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## Forced Feeding: New Legal Issues in the Biotechnology Policy Debate

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# Forced Feeding: New Legal Issues in the Biotechnology Policy Debate

Neil D. Hamilton\*

## INTRODUCTION: LOOKING BACK TO MOVE AHEAD

In the fall of 2000, I presented a paper, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*,<sup>1</sup> at the American Agricultural Law Association annual meeting in St. Louis. The paper inventoried the legal and policy issues shaping America's approach toward biotechnology and was designed to serve as a tool for understanding the ongoing debate. Thirty months have passed and the pace of consideration of issues relating to society's acceptance of biotechnology has not slowed. Just as the article was being finished, the StarLink fiasco was beginning. That episode alone has provided the grist for numerous lawsuits and other policy debates.<sup>2</sup>

In the intervening thirty months, several issues have become more settled. For example, except for skirmishes such as the failed ballot referendum in Oregon to mandate food labels,<sup>3</sup> American consumers appear for the most part to accept the Food and Drug Administration's decision not to require labeling on the use of genetically modified ingredients. In light of the obstacles the FDA placed in the way of anyone trying to label a food as being free of

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1. Neil Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81 (2001). This article subsequently received the American Agricultural Law Association's Award of Excellence for Professional Scholarship at the association's October 2002 meeting.

2. See *Kramer v. Aventis Crop Sci. USA Holding, Inc.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

3. See, e.g., Philip Brasher, *Oregon Voters Reject Food-Labeling Measure*, DES MOINES REG., Nov. 8, 2002, at 1D.

Genetically Modified Organisms (GMO), it may not be surprising the issue has subsided.<sup>4</sup> Other issues, such as the continuing conflict between the United States and the European Union over European resistance to accepting unlabeled GMO foods and the legality of such action under the World Trade Organization (WTO) rules, remain topics of current public debate.<sup>5</sup> Predictably, several new issues have emerged which were not addressed in the original article, the most significant being the controversy over planting pharma-crops, traditional commodities genetically modified to create traits and products with pharmacological value.<sup>6</sup>

What follows is an effort both to update many of the issues discussed in the previous article and to make the analysis more timely and complete. In doing so, the article will share whatever insights and observations are possible concerning the role that biotechnology will play in our food and agriculture system and how policy and law will be asked to shape that future.

#### RECENT DEVELOPMENTS IN BIOTECHNOLOGY POLICY—WHAT HAS WORKED AND WHAT HASN'T

Before discussing recent policy developments relating to agricultural biotechnology, it may be helpful to start with a brief summary of events from the last two years. On the domestic front, the public acceptance of biotechnology has continued with only a few minor interruptions. From the standpoint of farms, the continued and rapid adoption of genetic modification (GM) technology—especially in the form of Roundup Ready soybeans and *Bacillus thuringiensis* (Bt) corn—is remarkable.<sup>7</sup> This seems especially so in light of the

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4. See Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839 (Jan. 18, 2001), available at <http://www.cfsan.fda.gov/~dms/biolabgu.html>.

5. See, e.g., Philip Brasher, *Biotech Ban Tries Patience of U.S.*, DES MOINES REG., Mar. 4, 2003, at 1D (concerning Trade Representative Robert Zoellick's frustration that current geopolitical forces relating to U.S. plans to invade Iraq have for now led the U.S. to delay its plans to file a formal WTO complaint against E.U. policy on GMO foods).

6. E.g., Philip Brasher, *U.S. Tightens Rules for Growing Pharma Crops*, DES MOINES REG., Mar. 7, 2003, at 1D.

7. See, e.g., *ERS Research Identifies Benefits, Costs to Farmers of Using GE Crops*, FEEDSTUFFS, Aug. 26, 2002, at 3 (discussing the recent report by United States Department of Agriculture economists documenting the rapid adoption of genetically engineered crops,

continuing uncertainty whether some foreign markets will accept the crops. In particular, the resistance of European consumers to accepting gene-altered food appears to have hardened, perhaps as a method of resisting what is seen as America's attempted political and economic hegemony.<sup>8</sup> Around the world the use and development of biotechnology continues to progress, with Asia being an especially active region.<sup>9</sup> The continued development of new crop products by the biotech sector, such as the recently approved version of Bt corn for use with corn root-worm, a major pest in the United States, promises a continued flush of new products for use by farmers.<sup>10</sup>

As to the actual farm-level use of biotechnology, the main focus is on three issues: resistance management for Bt crops,<sup>11</sup> lingering concerns about how to resolve liability conflicts between biotech and non-biotech crops such as organic grain, and the potential use and regulation of pharma-crops.<sup>12</sup> From a legal perspective, recent litigation involving the StarLink episode has begun to provide some of the legal guidance that will be needed to resolve the unavoidable conflicts between production of biotech crops and non-GMO crops.<sup>13</sup> From an industry perspective, the resolution of intellectual property

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including sixty-one percent of the U.S. soybean crop and fifty-six percent of the cotton crop in 2001).

8. See Lizette Alvarez, *Consumers in Europe Resist Gene-Altered Foods*, N.Y. TIMES, Feb. 11, 2003, at A3.

9. See David Barboza, *Development of Biotech Crops Is Booming in Asia*, N.Y. TIMES, Feb. 21, 2003, at A3 (reporting that China, India, and Indonesia are already planting millions of acres of GMO crops and are investing heavily in developing locally adapted GM products).

10. See Philip Brasher, *EPA Gives Final OK to New Corn*, DES MOINES REG., Feb. 26, 2003, at 1D; Andrew Pollack, *U.S. Approves Type of Corn That May Cut Pesticide Use*, N.Y. TIMES, Feb. 26, 2003, at C10.

11. See, e.g., *Growers Must Follow Bt Planting Guidelines or Be Denied Seed*, IOWA FARM BUREAU SPOKESMAN, Nov. 23, 2002, at H10.

