

# Regulating Environmental and Safety Hazards of Agricultural Biotechnology For A Sustainable World

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Agricultural biotechnology today has considerable support in the U.S. agricultural community as an important means to improve agriculture. In certain other parts of the world, the value and perceived dangers of agricultural biotechnology are a subject of intense debate. A key task for U.S. policymakers is to assure that the regulatory and liability system that controls the development of agricultural biotechnology strikes a proper balance between the progressive and successful development of new technology and the need to protect the public and the environment from harm.

This Article seeks to illuminate the proper approach for regulating the environmental and safety hazards of agricultural biotechnology. This Article examines the structure and principles of such regulation in view of generally accepted principles of environmental regulation designed to create a sustainable world. The extent to which differing biotechnology regulatory approaches chosen by the United States and other parts of the world are consistent with sustainability principles should assist us in examining whether improvements in biotechnology regulation would be desirable.

This Article first presents an overview of key legal principles that support sustainability. This Article then reviews the major alleged risks of agricultural biotechnology. It then describes the existing U.S.

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and European agricultural biotechnology regulatory system designed to control those risks. Next, this Article analyzes the existing U.S. regulatory system using sustainability principles. In the course of that analysis, this Article considers lessons to be derived from three case studies: the permitting of Starlink™ corn, the discovery of Mexican maize containing genetically engineered corn genes, and the possible permitting of transgenic salmon for ocean fish farming. This Article also considers lessons from the broader regulatory history of pest-protected plants. Based on the analysis of sustainability issues related to agricultural biotechnology, this Article concludes that despite the obvious, substantial benefits that agricultural biotechnology can confer on society, the United States needs to improve its regulatory process to ensure a proper weighing of the full social benefits and costs of agricultural biotechnology and to clarify liability rules governing the use of agricultural biotechnology. These reforms should provide both better public protection and increased public support for the agricultural biotechnology industry.

## I. INTRODUCTION

The progress of agricultural biotechnology is often measured in the popular imagination by news accounts of groundbreaking scientific developments such as the cloning of Dolly, the sheep, by Scottish scientists. Although less sensational, an indication of potentially greater consequence is a recent report by the National Research Council (NRC) discussing the growing number of transgenic pest-protected crops commercially planted in the United States.<sup>1</sup>

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1. Comm. on Genetically Modified Pest-Protected Plants, Bd. on Agric. and Natural Res., Nat'l Research Council Genetically Modified Pest-Protected Plants: Science and Regulation xi (2000) [hereinafter NRC Report]:

Transgenic pest-protected crops were first commercially planted in the United States in 1995. Since then the acreage planted to transgenic crops has increased rapidly with some 70 million acres being grown in the United States, and 98.6 globally in 1999. Of this acreage, a large percentage (for example, 30 million acres in the US in 1999) is planted with transgenic pest-protected crop varieties containing the *Bacillus thuringiensis* (*Bt*) gene which confers protection from certain insect pests and with varieties that are herbicide-tolerant. In 1998, about 25% of the US cotton acreage and 21% of the corn acreage was planted with varieties containing *Bt* genes.

Remarkably, these millions of acres of crops were planted even though the Environmental Protection Agency (EPA) had not then adopted final regulations governing the approval process for transgenic pest-protected plants.<sup>2</sup> Although the EPA's proposed regulations have been on the books since 1994 and have generally been implemented in practice, the regulations were not finalized, even in part, until 2001.<sup>3</sup> In fact, some aspects of the proposed regulations are still not finalized, including certain exemptions recently found to be scientifically questionable, or in some cases even indefensible, by the NRC.<sup>4</sup> Moreover, probable violations of the inadequate EPA regulatory restrictions on the use of a genetically engineered corn strain, Starlink™ corn led to the "voluntary" removal of its EPA registration, the withdrawal of millions of acres of corn from the market, and the proposal of substantial changes in regulatory rules governing biotechnology plant crops in both the United States and Europe.<sup>5</sup>

These regulatory failures suggest that the actual marketplace use of genetically modified plants in the United States appears to be substantially outpacing the ability of the U.S. regulatory system to effectively control their use. In itself, this lack of effective control does not indicate that there is an inherent problem with agricultural biotechnology, but it does indicate, very strongly, that this is a good time to take a dispassionate look at whether the performance of the U.S. regulatory and liability system can be improved.

The remarkably rapid and widespread introduction of pest-protected crops in the United States, where most of the world's

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2. *See id.*

3. The EPA's final rule on plant-incorporated protectants (PIP), issued July 19, 2001, clarifies the relationship between plants and plant-incorporated protectants and establishes new regulations specifically for PIPs. *See Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants*, 66 Fed. Reg. 37772 (July 19, 2001).

4. The NRC Report, issued in 2000, criticized the EPA's proposed exemptions that would categorically apply to all viral coat proteins and transgenic pest-protectants derived from sexually compatible plants. *See NRC Report, supra* note 1, at 13. The EPA's final rule, issued in July 2001, fails to determine the propriety of these two exemptions. *See Plant-Incorporated Protectants*, 66 Fed. Reg. 37855 (proposed July 19, 2001). In fact, the EPA placed the entire NRC Report in the docket for rulemakings related to certain proposals on PIPs, and requested public comment on the document, particularly with regard to its conclusions about these exemptions. *See id.*

5. *See infra* Part VI.A.

existing acreage of such crops is planted, is in striking contrast to the situation in Europe, where many genetically modified U.S. products, such as BT corn, could not be sold for several years and now face sharply increased regulation.<sup>6</sup>

This contrast arose because over the past twenty years the United States and most other countries adopted divergent approaches to the environmental and safety hazard regulation of agricultural biotechnology.<sup>7</sup> The U.S. government accepts the view that agricultural biotechnology is merely a technical extension of traditional agricultural selective breeding practices, which it regards

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6. According to Jeffrey Francer:

[As of 2000], sales of corn from the United States to the European Union (EU) have been halted since 1997. EU nations barred the import of corn and its by-products—trade that had once averaged more than 2.1 million tons annually and accounted for almost 5 percent of all U.S. exports. While farmers in the states had been exporting corn to Europe since the early days of our Republic, this facet of international trade is effectively at a standstill, because portions of the American corn have been grown from genetically modified seeds. The European embargo of American-grown corn threatens \$500 million of annual U.S. corn exports, and at the time of this writing, the trade dispute has still not been resolved.

Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 257-58 (2000) (footnotes omitted).

7. As used in this Article, the term “agricultural biotechnology” means genetic modification of food or animals using recombinant DNA or cell fusion technology and includes items such as plant gene expression to produce toxins (sometimes referred to as “pest-protected plants”), cloning, and animal production of human drugs or vaccines. Animal cloning and drug production involve complex additional issues that fall outside the scope of this Article.

From another perspective, biotechnology could be described as:

allow[ing] scientists to manipulate genetic material, whether it involves the cloning and propagation of plants that possess the desired characteristics, or the creation of new varieties from existing stock. Biotechnological procedures allow scientists to move specific genes within an organism, or from one organism to another, whether the gene is from an organism of the same species or a different species. Generally speaking, the product of these processes can be described as “bioengineered,” “genetically engineered,” or “transgenic.” In the broadest sense, an agricultural product that has been genetically altered using biotechnological techniques is frequently called a “Genetically Modified Organism” (GMO) or a “Living Modified Organism” (LMO).

See Holly Saigo, Note, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 GEO. INT'L. ENVTL. L. REV. 779, 783 (2000).

This Article does not consider the moral, ethical, equity, and property rights or related economic efficiency issues raised by biotechnology except to the extent they arise within the framework of sustainability.

as both time-tested and largely harmless or self-correcting, and regulates biotechnology products accordingly.<sup>8</sup> The first major National Academy of Sciences' review of biotechnology in 1987 concluded that biotechnology products, rather than processes, should be the subject of risk analysis for regulation.<sup>9</sup> The recent NRC Report on genetically modified pest-protected plants reaffirmed this conclusion.<sup>10</sup>

The remainder of the world, however, considers that recombinant DNA and cell fusion biotechnology are capable of creating organisms and products that could not exist under conditions of natural selection. Although the European Union (EU), for example, acknowledges that there are benefits to agricultural biotechnology, it also has substantial concerns about the risks of that technology.<sup>11</sup> As

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8. See Francer, *supra* note 6, at 265-66. Francer explains that the U.S. government adopted a "Coordinated Framework for Regulation of Biotechnology" in 1986, under which "foods, drugs, medical devices, biologics, and pesticides developed through modern biotechnology would be regulated within the same statutory framework as comparable products using traditional techniques." *Id.* Furthermore, Francer notes that "[i]mplicit in the Coordinated Framework's policy—that additional legislation would not be needed to regulate biotechnology—are the assumptions that products developed through biotechnology do not pose inherent risks to human health and that the level of risk from biotechnology depends on the characteristics and consumption of individual products." *Id.* at 267.

