff’s class action attorneys.<sup>183</sup> *StarLink* left both of these economic and legal impacts behind, and it also left grounds that would be used to support a credible threat of “anticipatory nuisance” that can be used to impose strict containment on biotech crops where necessary.

Public nuisance law could be used by responsible biotech companies, growers, grain companies, or grocers who want to impose a higher level of stewardship for a particular biotech crop. If the chain

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

183. The history of litigation and legislation is worth reviewing as an example of how new nationwide class actions can suppress innovation. See generally *supra* note 151, at 115.

of commerce in a particular crop is threatened by potential commingling, *StarLink's* public nuisance precedent could be used to enjoin that which federal regulators may lack the resources or authority to oversee properly.

The economic threat posed by biotech crops to the marketplace is vastly outweighed by the threat to the agricultural biotechnology industry from such a novel legal development. In other words, the economic impact upon the United States economy from the loss of future innovations in agricultural biotechnology is a cataclysm well worth avoiding, through careful legal planning and cooperation.

## APPENDIX A

### GROWER CHECKLIST FOR LIABILITY FROM ZERO TOLERANCE STANDARDS FOR BIOTECH CROPS IN THE AGE OF TRACEABILITY<sup>184</sup>

The E.U. instituted a new program at the end of April 2004, of “Traceability and Labeling” that increases the risk of having shipments of grain from the United States turned away from E.U. ports. This is particularly true for non-GMO shipments of corn and soybeans. Shipments will have to disclose the types of biotech crops present in a particular shipment, to a tolerance of zero (the limits of detection) for certain varieties of biotech crops. It is possible that similar “zero tolerance” standards could proliferate among E.U. trading partners that are concerned about losing export trade to the E.U. in the next few years as parties to the Cartagena Protocol on Biosafety implement their own tracing system.

Identity preservation to a zero tolerance has been implemented successfully by the American Soybean Association for several years running, as it coped with E.U. “zero tolerance” for various new unapproved-in-E.U. varieties of biotech soybeans. ASA’s has developed an eleven-point plan that has succeeded in avoiding liability for growers and grain shippers, despite E.U. policies imposing zero tolerance for unapproved-in-E.U. varieties.<sup>185</sup> Growers should keep the following thoughts in mind:

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184. The authors adopted this checklist from information that was originally provided by the Minnesota Crop Improvement Association.

185. See American Soybean Association, *Minimum Requirements for Attempted Identity-Preserved Production, Harvesting, and Utilization of Biotechnology-Enhanced Varieties/Hybrids That Are Unapproved for Export to Major Markets*, at <http://www.soygrowers.com/publications/minrequire-IP.htm> (last visited Apr. 27, 2005).

## 1. Know What You Are Growing—including Foreign Material

Seed sales are not certified to a zero tolerance, but can contain several percentage points of seed that look the same but contain different genetics. If the seed company cannot provide information about the presence of “unapproved-in-E.U. varieties” in your seed, seek some assurances from your grower trade association about the commercial launch of the unapproved-in-E.U. variety.

## 2. Know What Your Neighbors Plan to Grow

Your neighbors may have decided to plant an unapproved-in-E.U. variety, or they may have planted seed containing some traces of that unapproved-in-E.U. variety. While the ideal situation is to have a neighbor who is as alert as you are, and also communicates with the seed company and grower association to rule out the possible presence of an unapproved-in-E.U. variety in his seed, you should take steps to document your efforts to investigate that neighbor’s use of unapproved-in-E.U. seed. When harvest time comes, it may be too late to make decisions about sharing combines, transports or elevator facilities with a grower who is not as careful as you.

## 3. Read What You Sign, Ask Questions, Take Notes

Your seed salesman may ask you to sign a growers agreement for unapproved-in-E.U. seeds. Read it carefully, ask questions, and note the responses. Also, even growers avoiding unapproved-in-E.U. seed may still be at risk from a neighbor’s crops. In that case, the growers should ask neighbors about the level of stewardship being implemented and suggest ways to avoid commingling of crops before delivery.

## 4. Do Not Sign Anything Related to Certain Potential Genetic Events

You should not sign any affidavit or statement certifying the absence of a particular genetic event, unless you are certain it is not being commercially marketed. This is recommended even if you know your production was in fact from a “non-GMO” seed source. The current grain distribution system, from your local elevator to the accumulation of product in a shipping container, may not be adequate to segregate your grain from other unknown sources. Your grain may in fact have been “non-GMO,” however the probability that it will be commingled during shipment with other grain that may *not* be “non-GMO” is high. Commingled shipments will be tested when

they arrive at their final destination. If any GM grain (e.g., Roundup-Ready soybeans) is present in the shipment, there is a high probability it will be detected. This could result in the entire shipment being rejected. You need to discuss with your legal counsel the degree of liability you have for this shipment as a result of certifying your portion of the shipment's "non-GMO" status by signing an affidavit.

#### 5. Check For the Following

Several quick litmus tests have become available to local elevators that claim to be able to detect the presence of GM grain. Grain producers need to realize that the sampling and testing phase of non-GMO export transactions is extremely critical and it is very important for you to:

- a. Discuss with someone knowledgeable what adequate procedures for sampling of your shipments need to be followed for the trait testing to be valid.
- b. Demand from those receiving your grain written confirmation that the entire shipment will be scientifically sampled and tested at each stage of the entire shipping process.
- c. Do not depend on quick and easy testing procedures to verify the presence of GM grain. The laboratory tests required to reliably test for the presence of GM traits are more complicated, time consuming and expensive than the quick tests. Contact your grower association to develop an official non-GMO grain certification program to assure your next year's production can enter this segment of the grain market with minimum risks to the grain producer.

### APPENDIX B

#### AMERICAN SOYBEAN ASSOCIATION POLICY

As a part of the Policy Resolution on Biotechnology Approvals, the American Soybean Association has generated a document entitled "Minimum Requirements for Attempted Identity-Preserved Production, Harvesting, and Utilization of Biotechnology-Enhanced Soybean Varieties that are Unapproved for Export to Major Markets."<sup>186</sup> As the name implies, the purpose of the document is to provide growers with a standardized set of procedures that would help to prevent the comingling of authorized and unauthorized varieties of soybean. Some of the guidelines contained therein are as follows:

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186. Document provided by Kim Nill, Technical Issues Director, International Marketing for the American Soybean Association.

There must be a contract between the seed company and each farmer, requiring delivery of *all* production from the biotechnology-derived seed, allowing on-farm midseason field inspections, requiring minimum isolation distances from other types of the crop, and other requirements inherent in certified seed production.

All unused seed must be returned to the seed company for proper disposal.

Designated delivery points must be facilities that do not deliver *any* crop into export channels.

The contract growing of biotechnology-enhanced varieties that are unapproved for export should be confined to restricted “closed-loop” geographic areas, and the number of the separate geographic areas kept to as few as possible, in order to minimize the likelihood for IP system failures.

Varietal verification testing of each load delivered by each farmer must be performed at each delivery point, with totals by farmer matched up with the midseason field yield estimates to ensure that each farmer delivered all of the biotechnology-enhanced crop he produces in each crop year.

Before handling or harvesting any other varieties of crops, each farmer must thoroughly clean out all [equipment] utilized in [handling] the biotechnology-enhanced crops.

No “test plots” of unapproved for export, biotechnology-derived varieties shall be allowed, other than the above contracted fields.

An outside third party will check verification of the establishment of a closed loop system and adherence to these requirements.