12. The USDA has announced much-awaited rules for the planting of pharma-crops. See Philip Brasher, *U.S. Tightens Rules for Growing Pharma Crops*, DES MOINES REG., Mar. 7, 2003, at 1D; Andrew Pollack, *U.S. Imposes Stricter Rules for Genetically Modified Crops*, N.Y. TIMES, Mar. 7, 2003, at A23. These rules, which include enhanced on-farm inspections requirements and limitations on the ability to rotate food crops on fields recently planted with pharma-crops, may have the effect of limiting the use of the technology in Midwestern states like Iowa. Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11,337 (Mar. 10, 2003) (to be codified at 7 C.F.R. pt. 340).

13. An excellent example of the costs and complexities involved in managing the inherent conflicts between these production systems can be seen in the recent \$110 million settlement of claims by non-StarLink growers. See *Non-StarLink Farmer Litigation*, at <http://non-starlinkfarmerssettlement.com> (last visited Nov. 14, 2004).

rights issues means the real legal and policy issues will relate to how the federal government proceeds with implementation of new regulations on farmers' use of the products—such as the required refuges to manage resistance and limitations on producing pharmaceuticals in rotation. In summary, the horizon is relatively bright with only a few clouds looming to challenge the continued growth and acceptance of biotechnology in American agriculture and our food system. Farmers are planting, American consumers are eating, and most foreign customers are buying. At least for now everything is relatively peaceful. Whether the future proves to be so tranquil will depend in part on how the legal issues summarized in the following eight categories play out.

*I. African Famine Provides New Opportunity to Attack Biotech Opponents—If We Don't Use It, People Will Die!*

The international development that provided perhaps the strongest opportunity for proponents of biotechnology to argue its benefits, and perhaps as importantly to castigate its opponents, came from an unlikely source: the need for increased food aid to relieve famines in southern Africa.<sup>14</sup> As America and other grain producing nations mobilized to respond to the need for grain, several potential recipient nations questioned whether the food aid, in particular corn in seed form rather than ground as meal, would contain GMOs. The debate brought into focus the contrast between American attitudes toward the safety of the crops and the further trade related impact of the leakage of seeds into production. Because the United States grain marketing system does not segregate or identify the type of corn, and given the increased prevalence of the planting of GMO seeds, the assumption would have to be that American food aid would contain GMOs. The issue for several African nations then became whether the risk of accepting the food aid—knowing at least some of the corn would be diverted and saved for seed and replanted—would lead to

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14. See, e.g., Henri E. Cauvin, *Between Famine and Politics, Zambians Starve*, N.Y. TIMES, Aug. 30, 2002, at A6; Henri E. Cauvin, *Zambian Leader Defends Ban on Genetically Altered Foods*, N.Y. TIMES, Sept. 4, 2002, at 6; Marc Lacey, *Engineering Food for Africans*, N.Y. TIMES, Sept. 8, 2002, at A16.

the presence of GMO corn in future crops.<sup>15</sup> The concern was how this development might affect a nation's status as "GMO free" for purposes of future sales to European countries and other countries concerned about GMOs.

The debate over these issues mushroomed into an international incident which illuminated several ethical issues. For instance, could a nation such as Zambia refuse food aid knowing that people might die rather than accept GMO crops, which have no known food safety risks for consumers?<sup>16</sup> On closer study, the food shortages appear to have subsided, except in Zimbabwe.<sup>17</sup> But the underlying conflict provided rich fodder for American policy makers and biotechnology promoters looking for an argument to throw back at Europeans resisting the use of GMOs.<sup>18</sup> Rather than simply alleging that the European Union's resistance stems from trade preferences or anti-technology elitism, United States officials, most notably Trade Representative Robert B. Zoellick, are now able to accuse the Europeans of callous disregard and active culpability in starving poor Africans solely to protect their sensitivities over eating GMOs. For example, Mr. Zoellick was quoted as saying, "I find it immoral that people are not being able to be supplied food to live in Africa because people have invented dangers about biotechnology."<sup>19</sup> While the Europeans protested they had not pressured African nations and do not promote starvation, the moral issue was joined.<sup>20</sup>

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15. See *supra* note 14.

16. See, e.g., Rekha Basu, *Africans' Logical Fear of GM Corn*, DES MOINES REG., Dec. 8, 2002, at 30; Danna Harman, *Some Africans Prefer Hunger to Biotech Corn*, DES MOINES REG., Nov. 20, 2002, at A1.

17. See, e.g., Rachel L. Swarns, *African Food Shortages Ending Everywhere Except Zimbabwe*, N.Y. TIMES, Jan. 31, 2003, at A16.

18. See, e.g., Philip Brasher, *Activists Push Fear of Food*, DES MOINES REG., Aug. 31, 2002, at 1A. The situation created great opportunity for sermonizing by U.S. proponents of biotechnology on the theme of how could a country choose to let its citizens starve rather than accept this wonderful gift from the West. See, e.g., Tim Burrack, *Safe, GM Food Can Save Starving Africans*, DES MOINES REG., Nov. 8, 2002, at 13A.

19. See Elizabeth Becker, *U.S. Threatens to Act Against Europeans over Modified Food*, N.Y. TIMES, Jan. 10, 2003, at A4.

20. *Id.*

## *II. Consumer Acceptance of GMOs—So Far So Good, but What About These Fish*

The most significant story relating to the consumption of GMO foods in the United States is, in many regards, the lack of a story. For the most part, American consumers don't seem to mind or care. When the FDA in January 2001 rejected for the latest and probably last time requests to require mandatory labeling of GMO foods, what little steam remained went out of this effort.<sup>21</sup> Instead, much of the attention of GMO opponents has shifted to fighting a rear-guard action to protect at least the availability of a food supply that is as free as possible of the presence of GMOs. The final approval of the USDA's national organic program standards and labeling requirements provided the focus for efforts to develop and expand this "alternative" food stream. Because the rules do not allow the use of biotechnology for organics, this provides an outlet for consumers seeking these foods.<sup>22</sup> From the perspective of American law, the FDA action rejecting labels for GMO foods flows from the agency's view of the purpose of food labels and the legal conclusion that this information is not material and labels not containing it are not misleading.<sup>23</sup>

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21. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592). For a general discussion of U.S. regulation of GM foods, see Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181 (1998).