9. NAT'L ACAD. OF SCIS., INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENV'T: KEY ISSUES (1987) (as quoted in NRC Report, *supra* note 1, at 5).

10. See NRC Report, *supra* note 1, at 43-45.

11. The EU's view of agricultural biotechnology can be summarized as follows:

Genetically modified organisms (GMOs) or 'living modified organisms' (LMOs) offer considerable potential for increasing agricultural productivity, but at the risk of unpredicted and unintended impacts on existing biological systems. For example, the transfer of genetic material from genetically modified agricultural crops to wild plants could reduce their genetic diversity, a potential problem where native ecosystems and agricultural land are adjacent. The traits of herbicide resistance and stress tolerance in GM crops have the potential to be transferred to weed species, increasing the competitive advantage of weeds over native varieties and reducing the susceptibility of the weeds to herbicides (CEAT 1994). There may also be direct effects, such as the toxicity of some GMO pollen to honeybees.

GM crops, and possibly livestock, can supplant native varieties (land races) by commercial pressures such as patenting and seed monopolies. These practices can present a direct threat to agrobiodiversity. They may also present a threat to "Food security", by reducing system complexity and thereby increasing the risk of widespread crop failure. Further challenges to sustainable development could arise as a consequence of control of the technology by a limited number of multinational corporations, and commercial pressures to develop monopoly mechanisms such as the

a result, the EU is prepared to allow countries to bar agricultural biotechnology products unless conclusive scientific evidence of their lack of harm is provided.<sup>12</sup>

This broad difference in regulatory approaches to agricultural biotechnology is based, in part, on the differing cultures, economies, and political and natural environments of different parts of the world.<sup>13</sup> It would be prudent to consider whether this apparently fundamental difference of view on biotechnology regulation is based solely on such sociopolitical factors, or may, instead, have some grounding in ecological principles. After all, the European approach to biotechnology regulation is similar, in important respects, to the way in which U.S. environmental laws regulate most environmental hazards, since individual American states are permitted by federal law to set health and safety standards for environmental risks in excess of federal minimum standards in many cases.<sup>14</sup> One way of answering the question about the ecological grounding of these differing regulatory approaches is to examine biotechnology

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'terminator gene'. The risk of adverse impacts from GMOs on biodiversity necessitates the development of international protocols for their transport, handling and use. Where technical, financial, institutional and human resources to address GMO biosafety are lacking, risks of negative impacts are higher. Use of GMOs requires the agreement of concerned states if there is any potential for adverse effects on conservation and sustainable use of biodiversity.

European Union, *Toward Sustainable Economic Development and Co-operation* 285 (2000), version 1.0, available at [http://europa.eu.int/comm/development/sector/environment/env\\_integ/env\\_integration\\_manual/pdf/BiodiversityBPGuide.pdf](http://europa.eu.int/comm/development/sector/environment/env_integ/env_integration_manual/pdf/BiodiversityBPGuide.pdf) (last visited Sept. 14, 2002).

12. The Cartagena Biosafety Protocol (Protocol) represents formal international recognition of this view. See CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY (Feb. 23, 2000), available at <http://www.biodiv.org/biosafety/protocol.asp#> (last visited Jan. 13, 2001). The Protocol contains exemptions for pharmaceuticals and certain other biotechnology products. *Id.* at 5-6.

13. The EU exists, after all, primarily as an effort to overcome the heavily protectionist trade policies of its member countries in order to promote free trade throughout the EU. It would not have been necessary to create such a group if these countries had permitted free trade. It is generally acknowledged that agriculture is one of the most, if not the most, heavily subsidized and protected industries within many countries of the EU. As a result, complaints about the alleged dangers posed by U.S. biotechnology products can be a remarkably convenient pretext for European trade protectionism. However, it by no means follows that simply because a foreign country has a protectionist economic interest in criticizing a biotechnology product that there is no basis for the criticism of the product.

14. See, e.g., Clean Air Act of 1965 § 112(d)(1), 42 U.S.C. § 7412 (1994); Clean Water Act of 1972 § 510, 33 U.S.C. § 1370 (1994); Comprehensive Environmental Response, Compensation, and Liability Act of 1980 § 114, 42 U.S.C. § 9614 (1994).

regulation in light of the broad lessons about sustainability learned from several decades of successful U.S. environmental regulation.

Fitting biotechnology regulation into the context of sustainable development is an important international goal, both from an environmental and economic perspective. The significance of this issue is described in the recent report of the EU-U.S. Consultative Forum on Biotechnology.<sup>15</sup>

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15. EU-U.S. Biotechnology Consultative Forum, Final Rep. 7 (Dec. 2000) [hereinafter Consultative Forum]:

One of the greatest challenges facing today's world is achieving sustainable agriculture in developed and developing countries. Today the world is not food secure in terms of access to food. Eight hundred million people are undernourished and 200 million children under five years of age are underweight. The world's population will increase by another 1.5 billion within the next 20 years. Improvements in yield on a reliable and sustainable basis will be needed to meet the demands of the growing population. The place of biotechnology and other technologies and approaches in today's world should be seen in this context.

The Consultative Forum endorses public responsibility for global governance of biotechnology as one contribution to sustainable agriculture. All stakeholders should take their share of responsibility in being open with citizens and consumers, establishing transparent and accountable mechanisms for developing accurate information, sponsoring participatory debate, and striving for comprehensive and comprehensible regulatory systems.

Conventional agriculture has significant limitations that support the effort to develop agricultural biotechnology:

With respect to agriculture, agronomists can use genetics to manipulate characteristics that are commercially important to crop production and the agribusiness industry. Specifically, agronomists work towards four main objectives. For each crop, agronomists seek to improve: (1) agronomic suitability of the crop plant to its environment, (2) quality of the crop produced, (3) yield of the crop produced, and (4) the resistance of plants to disease and pests.

Historically, the only way to improve qualities of crop plants has been to selectively breed the plants to enhance the desired characteristics. Cross-breeding different varieties of self or cross-pollinating plants results in the development of many unique and genetically diverse landrace varieties, also called cultivated varieties ("cultivars"), of crop plants that possess the qualities sought by the farmer. Although cross-breeding is an effective means of improving crop plants on a large scale, it can be incremental, time-consuming, and imprecise. There is no way to precisely control individual traits, such as resistance to a certain fungus, without concurrently altering a variety of other traits. Additionally, cross-pollinating plants do not discriminate as to what other plants with which they will reproduce. The plants will cross within their variety and across varieties, and can outcross with wild relatives. While such outcrossing can be seen as beneficial because it increases diversity of the genetic base, it can result in the expression of traits unexpected or contrary to the intention of the breeder.

## II. LEGAL PRINCIPLES SUPPORTING SUSTAINABILITY

There is no formal global consensus on environmental principles or policies necessary to create a sustainable environment. In part, this results from the U.S.'s refusal to ratify significant international environmental agreements over the past two decades. These include the Convention on Biological Diversity,<sup>16</sup> which was an outgrowth of the Rio de Janeiro Summit; its offshoot, the Cartagena Protocol on Biosafety,<sup>17</sup> and the Kyoto Protocol on Climate Change.<sup>18</sup> At the

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Consequently, agronomists have turned to biotechnology in seeking a better way to breed for the expression of specific desired traits.

Saigo, *supra* note 7, at 782-83 (footnotes omitted).

16. According to Saigo, the U.S.'s refusal to ratify the Convention on Biological Diversity should have been expected:

[T]he United States had repeatedly voiced three substantive objections to the provisions of the Convention. First, the Convention required developed countries to help fund environmentally sound development in developing countries, without imposing definite restrictions on the funding power that could be levied against the developed countries.

Second, the Convention called for essentially open technology transfer—specifically including transfer of biotechnologies in Article 16, Paragraph 1—between developing and developed countries. This, when analyzed in conjunction with other related provisions, disregards patents and other intellectual property rights. Not only does this provision require transfer of publicly owned technology, but also transfer of technology that is privately owned, despite the proprietary intellectual property rights of the owner. . . .

Third, the Convention calls for regulatory measures to be applied to biotechnology that are not required for other potentially environmentally harmful or diversity reducing activities. Article 8(g) of the Convention specifically requires nations “to regulate living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.” In addition to the language of Article 8(g), Article 19, paragraph 3 of the Convention states:

The parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

*Id.* at 802-04 (footnotes omitted).