22. National Organic Program, 7 C.F.R. § 205 (2004); see also Elizabeth Becker, *Organic Gets an Additive: A U.S.D.A. Seal to Certify It*, N.Y. TIMES, Oct. 21, 2002, at A10; *A New Organic Era*, N.Y. TIMES, Oct. 21, 2002, at A18. Unfortunately, in recent weeks the integrity of the new national organic program has been placed in jeopardy because of a rider in the 2003 omnibus spending bill, inserted at the request of Congressman Nathan Deal of Georgia. This rider would allow meat to be labeled as organic even if the animals were not fed organic feed, even though the price of organic feed is more than double the price of conventional feed. The inclusion of this loophole has triggered a new wave of concern and support for protecting the organic food label and could produce a backlash that will reignite concerns about the presence of GMOs in the food supply. See, e.g., *Staying Organic*, N.Y. TIMES, Mar. 5, 2003, at A22.

23. For a detailed analysis and criticism of the U.S. approach toward the regulation and labeling of GMO foods, see Thomas McGarity & Patricia I. Hansen, *Breeding Distrust: An Assessment and Recommendations for Improving the Regulation of Plant Derived Genetically Modified Foods* (Jan. 11, 2001), available at [http://biotech-info.net/breeding\\_distrust.html](http://biotech-info.net/breeding_distrust.html) (Jan. 11, 2001).

The most contentious episode in the United States over GMO labels was a ballot initiative in Oregon, where a coalition of consumer advocates and environmentalists placed a proposal to mandate labeling for GMO foods sold in Oregon on the fall 2002 ballot.<sup>24</sup> The food and biotech industry waged a multi-million dollar campaign to defeat the initiative and the United States government took the unprecedented step of warning the state that it believed such a law would interfere with the operation of the national food system.<sup>25</sup> The combination of ads, warnings, confusion, and other uncertainty no doubt helped contribute to the overwhelming defeat for the proposal.<sup>26</sup> Assuming that the law had passed, food manufacturers likely would have challenged it on First Amendment grounds as well as claiming federal preemption. Their challenge would have been similar to the successful fight waged by the food industry to defeat Vermont's 1994 attempt to require labeling of milk produced with bovine growth hormone.<sup>27</sup> In that case, the Second Circuit Court of Appeals ruled that the First Amendment prohibited the state from compelling this type of commercial speech from dairies.<sup>28</sup> The court observed that consumers concerned about health issues could purchase bovine-somatotropin-free milk from producers who voluntarily labeled their products as not containing the additive.<sup>29</sup>

But the assumption that producers who choose to employ alternative production techniques are free to communicate this fact on

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24. For a discussion of the contents of the proposed Oregon law and its potential impact on the food industry, see Patricia Callahan, *Oregon May Require Labels on Genetic Food*, WALL ST. J., Sept. 30, 2002, at B1; Elizabeth Weise, *FDA Tries to Remove Genetic Label Before It Sticks*, USA TODAY, Oct. 9, 2002, at 7D (concerning a letter from the acting commissioner of the FDA to the Governor of Oregon).

25. Brasher, *supra* note 3.

26. *Id.*

27. *Int'l Dairy Foods Assoc. v. Amestoy*, 92 F.3d 67 (2d Cir. 1996).

28. *Id.* at 72.

29. The court stated:

Absent, however, some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern, the manufacturers cannot be compelled to disclose it. Instead, those consumers interested in such information should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it.

*Id.* at 74.



food labels is not so clear. Farmers and consumers face numerous obstacles in their voluntary effort to label foods as being produced without GMO ingredients. A food marketer's ability to label a food product in this manner is subject to the FDA's "voluntary guidance" relating to such labels.<sup>30</sup> While the guidance appears to provide the basis for making such claims, the actual provisions make it next to impossible for food marketers to do so, short of complying with existing standards for organic food labeling, which is a separate, more costly and cumbersome system. While the details of that guidance are beyond this paper, suffice it to say that the FDA has ruled it is misleading to use the terms "GM" or "GMO free" in such labels and has placed the burden of proof on those who label their foods as being free of the products of bioengineering.<sup>31</sup> The guidance further warns that even a "statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled."<sup>32</sup>

The effect of the guidance and the goal of the food industry officials who requested it is not to promote voluntary labeling of GMO products, a label that while allowed is not found in the marketplace; instead, the purpose is to prevent the development of a GMO-free food sector.<sup>33</sup> By forcing those who want to market or purchase GMO-free foods to buy certified organic food, the food industry is able to prevent the proliferation of foods marketed as GMO-free and limit development of consumer awareness or curiosity about the presence of GMO ingredients. This approach to labeling is a marked contrast to the true "consumer right to know" approach such as that used in Europe.<sup>34</sup> One legal uncertainty that may threaten the success of this effort is that food industry initiatives use First

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30. Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developing Using Bioengineering, 66 Fed. Reg. 4839 (Jan. 21, 2001), *available at* <http://www.cfsan.fda.gov/~dms/biolabgu.html>.

31. *Id.*

32. *Id.*

33. For the development of the guidance, see *Food Industry Groups Petition FDA for Guides on Biotechnology-Free Claims*, FOOD SAFETY REP., May 10, 2000, at 586.

34. For an discussion of the legal rationale behind this view, which rejects the notion there is a "consumer right to know" under American food law, see Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49 (1997).

Amendment claims to free food marketers from the restraints of FDA regulations. Claims that have found support in the federal courts may place in doubt the government's ability to prohibit food marketers from making truthful and non-misleading claims about the lack of GMO ingredients. But that battle has yet to be fought.<sup>35</sup>

Before turning from the food safety and consumer acceptance issue, it is important to note that at least one category of food continues to raise legitimate consumer and even scientific concerns: meat and fish.<sup>36</sup> While most of the debate about the use of GM technology has related to crops, there are policy issues relating to the adequacy of the federal rules relating to animals. In particular, there are policy issues relating to the possible sale of genetically engineered salmon.<sup>37</sup> In August 2002, a panel of the National Research Council issued a report recommending that the FDA examine the use of gene-altered animals in food production.<sup>38</sup> The recent incident in which the University of Illinois allegedly sold genetically engineered pigs, an illegal act under the FDA experimental guidelines, brought the issue of GM meat and the integrity of FDA regulation of GM experimentation back to the

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35. See generally *Pearson v. Shalala*, 164 F.3d 650, 654–60 (D.C. Cir. 1999) (concerning the First Amendment limitations on the ability of FDA to regulate health claims in the marketing of dietary supplements and favoring disclaimers over prohibitions); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (limiting the ability of Congress to block advertising about drug compounding). This expanded view of First Amendment protections for commercial speech led the FDA to initiate a process to re-evaluate the scientific standards used to approve health claims for foods. See Request for Comments Notice, 67 Fed. Reg. 34,942 (May 16, 2002); Gina Kolata, *Stung by Courts, F.D.A. Rethinks Its Rules*, N.Y. TIMES, Oct. 15, 2002, at F1; *FDA Moves Ahead on Qualified Health Claims with Creation of Task Force*, 5 FOOD REGULATION REP. 32, Jan 22, 2003, at 3.

36. See, e.g., Jennifer L. Brown, *Ranchers Await FDA Decision on Cloned Bulls' Beef*, DES MOINES REG., Jan. 18, 2003, at D1; Andrew Pollack, *Cloned Cows Are Engineered to Speed Up Quicker Cheese Making*, N.Y. TIMES, Jan. 27, 2003, at A20.

37. See Andrew Pollack, *Study Faults U.S. on Assessing Altered Fish*, N.Y. TIMES, Jan. 15, 2003, at A16. The article concerns a report by the Pew Initiative on Food and Biotechnology which questions the adequacy of the FDA regulations for assessing the risks related to the production of genetically modified salmon. See PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *FUTURE FISH: ISSUES IN SCIENCE AND REGULATION OF TRANSGENIC FISH*, available at <http://pewagbiotech.org/research/fish> (last visited Nov. 7, 2004).

38. NATIONAL RESEARCH COUNCIL, *ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS* (2002); see also Warren E. Leary, *Panel Urges Caution in Producing Gene-Altered Animals*, N.Y. TIMES, Aug. 21, 2002, at A12; *Ranking Risks of Gene-Altered Animals*, N.Y. TIMES, Sept. 4, 2002, at A20.

public's attention.<sup>39</sup> In addition to lingering concerns about the wisdom of using GM technology in meat animals, there was at least one reported incident that raised concerns about possible food safety, or at least animal safety, of GM technology. In the summer of 2002, an interesting story emerged from Iowa concerning the possible relationship between fertility problems in swine and the usage of certain strains of Bt corn in feed.<sup>40</sup> Opponents looking for the smoking gun of health problems from using GMO crops hoped the story would prove to be a major controversy.<sup>41</sup> For scientists, the controversy raised several difficult and perhaps unanswerable questions. But the official response was that the problems were caused by the farmers, not the crops.<sup>42</sup>

### *III. StarLink—Biotech's Self-Inflicted Black Eye Illustrates Limits of Regulatory Structures*

The one incident in the last two years that most clearly illustrates the legal and policy dimensions of the biotechnology age is the StarLink affair. What began as a minor incident of some GM corn appearing in taco shells blossomed into a major episode that brought into focus a range of significant issues, including, among others:

- the research and marketing decisions of biotech companies;

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39. See Andrew Pollack, *F.D.A. Says Food Supply May Contain Altered Pigs*, N.Y. TIMES, Feb. 6, 2003, at A26; Elizabeth Weise, *Research Piglets Sold as Food Hard to Find*, USA TODAY, Feb. 7, 2003, at A3.

40. See, e.g., Tom Block, *More Iowa Sow Herds Experiencing Breeding Problems*, IOWA FARM BUREAU SPOKESMAN, May 18, 2002, at 1; Tom Block, *Pseudopregnancies Puzzle Swine Producer*, IOWA FARM BUREAU SPOKESMAN, Apr. 29, 2002. John Otte, *Swine Pseudopregnancy Mystery*, HOG PRODUCER, June 2002, at H1. For the biotech industry the issue was a concern, but for conspiracy theorists who believe GMO foods are a serious health threat, the story was heaven-sent. Even in light of what appears to be growing acceptance of the safety of GMO foods, some organizations continue to point out that questions remain. See, e.g., Justin Gillis, *FDA Policies for Gene-Altered Foods Faulted in Report*, WASH. POST, Jan. 7, 2003, at A5 (discussing the recent report by the Center for Science in the Public Interest concerning gaps in the regulatory system relating to biotechnology).

41. For example, Friends of the Earth, which had been responsible for exposing the StarLink contamination of corn products, took a special interest in this controversy and the disposition of a supply of corn from an Iowa farm. See <http://foe.org/camps/comm/safefood/gefood/iowa> (last visited Jan. 5, 2004).