17. See Cartagena Protocol on Biosafety: Signatures and Ratifications, available at <http://www.biodiv.org/biosafety/signinglist.asp> (last visited Apr. 4, 2002). The full text of the Cartagena Protocol on Biosafety can be found in the Cartagena Protocol to the Convention on Biological Diversity, United Nations Conference on Environment and Development, June 5, 1992, 31 I.L.M. 818, available at <http://www.biodiv.org/biosafety/protocol.asp> (last visited

same time, however, the United States, through its environmental policies, actually supports, and indeed developed, many of the core environmental principles embodied in these international agreements.<sup>19</sup> Thus, although there is no formal consensus for coordinated, international action on certain issues, in many cases, the United States subscribes to commonly held environmental policy principles.

Scientists agree that creation of long term environmental sustainability entails the creation of a balance, or equilibrium, between the supply of environmental goods and the demands on the environment.<sup>20</sup> There are a series of basic principles that, while not rigorously observed in practice, are generally accepted as factors in regulatory policy decision making in the United States that are supportive of creating an environmental equilibrium that would lead to sustainability: sustainable yield; maintenance of biological diversity; internalization of environmental costs of economic activity through liability or administrative rules; transparency of policy; and public participation.

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Apr. 4, 2002).

18. See Kyoto Protocol: Status of Ratification, *available at* <http://www.unfccc.de/resource/kpstats.pdf> (last updated Mar. 6, 2002) (lists signatories to the United Nations Framework Convention on Climate Change). The full text of the Kyoto Protocol can be found in the Kyoto Protocol to the United Nations Framework Convention on Climate Change, Dec. 10, 1997, 37 I.h.n. 22, *available at* <http://www.unfccc.de/resource/conv/index.html> (last visited Jan. 13, 2001).

19. For example, as early as 1973, the United States demonstrated its commitment to preservation of biological diversity through enactment of the Endangered Species Act, 16 U.S.C.A. §§ 1531-1540 (Supp. 1999). The United States' unwillingness to support many of these international environmental agreements stems in substantial part from disagreements with other countries about related issues raised by the agreements, such as proper intellectual property protection policy, redistributive policy issues, or proper trade policy, as opposed to disagreement on fundamental environmental protection principles. See, e.g., Saigo, *supra* note 7, at 811-15.

20. JOHN E. SMITH, BIOTECHNOLOGY 159 (3d ed. 1996):

For any technology to be considered sustainable it must not degrade the environment through either the overuse of resources or the creation of unbearable ecological burdens. It is becoming increasingly evident that humankind's activities within the environment are far exceeding the sustainable capacity of the earth. In essence, the environmental load equals the size of the world's population [multiplied by] the prosperity or welfare per head of population [multiplied by] the environmental use per unit of prosperity (welfare).

### *A. Sustainable yield*

The United States accepts as a matter of broad national policy that renewable resources, such as forests and crop land, should be managed in such a way that they will provide a sustainable, long term yield even where short term market considerations dictate otherwise.<sup>21</sup> The United States imposes sustainable yield limitations on permitted harvests of public renewable resources, such as national forests.<sup>22</sup> For many years, the federal government focused substantial resources on conserving private agricultural resources, such as soil.<sup>23</sup> In recent years, the federal government has become increasingly involved in limiting private resource losses through expanded conservation programs and increased attention to agricultural pollution.<sup>24</sup>

### *B. Maintenance of Biological Diversity*

The United States accepts, as a matter of national policy, the basic ecological principle that biological diversity should be maintained if

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21. See President's Council on Sustainable Development, *Sustainable America: A New Consensus for Prosperity, Opportunity, and A Healthy Environment for the Future* (Feb. 1996), available at [http://clinton2.nara.gov/PCSD/Publications/TF\\_Reports/amer-chap1.html](http://clinton2.nara.gov/PCSD/Publications/TF_Reports/amer-chap1.html), which sets forth "National Goals Toward Sustainable Development," including the following:

#### GOAL 4: CONSERVATION OF NATURE

Use, conserve, protect, and restore natural resources—land, air, water, and biodiversity—in ways that help ensure long-term social, economic, and environmental benefits for ourselves and future generations.

*Id.*

22. See, e.g., United States Department of Agriculture, Forest Service, Forest Product Emphasis Areas, available at [http://southernregion.fs.fed.us/planning/saa/sap\\_rx\\_10.htm](http://southernregion.fs.fed.us/planning/saa/sap_rx_10.htm) (last visited Apr. 4, 2002) (describing "Sustained Yield Timber Management" practices utilized by the Forest Service).

23. See, e.g., J. JEFFREY GOEBEL, THE NATIONAL RESOURCES INVENTORY AND ITS ROLE IN U.S. AGRICULTURE (1998), available at <http://www.statlab.iastate.edu/survey/nri> (last visited Apr. 9, 2002) (providing a historical account of the federal government's efforts to collect natural resource data since the 1930s).

24. For example, the Conservation Reserve Program, administered by the U.S. Department of Agriculture, offers cost-sharing and incentive payments to farmers who plant resource-conserving cover on their cropland. See Farm Service Agency Fact Sheet on the Conservation Reserve Program (Oct. 1999), available at <http://www.fsa.usda.gov/pas/publications/facts/html/crp99.htm> (last visited Apr. 4, 2002).

possible, and that government policy should require a searching and skeptical review of economic or ecological developments that significantly limit biological diversity.<sup>25</sup> The United States, for example, invests billions of dollars per year in the maintenance of biological diversity through protection and operation of its national parks, forests, and wildlife refuges, and in restoration projects such as the Everglades restoration project.<sup>26</sup> It also enforces the Endangered Species Act (ESA).<sup>27</sup> In situations where the government is required to approve private action through a permit process, the government is committed by the ESA to prevent extinction of species absent a truly compelling justification.<sup>28</sup>

### *C. Internalization of Environmental Costs of Economic Activity Through Liability or Administrative Rules*

The bedrock principle of government policy in regulating environmental costs in both the United States and Europe is that “polluters should pay.”<sup>29</sup> Liability rules and administrative rules

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25. See *supra* note 21 (stating the need to develop “measures of threats to habitat loss and the extent of habitat conversion, such as the rate of wetlands loss, [and to] decrease [] the number of threatened and endangered species,” to reflect how well the United States is contributing to the protection of natural systems world wide).

26. For example, the Department of the Interior reported spending of \$10.3 billion for fiscal year 2002. See Offices of Management and Budget, Budget of the United States Government, Fiscal year 2003, Department of the Interior, *available at* <http://www.whitehouse.gov/omb/budget/fy2003/bud17.html> (last visited Apr. 5, 2002).

27. 16 U.S.C. §§ 1531-1540 (Supp. 1999).

28. See *Tennessee Valley Auth. v. Hill*, 437 U.S. 153 (1978).

29. In the United States, the principle that those whose activities create environmental externalities should be forced to bear or internalize the full costs of the externalities is generally accepted. It serves as the policy basis for major federal statutes such as the Superfund Law, 42 U.S.C. §§ 9601-9675 (1994), and is discussed as a foundation principle of environmental policy in most introductory environmental law texts. See, e.g., ZYGMUNT J.B. PLATER ET AL., ENVIRONMENTAL LAW AND POLICY: NATURE, LAW, AND SOCIETY 37 (2d ed. 1998).

The EU also supports the “polluter pays” principle. European Commission, White Paper on Environmental Liability, Com 5 (2000). The EU has expressed a similar view on the need to assign a monetary value to externalities and thus to assist in controlling them. See Position Paper of the European Consultative Forum on the Env’t and Sustainable Dev.: EU sustainable dev. strategy § 3.3 (Oct. 30, 2000), *available at* [www.europa.eu.int/comm/environment/forum/agri.htm](http://www.europa.eu.int/comm/environment/forum/agri.htm):

“Externalities” are those environmental and social impacts which are not reflected in the price of goods and services. There are many ways in which these impacts can be recognised—for example through strategic environmental assessment or life cycle

should force the internalization of such social costs in the manner that lowers transaction costs to the maximum extent possible. There are at least two critical features of such a regulatory or liability system: (1) proper identification of the full social costs of an activity; and (2) choice of efficient methods of requiring internalization of those costs. The first element of cost internalization is of particular concern where the social costs of an activity are not obvious or correctly perceived, while its benefits are. This imbalance between the perception of actual costs and benefits existed in the early development of the U.S. chemical industry.<sup>30</sup> As a result, chemical pollution of certain kinds accumulated for some years before its serious adverse effects became fully apparent, leading ultimately in some cases to a complete U.S. ban on continued use of the chemicals concerned.<sup>31</sup>

A related issue is that of financial assurance requirements. Activities that involve unusually large amounts of risk to third parties or the environment should be conducted only by entities that can afford to bear the full financial cost of errors in the conduct of those activities so that society at large is not required to bear such costs.