42. See *Researchers Dispute Claims Against Corn*, DES MOINES REG., Oct. 11, 2002, at 2A.

- the adequacy of the U.S. regulatory system for marketing GMO products;
- the cavalier attitudes some seed companies and farmers have toward use of GMOs;
- the ability of the legal system to develop and apply rules for allocating liability in cases of unintentional product contamination;
- the difficulty of developing marketing systems to segregate products not approved for use throughout America's food system;
- the role that the government should play in protecting the integrity of the grain supply;
- the inherent tension between the interests of the food industry and the interests of the biotech community over the use and proliferation of products that raise regulatory and consumer acceptance risks; and
- the impact of such products on export markets for American crops.

The list of issues triggered by the StarLink affair shows how this area of American law and policy is still developing. The legacy of the StarLink affair can be seen in the court rulings and litigation allocating the costs and damages from the incident, proposals for state legislation to address GMO contamination, and new regulatory proposals to restrict the use of similar technologies.<sup>43</sup>

When boiled down to its essence, the StarLink affair resulted from the combination of a foolish (and in retrospect incredibly costly) decision by Aventis to bring to the market a corn product not approved for both food and feed uses and the unreasonable decision of the Environmental Protection Agency (EPA) to allow such split registration. These two actions were especially unfortunate in light of the inability of the grain market to provide for the segregation of the crops, and the apparent unwillingness of some of the companies marketing the technology to communicate and enforce the limitations

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43. For an article discussing many of the possible legal theories available to resolve pollen drift related damages akin to the StarLink affair, see Amelia P. Nelson, *Legal Liability in the Wake of StarLink: Who Pays in the End?*, 7 *DRAKE J. AGRIC. L.* 241 (2002).

on its use to farmers. Given this background it was entirely predictable that StarLink corn would find its way into the food supply. When the history of the StarLink affair is written, it will reveal many lessons. One important lesson is that without the brave actions of lawyers in the Iowa Attorney General's Farm Division, who stepped in to prevent the seed companies' initial attempts to unreasonably allocate the costs and liabilities to the "offending" farmers (many of whom had never seen the restrictive terms of the product approval) the whole episode may have evolved quite differently. These and other lessons should make the StarLink episode a powerful and highly instructive moment for all concerned. Whether we will be wise enough to be so educated is yet to be seen.

A key question raised by the StarLink episode is whether we will take additional steps to insure that crops not approved for use in certain markets will in fact be kept from them. The current approach relied on by biotech companies is to place most of this responsibility on the producers. This is done by placing language in the technology transfer agreement to make producers responsible for post harvest "channeling." For example, the provision used in the Grower's Copy of the "2002 Monsanto Technology/Stewardship Agreement" provides, in part:

Channeling: Grain/commodities harvested from Roundup Ready corn, YieldGard Corn Borer with Roundup Ready corn, Roundup Ready canola and Roundup Ready sugarbeets are approved for U.S. food and feed use, but not yet approved in certain export markets where approval is not certain to be received before the end of 2002. As a result, the grower is required to direct such grain/commodities to the following approved market options: feeding on farm, use in domestic feed lots, elevators that agree to accept the grain, or other approved uses in domestic markets only.<sup>44</sup>

In the "you agree" portion of the contract, the grower agrees "[t]o channel grain produced to domestic use as necessary to prevent

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44. See 2002 Monsanto Technology / Stewardship Agreement (on file with author).

movement to markets where the grain has not yet received regulatory approval for import.”<sup>45</sup>

#### *IV. Pharming—New Crops Present Practical Challenges to Protecting the Food Supply and Promise New Round of Legal Issues*

No doubt the biggest story in the last year in agricultural biotechnology circles has been the attention given to the idea of pharming: the production of genetically modified crops engineered to express some form of a pharmaceutically useful product. This “new” form of biotechnology has received considerable attention in the farm press and has generated a seemingly unrealistic set of economic expectations by Midwestern farmers and politicians.<sup>46</sup> From a legal standpoint, the development of pharming raises a whole new set of legal and policy issues, primarily because of legitimate concerns about the food safety risks of using food crops to produce drugs and the liability issues this will produce. Because of the nature of the risks, pharming has helped illuminate some of the fault lines that exist in the larger food system, perhaps as best illustrated by the tensions between food manufacturers (who remember well the costs and public relations impact of the StarLink episode) and the farming and biotech communities, both of which appear to have never met a technology they don’t think should be widely available and utilized.<sup>47</sup> To date, the food sector has been supportive of the development and use of agricultural biotechnology. Perhaps this is due to its own doctrinal resistance to government regulation. Remarkably, the pharma-crop situation has led the National Food Processors

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45. *Id.*

46. *Id.* The hoped for economic returns to farmers from pharma-crops may run aground on three shoals of industrialized agriculture: the number of acres actually needed for their production may be limited; the increased prices paid to farmers may be minimal because they did not contribute to the invention of the technology, but instead are only providing land and services; and the additional costs and risks associated with raising the crops and meeting the regulatory requirements for production will reduce the benefits. The reality is that there is little reason to expect pharma-crops to provide returns any larger than conventional crops.

47. For example, a General Mills executive speaking on a biotech panel in Chicago warned that food manufacturers receive no benefit from the current technology, noting, “candidly, we have told the biotech industry that we are in a perilous situation until consumer benefits arrive.” Ameet Sachdev, *Biotech “Perilous” for Food Industry*, DES MOINES REG., June 20, 2002, at 1A.