#### *D. Transparency of Policy*

The United States accepts that the government should make clear to the public what its policy will be and the basis on which its policy has been and will be formulated. This responsibility includes a broad right of citizen access to information obtained by the government unless that information is subject to explicit statutory protection against disclosure of, for example, trade secret information.<sup>32</sup>

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assessment. Full account should be taken of hidden or neglected environmental and social external factors in decision-making at the policy, business and individual levels. They should be identified, quantified, and when possible given monetary value.

30. See generally RACHEL CARSON, *SILENT SPRING* (Fawcett Crest 1964) (1962); *United States v. Hooker Chem. & Plastics Corp.*, 607 F. Supp. 1052 (W.D.N.Y. 1985).

31. The use of asbestos, a naturally occurring material, is another example of a situation where the benefits were obvious long before the major social costs became apparent. The result has been a social tragedy involving numerous fatalities, severe crippling illnesses, and industrial bankruptcies, as the U.S. tort liability system began to create a balance between the costs and benefits of asbestos use years after that use first began.

32. See, e.g., The United States Freedom of Information Act, 5 U.S.C. § 552 (2000).

### *E. Public Participation*

A distinctive feature of U.S. environmental law is that it authorizes substantial public participation in the process of forming and enforcing regulations for environmental protection.<sup>33</sup> Unlike most other countries in the world, the United States accepts the concept that members of the public outside of the government should be given an opportunity to influence public policy through the indirect mechanism of electoral accountability and also through direct efforts to influence regulatory policy by public comment and court challenges to unlawful government action.

### III. POTENTIAL RISKS OF AGRICULTURAL BIOTECHNOLOGY

To analyze the existing U.S. regulatory system, it is necessary to consider the risks of agricultural biotechnology that must be regulated in order to achieve the claimed benefits of the technology. For purposes of this analysis, the author accepts the fundamental conclusion of the NRC Report that biotechnology is not “inherently dangerous.”<sup>34</sup> However, biotechnology has the potential to create products that may give rise to human health or environmental risks. In some ways, these health and environmental risks are similar to those that can be created by conventional agriculture.<sup>35</sup> According to

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33. There are citizen suit provisions in virtually every major federal environmental law allowing private individuals to directly compel compliance through court action. *See, e.g.*, Clean Air Act § 304, 42 U.S.C. § 7604 (1994); Clean Water Act § 505, 33 U.S.C.A. § 1365 (1993); Resource Conservation and Recovery Act § 7002, 42 U.S.C.A. § 6972 (1994); Comprehensive Environmental Response, Compensation, and Liability Act § 310, 42 U.S.C. § 9659 (1994). A notable exception, pertinent to this article’s subject matter, is the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y (Supp. 1999).

34. *See* NRC Report, *supra* note 1. This conclusion actually appears to be shared by at least certain elements within the EU. *See* European Comm’n, White Paper on Environmental Liability, 17 (Feb. 9, 2000), available at [http://europa.eu.int/comm/environment/liability/white\\_paper.htm](http://europa.eu.int/comm/environment/liability/white_paper.htm) (stating that “activities with respect to genetically modified organisms (GMOs), are not dangerous per se, but have the potential, in certain circumstances, to cause damage to health or significant environmental damage”).

35. For example, the common goldfish, created by conventional agricultural breeding, is now one of the most widely dispersed “exotic” species found in the United States, and is generally regarded as directly responsible for having caused the extinction of several native American fish species. *See* Office of Science and Technology Policy, *CEQ/OSTP Assessment: Case Studies of Environmental Regulation for Biotechnology*, Case Study One: Salmon plus sidebar, at 39, available at <http://www.ostp.gov/html/012201.html> (last visited

the NRC Report, “[T]oxicity, allergenicity, effects of gene flow, development of resistant pests, and effects on non-target species are concerns for both conventional and transgenic pest-protected plants.”<sup>36</sup>

The NRC found that “the Committee is not aware of any evidence that foods *on the market* are unsafe to eat as a result of genetic modification.”<sup>37</sup> At the same time, however, as discussed below, the NRC agreed that considerable additional research and regulatory review should be conducted to assess certain key risks posed by future pest-protected plants.

In addition, biotechnology has the ability to create risks that cannot be created by conventional agriculture. Agricultural biotechnology can introduce into a species novel genetic materials that cannot be introduced by conventional breeding techniques.<sup>38</sup> Moreover, genetically engineered plants and animals may have characteristics that permit them to be relatively successful in competing with wild varieties of these plants and animals in the short-run, but the genetically engineered organism may also lack certain characteristics of the wild varieties making them more vulnerable to eventual extinction in the long-run. Theoretically, the result is that a genetically engineered crop variety could first extinguish its wild-type competitors and then itself be extinguished.<sup>39</sup> Critics of genetically engineered agriculture raise specific risks, discussed below, that they contend are of major concern.<sup>40</sup>

In analyzing these alleged risks, it is important to bear the following points clearly in mind. First, many of these risks or costs of agricultural biotechnology are also risks or costs associated with conventional agricultural practices. Therefore, the agricultural

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Mar. 19, 2002) [hereinafter Case Studies], *reprinted in* ANDERSON ET AL., BIOTECHNOLOGY DESKBOOK 151 (2001) [hereinafter Deskbook]. Similarly, the National Academy of Sciences points out that the conventional breeding of potatoes for certain desirable characteristics has in some cases caused potentially harmful increases in the levels of certain known toxins found in potatoes. *See* NRC Report *supra* note 1, at 70.

36. NRC Report, *supra* note 1, at 6.

37. *Id.* at 8 (emphasis added).

38. *Id.* at 23-24.

39. *See* Case Studies, *supra* note 35, Case Study One at 43; *supra* note 35, at 155.

40. Most of the following alleged risks are discussed by Holly Saigo. *See* Saigo, *supra* note 7, at 787-96 (footnotes omitted).

biotechnology regulatory system must compare the *marginal* costs associated with agricultural biotechnology with its *marginal* benefits. The proper performance of the agricultural biotechnology regulatory and liability system depends upon whether it properly compares the marginal costs of agricultural biotechnology to the marginal benefits on a life-cycle basis.

Second, the relevant comparison of marginal benefits and costs of agricultural biotechnology is not simply conventional agricultural means for producing similar food or feed, but the total social costs required to sustain such conventional agricultural practices. For example, if conventional agricultural practices require large amounts of pesticide use in order to protect their crops, and these pesticides can be eliminated or sharply reduced by use of biotechnology crops, then this change would clearly be a marginal benefit of biotechnology. However, this marginal benefit needs to be weighed against the cost involved, such as increases in the rate at which crop pest became resistant to a particular type of genetically engineered pest control compared to the comparable conventional control.

The objective of agricultural biotechnology regulation should be to minimize the total social cost of agricultural production, not simply to limit one aspect of that cost while ignoring increases in cost in other areas. In short, successful regulation must involve a full, open accounting for total social life-cycle costs and must permit analysis of marginal benefits and costs.

#### IV. ALLEGED MAJOR RISKS OF AGRICULTURAL BIOTECHNOLOGY

##### *A. Migration of Transgenes into Non-Target Organisms*

According to Saigo:

The overarching concern about transgenic plants is that the engineered genes will migrate or escape into other organisms. The most likely way for plants to exchange transgenes is through outcrossing. Outcrossing is the process through which domesticated plants hybridize with wild relatives, producing a new variety. Although outcrossing is a common occurrence in conventional agronomy, outcrossing in transgenic plants may occur at significantly higher rates. Startlingly, a recent study

found that genes from transgenic plants might be up to twenty times more likely to outcross into relative species than the plant's natural genetic material.<sup>41</sup>

Other observers of biotechnology, however, suggest that the risk of such genetic migration is not large:

The possibility of gene transfer to compatible wild relatives has been given serious examination. Is it possible that herbicide and pest resistance incorporated into transgenic plants could find its way into other species and increase their 'weediness'? Under normal conditions gene transfer between close relatives is a very rare phenomenon and there is little evidence this will change with transgenic organisms. While such events are theoretically possible, their occurrence would be at such a low frequency that in practice the results are of virtually no consequence or concern.<sup>42</sup>

The NRC Report essentially states that there is insufficient empirical evidence to make a decision about the seriousness of this alleged risk of gene migration.<sup>43</sup>

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41. *See id.* at 787 (footnotes omitted).