Organization to propose a moratorium on the use of the technology until the possible risks of contamination of the food supply can be addressed.<sup>48</sup> This came after the surprising offer by the biotechnology industry to limit the use of the technology in large parts of the country.<sup>49</sup>

The public debate over the production of pharma-crops and the adequacy of their regulations began in the summer of 2002, when a coalition of environmental groups, GE Food Alert, raised concerns about the safety of the technology and the adequacy of the USDA's effort to police the field experiments underway.<sup>50</sup> After these concerns became public, rumors of possible government actions against companies that raised the crops under experimental field permits emerged. The issue revolved around whether the companies followed agency guidelines that were designed to insure that no pollen from the crops drifted into neighboring fields and that precautions were taken to see that volunteer crops did not emerge the next year.<sup>51</sup>

While these rumblings were heard in farm country, the biotech industry stunned its supporters in the Midwest, especially in Iowa, by launching what amounted to a pre-emptive strike in an attempt to head off public concerns about possible contamination of the food supply with drugs. In late October, the Biotechnology Industry Organization (BIO) members announced a voluntary agreement to redline much of the Midwestern corn belt and not plant pharma-corn in these areas to avoid possible contamination within the food supply.<sup>52</sup> The surprise announcement caused difficulty for Governor

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48. See Anne Fitzgerald, *Coalition Urges More Attention to Food Safety*, DES MOINES REG., Feb. 8, 2003, at D1. This article concerns the coalition led by the Grocery Manufacturers of America and their petition to the FDA for stringent regulation of pharma-crops, using the same approach as with brick and mortar drug manufacturing facilities. Their proposal included requests that the FDA prohibit the use of corn and other food crops for production of plant based drugs and a request that the USDA stop issuing field trial permits for the crops. *Id.*

49. See, e.g., Philip Brasher, *Iowa Denied New "Drug" Corn*, DES MOINES REG., Oct. 23, 2002, at 1A.

50. See, e.g., Anne Fitzgerald, *Critics: Altered Crops Pose Risk to Health*, DES MOINES REG., July 12, 2002, at 1D.

51. See, e.g., Anne Fitzgerald, *Pioneer Fined for Violating Biotech Corn Permits*, DES MOINES REG., Dec. 13, 2002, at 1D (concerning fines the EPA assessed to Pioneer and Dow AgroSciences for violation of requirements on growing experimental crops).

52. See Brasher, *supra* note 49.

Vilsack in his Iowa re-election campaign and illustrated the split between the food manufacturers and the biotech industry.<sup>53</sup> The sudden action by the biotechnology industry led to editorials and a public relations campaign to get the policy reversed.<sup>54</sup> The industry action brought into question the future of biotech plantings and research at universities like Iowa State, which had made considerable investments in its Plant Sciences Institute.<sup>55</sup> The industry eventually agreed to lift the moratorium and comply with the federal government's new enhanced rules.<sup>56</sup> But the adequacy of the federal rules on pharma-crops next came into focus in what came to be known as the ProdiGene incident.

In late 2002, the enforcement of federal rules on the planting of biotech crops was brought into focus in a pharming case involving the Texas company ProdiGene.<sup>57</sup> Facts indicate that the company had failed to adequately enforce its field cleanup requirements on two sites in Nebraska and Iowa. This led the government to assess a three million dollar fine against the company, part of which was to cover the cost of the 500,000 bushels of contaminated grain the government had to purchase and incinerate.<sup>58</sup> The dispute, following on the heels of the BIO "redlining" proposal, brought extra focus on the adequacy of the federal regulatory structure.<sup>59</sup> As a result of the ProdiGene incident, the FDA took a renewed interest in the adequacy of its rules and, in mid-November, announced plans to increase the monitoring of the companies involved in pharming research.<sup>60</sup>

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53. See, e.g., Editorial, *Lift the Moratorium*, DES MOINES REG., Oct. 25, 2002, at 14A.

54. See, e.g., *Lift the Moratorium*, DES MOINES REG., Oct. 25, 2002, at 14A.

55. See Philip Brasher, *ISU Vows Biotech Research Will Go On*, DES MOINES REG., Oct. 25, 2002, at 1A.

56. See, e.g., Philip Brasher, *Biotech Group Lifts Corn Ban*, DES MOINES REG., Dec. 4, 2002, at 1A; *Bring on "Biopharming"*, DES MOINES REG., Dec. 5, 2002, at 12A.

57. Press Release, United States Department of Agriculture, *USDA Announces Actions Regarding Plant Protection Act Violations Involving Prodigene, Inc.* (Dec. 6, 2002), available at <http://www.usda.gov/news/releases/2002/12/0498.htm> (last visited Nov. 7, 2004).

58. See Andrew Pollack, *U.S. Investigating Biotech Contamination Case*, N.Y. TIMES, Nov. 13, 2002, at C7; Philip Brasher, *Biotech Corn May Have Tainted Soybeans*, DES MOINES REG., Nov. 13, 2002, at 1A.

59. See, e.g., Philip Brasher, *Prodigene Must Pay \$3 Million in Corn Case*, DES MOINES REG., Dec. 7, 2002, at 1A; Justin Gillis, *Tiny Shoots Lead to Big Biotech Headache*, DES MOINES REG., Dec. 29, 2002, at M1; Andrew Pollack, *Spread of Gene-Altered Pharmaceutical Corn Spurs \$3 Million Fine*, N.Y. TIMES, Dec. 7, 2002, at A15.

60. See Philip Brasher, *FDA to Tighten Biotech Crop Inspection*, DES MOINES REG., Nov.



*V. Intellectual Property Rights and Agriculturally Important Genetic Material—Supreme Court Clears Last Doubt*

When I wrote the article in 2000, one cloud on the horizon of the application of intellectual property protections to plant genetic material was an Iowa case involving a fight between Pioneer Hi-Bred International and an agricultural retailer over infringement of Pioneers' patent rights in its corn varieties. The case raised the issue of whether the language of the Plant Variety Protection Act (PVPA) preempted the ability of the Patent Office to grant patent protection for plant varieties such as the corn in dispute. The district and appellate courts predictably upheld the patents and ruled that the PVPA does not prevent their issuance.<sup>61</sup> The courts held that there was no conflict and patents on varieties were legal.<sup>62</sup> Surprisingly, the United States Supreme Court decided to take certiorari in the case and hear further arguments.<sup>63</sup> To make a long story short, the Court heard the case, considered the issues, and in a six to two decision reaffirmed what the seed and biotech communities believed all along—the PVPA does not preempt granting patents on plant varieties.<sup>64</sup> This case is significant because it shows that the Court is not going to revisit the larger issue concerning the wisdom or legality of granting patents on living materials. While other policy issues of trade, pollen drift, and regulatory enforcement continue to engage the public, the inside baseball aspect of biotechnology continues with fights over intellectual property rights between the major players over ownership and control of significant parts of the technology.<sup>65</sup>

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20, 2002, at 1D; *Set Tough Rules for Biofarms*, DES MOINES REG., Nov. 14, 2002, at 18A.