42. SMITH, *supra* note 20, at 215.

43. NRC Report, *supra* note 1, at 88-89 (emphasis added). The report states:

We know little about the extent to which insects and diseases limit wild, weedy populations that are sexually compatible with cultivated species. Critics of biotechnology argue that the spread of beneficial traits could quickly lead to the spread of weeds; advocates of transgenic crops maintain that this risk is small or nonexistent. *Empirical data with which to address the question are lacking . . . .*

Because of the uncertainties described above, it is premature to predict the ecological impacts of gene flow from transgenic pest-protected plants. Meanwhile, regulatory decisions must be made in a timely fashion. *It seems unlikely* that the transfer of one or two novel crop genes for pest-protection would transform a wild species into a problematic weed, although *in some cases* unwanted population increases of weedy species could result. Moreover, the cumulative effects of beneficial crop genes could potentially lead to expensive and ecologically damaging problems in weeds that are already difficult to control, such as Johnson grass (*Sorghum halepense*) . . . .

*Consequences of gene flow other than weediness are also perceived to be detrimental to preserving biodiversity.* For example, the spread of transgenes to wild relatives that are rare or endangered is sometimes considered as a potential ecological risk, especially in regions that are centers of diversity for crop relatives . . . .

The considerations noted in the Report led the NRC to recommend that “[c]riteria for evaluating the merit of commercializing a new transgenic pest-protected plant should include whether gene flow to feral plants or wild relatives is likely to have a significant impact on these populations.”<sup>44</sup>

This NRC recommendation would constitute a marked change from current EPA regulatory practice, which apparently disregards the impact of gene outcrossing to conventionally bred relatives of the pest-protected plants. According to the EPA’s analysis of the permitting process for MON810, a variety of BT-corn has:

[t]he potential for outcrossing to traditional cultivars of maize from MON810 or other registered plant-pesticides is not currently reviewed within the guidelines (40 CFR). Since the mammalian toxicity and environmental evaluations have indicated that the plant-pesticidal substance (i.e., d-endotoxin) is not a threat to man or the environment, there is not a risk associated with MON810 pollen fertilizing traditional maize. Traditional culture methods and breeding (i.e., seed production) have resulted in cross-pollination between open pollinated varieties, hybrids and inbred lines for centuries with no known ill effects. This has similarly transferred genes for disease and insect resistance between varieties in the past.<sup>45</sup>

### *B. Increased Creation of Resistant Weeds and Pests*

A well-established limitation of conventional weed and pest control through herbicides and pesticides is that weeds and pests can develop effective resistance to them over time.<sup>46</sup>

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44. *Id.* at 92.

45. *See* Case Studies, *supra* note 35, Case Study Two: Bt-Maize plus sidebar, at 21; Deskbook, *supra* note 35, at 180; *see also* discussion of Mexican maize issue, *infra* notes 155-61 and accompanying text.

46. A striking example of this phenomenon is need for rebreeding of the American wheat crop to protect it from various forms of wheat rust, which are fungi. The fungi develop resistance within approximately five years, so the wheat crop must be rebred within that period of time. *See* NRC Report, *supra* note 1, at 104-08.

Although the inheritance of resistance through outcrossing is not unique to biotechnology, this type of interaction is arguably more dangerous than that posed by conventional breeding techniques. Combined with the rapidity with which transgenes may jump into wild populations and the high levels of immunity transgenes can confer, the threat of the superweed is one that cannot be ignored. There are already examples of herbicide resistant genes that have migrated from transgenic oilseed rape and sugar beet into wild relatives.<sup>47</sup>

The NRC acknowledged concerns regarding the possibility of increased weediness when it found that “transfer of either conventionally bred or transgenic resistance traits to weedy relatives potentially could exacerbate weed problems, but such problems have not been observed or adequately studied.”<sup>48</sup>

Both the EPA and the NRC Reports acknowledge concerns about increased pest-resistance as a result of the use of pest-protected plants. The EPA imposes restrictions on the planting of certain genetically modified pest-protected plants (GMPPs) during the registration process that are specifically designed to limit the increase in resistance by pests exposed to pest-protected plants.<sup>49</sup> The NRC

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47. See Saigo, *supra* note 7, at 789-90 (footnotes omitted).

48. NRC Report, *supra* note 1, at 9.

49. One article describes this process of EPA restriction with respect to Bt corn as follows:

One of the principal concerns still under study by government, academia, and industry is the possibility that placing the B.t. protein in the plant where it is expressed at all times might accelerate the development of resistance to the protein in the pest population. To date the only documented case of resistance to the protein resulted from the use of the conventional B.t. sprays. Nevertheless, the EPA has consulted with the USDA and panels of outside scientific advisors on the resistance issue and has mandated additional risk mitigation measures for B.t. crops to minimize the likelihood of insect resistance developing to B.t. products, conventional or genetically engineered. These measures include post-market monitoring for resistance and the evaluation of new monitoring methods. The majority of these new requirements have been applied to B.t. corn and cotton products and are included in insect resistance management (“IRM”) plans that must be approved by the agency and implemented under the direction of the registrants.

See Stanley H. Abramson & J. Thomas Carrato, *Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L.J. 241, 258 (2001) (internal footnotes omitted).

Report recommends further systematic study of this issue because it concludes that the rate at which such pest resistance will develop cannot be predicted based on current scientific knowledge.<sup>50</sup>

### *C. Potential Adulteration of Foods by Transgenes*

Both in Europe and the United States, there are concerns about the human health effects of genetically engineered foods.<sup>51</sup> At present, the United States and Europe both lack monitoring systems to track such health effects from genetically modified foods or feed. The EU has proposed regulations, discussed below, to require “traceability,” which would essentially create a tracking system to permit review of health effects.<sup>52</sup> The United States does not presently require genetically modified food labeling, crop segregation, or other measures that could be used to provide tracking capability, since such capability is deemed unnecessary.<sup>53</sup>

According to Saigo: “Studies have shown substantial and potentially dangerous differences between some of the transgenic products and their unmodified counterparts. For example, soybeans modified to contain genes from brazil nuts were found to contain brazil nut allergens, posing potential problems for individuals who are allergic to nuts.”<sup>54</sup>

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50. See NRC Report, *supra* note 1, at 9.

51. See, e.g., David Barboza, *As Biotech Crops Multiply, Consumers Get Little Choice*, N.Y. TIMES, June 10, 2001, at 1.

52. See *infra* Part V.B.

53. For example, the FDA does not require genetically modified food to bear special labeling, because there is no evidence that such foods “present any different or greater safety concern than foods developed by traditional plant breeding.” Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992). As a result of the Starlink™ corn regulatory failure, discussed below, the EPA now states that as a matter of policy it will not permit registration of a genetically modified food source unless it is deemed safe for both human and animal consumption. In and of itself, this step does not provide GMO monitoring or tracing capability, however.

54. See Saigo, *supra* note 7, at 792 (footnotes omitted).

As a result of these laboratory findings, these soybeans were never commercially marketed:

In the mid-1990’s the seed company Pioneer Hi-bred dropped plans to commercialize transgenic soybeans containing a gene from Brazil nuts after research showed that the soybeans would cause allergic reactions in Brazil nut allergic individuals.

The potential addition of new allergens to foods via genetic engineering is a serious public health concern. Roughly 2.5 to 5 million Americans suffer from food allergies.

The NRC acknowledged the legitimacy of concerns about possible allergenicity, but noted that there is a lack of available direct scientific methods to test for allergenicity.<sup>55</sup> The NRC therefore recommended development of better testing methodologies so that this issue can be examined before foods are commercialized.<sup>56</sup> The NRC Report further states that new GMPP cultivars “will need to be monitored for impacts that could not have been detected in the laboratory experiments” that reviewed health and safety issues.<sup>57</sup> The NRC acknowledged the need to address concerns regarding toxicity resulting from pest-protected plants and recommended that long term toxicity testing may be warranted “[f]or some novel pest-protectants developed for future commercialization.”<sup>58</sup>

#### *D. Non-Target Species Impacts*

Over the past year or two, there has been considerable controversy about the possibility that genetically modified pest-protected plants could have direct or indirect unintended harmful consequences on

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Although reactions in many individuals are limited to unpleasant symptoms such as gastrointestinal distress or skin rashes, allergic reactions in some individuals can cause anaphylactic shock and death.

Unfortunately, there is currently no predictive methodology for testing the allergenicity of most proteins introduced to foods via genetic engineering. Testing is only possible for proteins from commonly allergenic foods such as nuts. Blood serum is available from individuals with common food allergies, thus allowing proteins from commonly allergenic foods to be screened for “antibody-antigen” reactions. However, for most proteins, including those from foods that are not commonly allergenic and those from non-food sources such as bacteria, no such testing is possible. In other words, most proteins added to foods via genetic engineering cannot be tested for allergenicity.