61. *Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc.*, 49 U.S.P.Q.2d 1813 (N.D. Iowa 1998), *aff'd* 200 F.3d 1374 (Fed. Cir. 2002).

62. *Id.*

63. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001).

64. *Id.*; see also Kevin M. Baird, Recent Development, *Patent Protection of Plants Grows Under the Supreme Court's Latest Decision*, 2002 U. ILL. J.L. TECH. & POL'Y 269 (2002); Anne Hazlett, *Supreme Court Holds Utility Patents May Be Issued for Plants*, AGRIC. L. UPDATE, Jan. 2002, at 4, 4-5; Mark D. Janis & Jay P. Kesan, *Intellectual Property Protections for Plant Innovation: Unresolved Issues After J.E.M. v. Pioneer*, 20 NATURE BIOTECH., Nov. 2002, at 1161.

65. See, e.g., David Elbert, *Pioneer Sues Rival Over Patent*, DES MOINES REG., Oct. 18, 2002, at 1D; Andrew Pollack, *Dispute Ends for Monsanto and DuPont*, N.Y. TIMES, Apr. 3, 2002.

From a farmer's perspective, the most immediate intellectual property rights issue is the impact of technology transfer agreements and product labeling on the ability to save and replant biotech crops. The bottom line is that biotech crops are only marketed under arrangements that comprehensively prevent this opportunity (because they do not allow leakage of the technology). The legality of these agreements has been debated in connection with the Roundup Ready technology agreement, but there is little doubt about their enforceability. In the last year some of the first court cases illuminating the issue have been decided.<sup>66</sup> The cases present few surprises and hold that the language of the planting restrictions is enforceable.<sup>67</sup> Of the court cases involving seed patent infringement and possible pollen drift, the fight between Canadian farmer Percy Schmeiser and Monsanto of Canada concerning his alleged infringement on Roundup Ready canola has received the greatest attention in the international press.<sup>68</sup> The Canadian district court ruled that Mr. Schmeiser had infringed upon Monsanto's rights, rejecting Mr. Schmeiser's theory that the canola came onto his property through drift or other unintentional sources.<sup>69</sup> In September 2002, the Canadian Court of Appeals upheld the decision.<sup>70</sup> The case may still go up for further appeal.

#### *VI. State Initiatives to Allocate Responsibility and Liability for Pollen Drift—Who Pays for “Adventitious” Presence?*

In my 2000 article, I commented that “[g]enetic pollution or ‘pollen drift’ is perhaps the most intellectually interesting legal issue relating to biotechnology.”<sup>71</sup> I still believe this is true, although the

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66. See, e.g., *Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed. Cir. 2002); *Monsanto v. Swann*, 308 F. Supp. 2d 937 (E.D. Mo. 2003).

67. See, e.g., David Moeller, *Monsanto Gets Injunction Against Seed-Saving Farmer*, 17 FLAG NEWSLETTER (Farmers Legal Action Group), Fall 2002, at 9; Donald Uchtmann, *Can Farmers Save Roundup Ready Beans for Seed? McFarling and Trantham Cases Say “No”*, AGRIC. L. UPDATE, Oct. 2002, at 4–5.

68. Information about this dispute can be found at <http://percyschmeiser.com> (last visited Jan. 5, 2005).

69. See *Monsanto Canada, Inc. v. Schmeiser*, 2001 FCT 256.

70. See *Schmeiser v. Monsanto Canada, Inc.*, 2002 FCA 309.

71. Hamilton, *supra* note 1, at 103.

development of legal precedent addressing this issue has been limited.<sup>72</sup> The StarLink litigation and settlement is perhaps the most significant development because it establishes responsibility for damages resulting from the use of the technology. However, because the case involved a violation of the regulatory approval of the product, it may not serve as controlling precedent in the more difficult case where the lawful use of an approved product results in measurable commercial damages to a non-compatible crop. As a result, courtroom battles to resolve conflicts over pollen drift from the production of GMO crops and the potential liability from contaminating neighboring non-GMO crops still loom on the legal horizon.<sup>73</sup>

State attempts to regulate the actual planting and use of biotech crops is another legal front on which several developments have occurred. For example, in March 2001, the North Dakota legislature considered, but rejected, a proposal prohibiting the planting of GMO wheat for two years.<sup>74</sup> In 2002, the Indiana legislature passed legislation designed to inject state law into the questions of liability and responsibility for use of biotech crops.<sup>75</sup> In 2003, the Iowa General Assembly introduced a new legislative approach to addressing pollen drift damages by creating a “Grain Integrity Indemnity Fund.”<sup>76</sup> This idea, based on the state’s grain indemnity fund, which protects farmers who store or sell grain from financial losses, would assess a small fee or excise tax on each bushel of grain sold in the state to fund a twenty-five million dollar indemnity fund to cover validated claims of damages from pollen contamination. While the idea can be criticized for failing to allocate the financial liability to either the developers of the technology or the actual users, the approach has the major benefit of providing an accessible pool of

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72. For an excellent discussion of many of the dimensions of this issue, as influenced by the StarLink affair, see Thomas P. Redick & Christina G. Bernstein, *Nuisance Law and the Prevention of “Genetic Pollution”*: Declining a Dinner Date with Damocles, 30 ENVTL. L. REP., May 2000, at 10,328.