Testimony of Rebecca J. Goldberg, Ph.D., Senior Staff Scientist, Environmental Defense Fund and Member, National Research Council Committee on Genetically Modified Pest-Protected Plants, before the United States House of Representatives Committee on Science, Subcommittee on Basic Research, at 3 (Oct. 5, 1999), *available at* [http://www.house.gov/science/goldburg\\_100599.htm](http://www.house.gov/science/goldburg_100599.htm).

55. See NRC Report, *supra* note 1, at 7.

56. *Id.* at 7.

57. *Id.* at 96.

58. *Id.* at 8:

The EPA should provide clear, scientifically justifiable criteria for establishing biochemical and functional equivalency when registrants request permission to test non plant-expressed proteins in lieu of expressed proteins.

non-target organisms. For example, there is disagreement over studies showing that Bt-corn toxins can kill monarch butterflies, which often feed on milkweed found in and around cornfields.<sup>59</sup> Industry acknowledges that Bt-corn toxins can harm monarch butterflies, which are from a family similar to the family that the toxins are in fact designed to kill.<sup>60</sup> Industry supporters, however, argue that very little corn pollen lands on milkweed leaves, and therefore monarch larvae would only be exposed to pollen in concentrations too small to harm them.<sup>61</sup>

The NRC clearly believed that the risk of impacts on non-target organisms is a risk worth careful consideration in the regulatory process. For example, the NRC Report notes: “If a pest-protected plant causes dramatic decreases in some herbivore or omnivore populations, there will be less nutrient material for the next level in the food chain. It is theoretically possible that a specialized predator, parasite, or pathogen of an affected herbivore could become locally extinct.”<sup>62</sup>

The EPA’s registration of MON810 and other Bt-corn varieties, has now become controversial.<sup>63</sup> Environmentalists believe that during registration, the EPA did not require sufficient analysis of the impact of Bt-corn plants that produced lepidopteran toxins on non-target species, such as the monarch butterfly.<sup>64</sup> Environmentalists note that there are approximately nineteen non-target butterfly and moth species that are either threatened or endangered and feed in or near Bt cornfields.<sup>65</sup> The NRC Report agrees that impacts on nontarget lepidopterans are likely at least where Cry1A Bt toxins are concerned.<sup>66</sup>

The NRC Report points out, however, that the impact of pest protected plant toxins on non-target species needs to be compared to

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59. See Deskbook, *supra* note 35, at 13.

60. See, e.g., Biotechnology Industry Organization, Backgrounder on Monarch Butterflies at Bt. Crops, available at <http://www.bio.org/food&ag/monarch.html> (last visited Apr. 5, 2002).

61. *Id.*

62. NRC Report, *supra* note 1, at 72.

63. *Id.* at 75.

64. *Id.*

65. *Id.*

66. *Id.*

the impact of pesticides. There might be a net biodiversity benefit resulting from the use of the pest-protected plants. The NRC Report finds that both pest-protected and conventional crops “could have effects on nontarget species, but these potential impacts on nontarget organisms are generally expected to be smaller than the impacts of broad spectrum synthetic insecticides, and therefore, the use of pest-protected plants *could lead* to greater biodiversity in agroecosystems where they replace the use of those insecticides.”<sup>67</sup>

The NRC went on to recommend that “[c]riteria for evaluating the merit of commercializing a new transgenic pest-protected plant should include the anticipated impacts on nontarget organisms compared with those of currently used pest control techniques.”<sup>68</sup>

#### *E. Crop Plants and Biodiversity Effects*

Both conventional agricultural plant breeding practice and genetically engineered plants share the risk of biodiversity loss. Biodiversity is important not as an end in itself, but rather as a protection against possible vulnerability of part of an overall ecosystem to attack by predators. The more prominent a single variety of a crop plant becomes, for example, the more susceptible the agricultural system is to large scale failure in the event that the prominent variety comes under attack by a pest resistant to control or a new disease.<sup>69</sup> Whether this risk is larger in the case of genetically engineered crops than in the case of conventional agriculture is difficult to assess. In either case, the prominence of a crop variety is probably largely a matter of the perceived relative economics of planting than crop variety at a given time. In other words, the more economic savings there appear to be from producing a given crop variety, the more likely it is that the less costly crop variety will be planted. It is important, in short, that the market be given proper signals by regulators so that there is no artificial bias in favor of a particular crop variety, whether produced by conventional crop

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67. *Id.* at 80 (emphasis added).

68. *Id.*

69. Saigo gives two prominent examples of large scale crop failures that resulted from a lack of genetic diversity flowing from conventional crossbreeding: the Irish potato famine and the Southern corn blight in the early 1970s. See Saigo, *supra* note 7, at 795-96.

breeding or genetic engineering. To the extent that market failure concerns may, in some cases, require regulations for sustainable yield and biodiversity protection, such concerns would apply equally to agricultural biotechnology and conventional agriculture.

The NRC acknowledged the need for long term environmental monitoring of pest-protected crops. In one of its recommendations, the NRC noted the need to “[m]onitor ecological impacts of pest-protected crops on a long term basis to ensure the detection of impacts that may not be predicted from tests conducted during the regulatory approval process.”<sup>70</sup>

## V. EXISTING AND PROPOSED REGULATION OF AGRICULTURAL BIOTECHNOLOGY IN UNITED STATES AND EUROPE

### A. *United States*

The existing regulation of agricultural biotechnology in the United States is based on the 1986 Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), created by presidential authority based on existing legislation.<sup>71</sup> The Coordinated Framework divided biotechnology regulatory authority between three regulatory agencies: the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the EPA.<sup>72</sup> The idea was that each agency would regulate those biotechnology products that corresponded to the conventional products subject to regulation under that agency’s existing legal authorities. Over the subsequent ten years, these agencies established policies to guide their use of legislative authorities under which they regulated various aspects of biotechnology.<sup>73</sup> During this same period, Congress did not approve any legislation specifically altering biotechnology regulation, and none has received Administration support.<sup>74</sup>

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70. NRC Report, *supra* note 1, at 10 (emphasis omitted).

71. *Id.* at 10-11.

72. *Id.* at 11.

73. *Id.*

74. There were amendments during that period to some of the prior regulatory statutes under which the agencies now also regulate biotechnology products. For example, the EPA’s pesticide regulatory authorities were modernized by congressional action. *See, e.g.*, 7 U.S.C. § 136(66) (Supp. 1999) (Defining “unreasonable adverse effects on the environment” to include

In theory, the Coordinated Framework should have provided for comprehensive review of agricultural biotechnology. However, although there was a division of jurisdiction within the framework, control over transgenic pest-protected plants was not addressed by the original framework document.<sup>75</sup> Perhaps it did not occur to regulators who claimed they created a comprehensive framework for biotechnology regulation that within a few years' creation of such plants would either be possible or desirable. Although the EPA proposed a rule to cover pesticidal substances in pest-protected plants in 1994, this rule is not yet finalized.<sup>76</sup> In recognition of this unfortunate state of affairs, the NRC concluded that "there is an urgency to complete the regulatory framework for transgenic plant products because of the potential diversity of novel traits that could be introduced by transgenic methods and because of the rapid rate of adoption of and public controversy regarding transgenic crops."<sup>77</sup>

#### 1. USDA Regulation for Plant Protection

The USDA is responsible for regulating plants, including genetically altered organisms, under the Plant Protection Act (PPA) which gives the USDA the authority to:

prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism . . . if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.<sup>78</sup>

The USDA exercises this authority under a permit system run by the Animal and Plant Health Inspection Service (APHIS). APHIS issues field test permits for new plants that have the potential to

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human dietary risks from pesticide residues on foods, for purposes of pesticide registration under FIFRA.). Some consideration was given during the Clinton Administration to possible new systematic biotechnology legislation, but none was ever proposed. *See, e.g.*, William Y. Brown, *Promise and Peril*, *The Environmental Forum*, 38 (Sept.-Oct. 2001).

75. *See* NRC Report, *supra* note 1, at 145.

76. *See supra* note 3.

77. NRC Report, *supra* note 1, at 11.

78. Deskbook, *supra* note 35, at 15 (quoting 7 U.S.C. §§ 7701-7772) (2000)).

create pest problems in domestic agriculture, which could include articles developed through biotechnology.<sup>79</sup>

The APHIS permitting process applies to “regulated articles,” defined as “any organism which has been altered or produced through genetic engineering,” if the donor organism belongs to certain genera or taxa and meets the definition of a “plant pest.”<sup>80</sup> “Plant pest” is broadly defined, encompassing “direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees.”<sup>81</sup>

APHIS permits control the “introduction” of a regulated article, which includes importation, interstate movement, or release into the environment.<sup>82</sup> Therefore, the permitting scheme applies only

when a person seeks to introduce genetically engineered organisms into the environment or interstate commerce. A typical permit will cover small-scale field testing of a genetically engineered plant prior to commercialization. While APHIS automatically requires a permit if the donor or recipient organism is a known plant pest, it reserves the right to require a permit for a product it has “reason to believe” is a plant pest.<sup>83</sup>

Thus, USDA regulatory review of agricultural biotechnology is limited to whether the proposed biotechnology application involves the creation of a “plant pest” which will be released into the

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79. *See id.* at 17.

80. *See id.* “Regulated article status has been applied to most of the genetically modified plants that have been developed to date.” *Id.*

81. *See id.* at 15.

82. *See id.* at 17.

83. Abramson & Carrato, *supra* note 49, at 247-48 (internal footnotes omitted). Abramson and Carrato note:

APHIS has issued some 932 permits for genetically engineered organisms since the program began in 1987, primarily for small-scale field tests involving crop plants. Based on its experience with the permit program, APHIS has provided a number of exemptions for articles which do not pose a plant pest risk. One of the more significant exemptions authorizes the introduction of certain regulated articles without a permit, provided that APHIS is notified in advance.

*Id.*

environment. If no “plant pest” is involved, then the USDA’s regulatory review is complete. The NRC Report notes that the narrow scope of USDA’s regulations may prevent the agency from regulating some genetically engineered crops that it wishes to regulate.<sup>84</sup> The USDA does not actually consider in its regulatory review process many of the potential biotechnology risks discussed above that may adversely affect agriculture.

## 2. FDA Regulation for Food Safety

Food safety is regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>85</sup> The FFDCA defines “food” as: “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”<sup>86</sup> FDA approval is not required prior to marketing a food, but there are prohibitions against misbranding or adulterating food.<sup>87</sup> Genetically modified food could fall under the FDA’s pre-market approval authority if it is considered adulterated, based, for example, on a finding that the modification is an “unsafe food additive.”<sup>88</sup> Similarly, genetically modified food could be found to be “misbranded” if the food is not described on its label by “a common or usual name.”<sup>89</sup>

A food additive may include “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component . . . of any food . . . .”<sup>90</sup> However, certain substances are not considered food additives because they are “GRAS,” or “generally recognized, among experts qualified by scientific training and experience to evaluate [their] safety as having been adequately shown . . . to be safe under the conditions of its intended use.”<sup>91</sup>

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84. See NRC Report, *supra* note 1, at 161.

85. 21 U.S.C. § 301 (1997).

86. See Deskbook, *supra* note 35, at 25 (quoting 21 U.S.C. § 321(f) (Supp. 1998)).

87. See 21 U.S.C. § 331 (1997).

88. See Deskbook, *supra* note 35, at 25.

89. See *id.* at 26.

90. *Id.*

91. *Id.* at 27.

The FDA does not regulate biotechnology foods differently than those produced through conventional breeding and does not require pre-market approval or special labeling of such foods.<sup>92</sup> In 1992, the FDA published a policy statement for foods derived from new plant varieties, which states that FDA may use its authority over food additives, under FFDCFA section 409, to require pre-market approval where necessary to protect public health.<sup>93</sup> Although genetic material transferred to plants through biotechnology is “presumed to be GRAS,” and hence not normally regulated as a food additive, an “expression product,” or substance introduced into food because of the genetic engineering such as carbohydrates, fats, and oils, may be regulated as a food additive.<sup>94</sup>

One key result of the FDA’s 1992 policy is that manufacturers of genetically modified foods are not required to label those foods as genetically modified because the FDA does not regard them as less safe than conventionally produced foods.<sup>95</sup> Another result is that developers of biotechnology foods are not required to consult the FDA prior to marketing their products, although they are encouraged to do so.<sup>96</sup> In January 2001, the FDA proposed regulations, discussed

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92. *See id.*

93. *See* Abramson & Carrato, *supra* note 49, at 251.

94. *See id.* at 251-52.

95. *See* Cliff D. Weston, *Chilling Of The Corn: Agricultural Biotechnology In The Face of U.S. Patent Law And The Cartagena Protocol*, 4 J. SMALL & EMERGING BUS. L. 377, 407 (2000) (footnotes omitted):

Proponents [of GMO labeling] argue that the information should be made available to give the consumer the choice of purchasing GMO or traditional products. They assert that agricultural biotech companies should have no objections to labeling since the industry claims the products are safe. Critics of the plan respond that much of the resistance to GMOs has been based on hype and unreasonableness rather than objective science. They claim that labeling would amount to placing a “skull and crossbones” on the products and that labeling is unnecessary under the FDA guidelines.

96. *See* Abramson & Carrato, *supra* note 49, at 252-53. However, although consultation is not mandated:

[a]s a practical matter, companies developing new biotechnology food products have routinely consulted with FDA scientists as an integral part of their product stewardship programs. Through calendar year 2000, the FDA has conducted 49 final consultations under its 1992 policy. . . . A letter from the FDA acknowledging completion of the consultation process is evidence of a final consultation. The letter provides assurance to potential customers that the product has been reviewed by federal food safety

below, that would require premarket notification to the FDA before introduction of genetically modified foods.<sup>97</sup>

### 3. EPA Regulation of Pesticides

The EPA has statutory authority to regulate the manufacture, importation, sale, and use of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>98</sup> The EPA further regulates pesticides under the FFDCA, which requires that the EPA establish a tolerance for pesticides used for food or animal feed.<sup>99</sup>

Under FIFRA, any pesticide, which is “any substance or mixture which is intended for preventing, destroying, repelling, or mitigating a pest . . . .” sold or used in the United States, must be registered with the EPA.<sup>100</sup> The intended use of a product governs whether it is a pesticide and intent is present where “(a) the seller claims, states or implies that a substance can be used as a pesticide; (b) the substance has no other commercially valuable use except as a pesticide; or (c) the seller has actual or constructive knowledge that the substance will or is intended to be used as a pesticide.”<sup>101</sup> Sale or distribution of a pesticide is prohibited without EPA registration, which will be granted where the pesticide is effective, the labeling meets certain statutory requirements under FIFRA, and the expected use will not cause unreasonable adverse effects on the environment.<sup>102</sup>

Any substance that is a pesticide under FIFRA and is used on food or feed crops is subject to regulation under the FFDCA, and the EPA

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officials and also demonstrates that the developer has met the prevailing “standard of care” for such products.

*Id.*

97. See *Premarket Notice Concerning Bioengineered Foods*, 66 Fed. Reg. 4706 (Jan. 18, 2001); see also Abramson & Carrato, *supra* note 49, at 252-53.

98. See *Deskbook*, *supra* note 35, at 33.

99. See *id.* (stating that a “tolerance” is the “maximum level of pesticide residue that may be present in food or animal feed”).

100. See *id.* (defining a “pest” as “any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism, except microorganisms on or in living man or other living animals”).

101. See *id.*

102. See *id.* at 34.

must establish a tolerance for the pesticide.<sup>103</sup> The EPA may register a pesticide for use on food or animal feed for these three reasons: if any residue will fall within the established tolerance; if the EPA grants an exemption from the tolerance requirement; or, if the pesticide is GRAS.<sup>104</sup> The EPA may exempt a pesticide from FIFRA requirements if the pesticide is adequately regulated by another agency or if the EPA determines that the pesticide poses “no unreasonable risk.”<sup>105</sup>

In 1994, the Biopesticides and Pollution Prevention Division was established within the EPA’s Office of Pesticides and Prevention and is responsible for registering “biopesticides,” which are derived from natural materials such as plants, animals, or microorganisms.<sup>106</sup> The EPA extended its FIFRA authority to genetically engineered pesticides and regulates them as “plant pesticides,” defined as “a pesticidal substance that is produced in a living plant and the genetic materials necessary for [its] production . . . where . . . intended for use in the living plant.”<sup>107</sup> As discussed above, the EPA issued a final rule on July 19, 2001 that generally outlines its approach to plant pesticides (PIPs), but does not address all outstanding issues regarding substances that will be exempted from the FIFRA requirements.

### *B. Trends in European Regulation*

European regulation consists of EU regulations and directives, but can also be considered to include international agreements to which the EU subscribes, such as the Cartagena Biosafety Protocol, and EU liability rules governing agricultural biotechnology. This section sketches out recent EU regulatory proposals as a basis for comparison with the U.S. regulatory system.

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103. *See id.* at 33.

104. *Id.*

105. *Id.* at 35.

106. *See id.* at 36.