73. See, e.g., Anne Fitzgerald, *Specialty Pollen Concern Blowin’ in Wind*, DES MOINES REG., Mar. 7, 2002, at 1D.

74. See Andrew Pollack, *Proposal to Bar Altered Wheat Seems Doomed*, N.Y. TIMES, Mar. 31, 2001, at A9.

75. H.B. 1119, 112th Gen. Assemb., 2d Reg. Sess. (Ind. 2003).

76. H.F. 80-108, 1st Sess. (Iowa 2003).

funds for compensating injured growers. Instead of requiring each dispute to become a courtroom battle over proof of causation and the measurement of damages, the indemnity fund approach would give farmers what they need most: a way to cover their damages.

*VII. International Trade Restraints on Marketing GMO Crops—  
When Will We Be Heard?*

The most contentious area of the biotechnology debate continues to be the relationship between the United States and the European Union and the issue of European regulations on the importation and labeling of American-raised GM crops. While the European Union has made progress in developing new standards, perhaps the best way to describe the situation in the winter of 2003 was mounting tensions moving inexorably toward a WTO trade war.<sup>77</sup> The only problem from the United States perspective was that another, more important, war moved onto center stage. It was politically and diplomatically difficult to bash the Europeans over GMO policy while trying to motivate them to support our efforts to wage war on Iraq.<sup>78</sup> As a result, the drumbeat for a trade war with the Europeans over GMO policy, which many see as a much-needed test of the resolve and efficacy of WTO rules and processes and a defense of sound science, has had to take a back seat to more pressing geo-political concerns.<sup>79</sup> Even among those nations embracing biotechnology there exists issues relating to free trade in the technology and efforts to protect domestic economic opportunities. The situation in China is perhaps the best example of this schizophrenic situation: the nation embraces the use of biotechnology but uses an uncertain regulatory environment to chill the ability of Western companies to export crops to the country.<sup>80</sup> While Chinese regulations on biotechnology

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77. See, e.g., Philip Brasher, *Fear Threatens U.S. Crop Sales in Europe*, DES MOINES REG., Nov. 11, 2002, at 1A.

78. See Elizabeth Becker, *U.S. Delays Suing Europe over Ban on Modified Food*, N.Y. TIMES, Feb. 5, 2003, at A6.

79. See Philip Brasher, *Biotech Ban Tries Patience of U.S.*, DES MOINES REG., Mar. 4, 2003, at 1D.

80. See Joseph Kahn, *The Science and Politics of Super Rice*, N.Y. TIMES, Oct. 22, 2002, at C1.

continue to evolve and raise concerns for United States exports, some American companies have been able to develop plans for moving forward with China.<sup>81</sup>

### *IX. Resistance and GMOs—Refuges, Roundup and Resistant Weeds*

From a technological standpoint, one significant issue related to the widespread adoption of GMO technology is how its use will eventually lead to the development of resistance in the target pest. From a regulatory perspective, this concern is most directly at issue in the regulation of bio-pesticides such as Bt corn. The regulatory focus is on the need for farmers to follow resistance management plans, which include planting non-Bt refuges. The counter-intuitive nature of requiring farmers not to use an effective technology and the unwelcome task of actually enforcing regulations relating to refuges help complicate this topic. In late November 2002, the EPA announced a “two-strikes” policy concerning farmer compliance with the field refuge requirements for planting Bt corn, including roles for companies to aid in the enforcement.<sup>82</sup> The issue of resistance management took another turn early in 2003, when new research was reported indicating the increased appearance of weeds resistant to the use of Roundup.<sup>83</sup> The significance of the story was emphasized when it became the subject of a somewhat surprising editorial, entitled “Too Much Roundup.”<sup>84</sup>

### CONCLUSION: THE FUTURE OF LAW AND BIOTECHNOLOGY

This article provides a concise update of many of the significant legal and policy issues shaping American law as relates to agricultural biotechnology. Some issues, such as the international bio-safety protocol and the recent completed international agreements

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81. See, e.g., Anne Fitzgerald, *Joint-Venture to Produce, Sell Seed Corn to Chinese Farmers*, DES MOINES REG., Dec. 12, 2002, at 1D (concerning a recent agreement between Pioneer Hi-Bred International and a major Chinese seed corn company).

82. See Philip Brasher, *Rules Govern Biotech Planting*, DES MOINES REG., Nov. 27, 2002, at D1.

83. Philip Brasher, *Roundup-Resistant Weeds Are Cropping Up All Over*, DES MOINES REG., Jan. 10, 2003, at A1.

84. *Too Much Roundup*, INT'L HERALD TRIB., Feb. 20, 2003, at 8.

on plant genetic resources, were beyond the scope of this discussion. Other areas of ongoing litigation, such as the StarLink settlement, could be the basis for their own lengthy treatment. What is clear from this discussion is that a series of significant legal and policy questions will continue to shape how agricultural biotechnology will be accepted in America. As the article makes clear on the issue of food safety and consumer acceptance, unless some new incident occurs to provide evidence of safety concerns, the marketplace will continue to welcome GMO foods. In the near term, one of the most significant issues is whether genetically altered salmon will be marketed, and if so, what type of environmental restrictions will be placed on its production. From the perspective of farmers and state legislators, the future of pharma-crops will offer both promise and problems. It will be interesting to see whether the market reality for the crops can match the expectations they appear to be generating. On the international front, the tension between the United States and the European Union over GMOs will remain a source of conflict that may or may not be addressed when the European Union approves its long-promised policy on the production of GMO crops. Biotechnology is a powerful and elegant technology that will undoubtedly play a role in the future of world agriculture. The complex social issues relating to biotechnology will test the ability of the legal system to develop rules and mechanisms to guide its use.