107. *See id.*

## 1. Tracing/Labeling/Premarket Reviews

The European Community proposed genetically modified organisms (GMOs) premarket review and tracing regulations. The proposed tracing regulations are described generally by the European Commission as follows:<sup>108</sup>

[T]he [regulations will provide the] ability to trace GMOs and products produced from GMOs at all stages of the placing on the market throughout the production and distribution chains facilitating quality control and also the possibility to withdraw products. Importantly, effective traceability provides a ‘safety net’ should any unforeseen adverse effects be established. The retroactive tracking of the movement of GMOs and products produced from GMOs through the production and distribution chains will be facilitated by traceability requirements based on transmission and retention of relevant information for such products, at all stages of their placing on the market.<sup>109</sup>

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108. See Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council Concerning Traceability and Labelling of Genetically Modified Organisms and Traceability of Food and Feed Products Produced From Genetically Modified Organisms and Amending Directive, 2001/18/EC, 2-3 (July 25, 2001).

109. *Id.* at 2-3. According to the Commission,

such a traceability “system” limits discontinuity of product specific information through the chains and thereby facilitates:

- withdrawal of products should an unforeseen risk to human health or the environment be established;
- targeted monitoring of potential effects on human health or the environment, where appropriate;
- control and verification of labelling claims.

*Id.* According to the report of the U.S.-European Union Consultative Forum:

Effective monitoring requires the ability to trace the presence of genetically modified products. At the present time, no obvious health effects have yet been identified with crops or foods that have been approved. Anticipated effects are likely to be of low-level, evident only after long periods of use among especially at risk population groups, difficult to detect with certainty and thus, monitoring for such effects is likely to be costly to implement. However, the capacity to trace these products is essential to ensuring consumer choice, understanding the causes and establishing liability in cases of unanticipated negative effects, ensuring effective product recall should a safety problem arise, and, in some cases, validating benefit claims.

The traceability regulations would impose a series of requirements on participants in various stages of the food production and distribution process for information transfer and recordkeeping on GMOs designed to make it possible, among other things, to institute a recall of genetically modified food in the event human health concerns necessitated a recall.<sup>110</sup> The United States has no comparable regulations.

The European Commission (EC) also recently proposed new European regulations on labeling and safety review of genetically modified food and feed.<sup>111</sup> These regulations would require mandatory premarket safety review of genetically modified food and feed, and authorize new, broader GMO labeling requirements for such products. The United States has no comparable requirements.

## 2. Cartagena Biosafety Protocol

The Cartagena Biosafety Protocol, to which the EU subscribes, contains a number of key provisions, including provisions requiring labeling of GMO food and feed, and the “precautionary principle.”<sup>112</sup>

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Consultative Forum, *supra* note 15, at 12.

110. *See* Commission on the European Communities, *supra* note 109, at 2-3.

111. *See id.*

112. Weston describes the precautionary principle provision and the issues it raises as follows.

The Protocol declares that:

[L]ack of scientific certainty due to insufficient relevant scientific information and knowledge . . . shall not prevent [a subscribing country] from taking a decision regarding GMO imports. This provision permits countries to apply the precautionary principle in addressing GM imports. The principle permits a country to take action to protect itself—by barring import of a genetically modified organism—even if there is a lack of scientific certainty it would be dangerous. The immediate concern for the U.S. biotech industry is that this principle will allow Europe and other nations to improperly implement isolationist or protectionist policies to aid their domestic industries. The determination of the level of insufficiency of scientific evidence is placed in the hands of those contemplating GM product bans rather than in an impartial body. Having to present evidence of absolute safety is an insurmountable burden; the question of how far below that threshold scientific certainty may fall before becoming insufficient is left to officials balancing civic duties with the need to appease their constituencies. A nation desirous of domestic industrial or agricultural protection, a goal generally not permitted by the General Agreement on Trade and Tariffs (GATT), may now undertake such protection under the auspices of the

### 3. EC White Paper on Environmental Liability

In early 2000, after lengthy deliberations, the EC developed a White Paper on Environmental Liability (White Paper) that will serve as the basis for European Community regulations on environmental liability to be developed over the next several years.<sup>113</sup> The White Paper recognizes that, under the EC Treaty, European Community policy on the environment “shall contribute to pursuit (among other things) of the objective of protecting human health.”<sup>114</sup>

The EC outlines in its White Paper the goals for an EU environmental liability regime generally and as applied to biotechnology.<sup>115</sup> The EU’s White Paper comes to the same fundamental conclusion reached by U.S. regulatory authorities, that GMO activities are not inherently dangerous, but they do have the

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Protocol. It invites nations to overweigh concerns based on public opinion in order to declare the perceived risks too great to be assuaged by the available scientific findings.

Weston, *supra* note 95, at 405.

113. European Comm’n, White Paper on Environmental Liability (Feb. 9, 2000) [hereinafter EU White Paper].

114. *Id.* § 4.2.1.

115. *Id.* § 4.2.2 (footnotes omitted) (emphasis added):

The objective of nearly all national environmental liability regimes is to cover activities that bear an inherent risk of causing damage. Many of such activities are currently regulated by Community environmental legislation, or Community legislation that has an environmental objective along with other objectives. A coherent framework for the liability regime needs to be linked with the relevant EC legislation on protection of the environment. In addition to ensuring restoration of the environment where this is currently not possible, the liability regime would therefore also provide . . . legislation in the field of biotechnology; and legislation in the field of transport of dangerous substances. In the further shaping of an EC initiative, the scope of activities will need to be defined with more precision, for instance by setting up a list of all the pieces of relevant EC legislation with which the liability regime should be linked. *Moreover, some of these activities, such as activities with respect to genetically modified organisms (GMOs), are not dangerous per se, but have the potential, in certain circumstances, to cause damage to health or significant environmental damage. This could be the case, for example, in the event of an escape from a high-level containment facility or from unforeseen results of a deliberate release. For this reason, it is considered appropriate for such activities to come within the scope of a Community-wide liability regime. In these cases, the precise definition of the regime, for instance the defences to be allowed, might not be the same for all activities related to GMOs, but may have to be differentiated according to the relevant legislation and the activities concerned.*

potential in some cases to cause health or environmental damage.<sup>116</sup> The White Paper apparently proposes to include GMO related activities within the general ambit of the strict liability regime it envisions for environmental harms.<sup>117</sup> Although the White Paper does not provide specific details on this point, it appears to suggest that some GMO-related activities would be subject to strict tort liability for damage caused by the activity, while other activities might be permitted defenses, relating, perhaps, to the social utility of the activities concerned.<sup>118</sup>

The European Community's proposed agricultural biotechnology regulations represent a much different, and apparently far more interventionist, approach to regulation of agricultural biotechnology than that adopted by the United States. It is too soon, for two reasons, to predict to what extent the tort liability system to be adopted for agricultural biotechnology in the EU will resemble that in the United States. First, the ultimate nature of the EU system is unclear. Second, as discussed below, the U.S. tort liability system is still in flux as far as agricultural biotechnology is concerned.

## VI. AGRICULTURAL BIOTECHNOLOGY REGULATORY FAILURES

Despite the supposed comprehensiveness and quality of the Coordinated Framework, there were a series of regulatory failures involving agricultural biotechnology over the past several years. These failures raise questions about the quality and reliability of the U.S. agricultural biotechnology regulatory system.

### *A. StarLink™ Case Study*

One genetically modified product that received attention both in the United States and abroad is StarLink™ corn, a type of corn genetically engineered to produce a pesticide to kill the European corn borer, a destructive pest.<sup>119</sup> As explained before, pesticides,

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116. *Id.*

117. *Id.* § 4.2.2.

118. *Id.* §§ 4.2-4.3.

119. The European corn borer is "the most damaging insect pest of corn throughout the United States and Canada," responsible for over \$1 billion in crop losses and control costs each

including those substances inserted directly into the subject plant through genetic engineering which produce an insecticide within the plant, must be registered with EPA under FIFRA.<sup>120</sup>

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year. K.R. Ostlie et al., eds., *Bt Corn & European Corn Borer: Long-Term Success Through Resistance Management* (1997), available at <http://www.extension.umn.edu/distribution/cropsystems/DC7055.html#ch1> (last visited Jan. 3, 2002). To combat the pest, scientists have transferred genetic material from *Bacillus thuringiensis* (Bt), a naturally occurring soilborne microorganism, into food crops. The Bt gene produces crystal-like proteins (Cry proteins that are d-endotoxins) that kill specific groups of insects by binding to the intestinal lining of insects that eat the proteins, and rupturing intestinal cells. *See id.*

120. On May 5, 1995, the EPA granted the first registration for this type of “plant-incorporated protectant” for the NewLeaf A3 potato, another form of Bt crop. *See* Abramson & Carrato, *supra* note 49, at 256. In registering the Bt protein for this use, the EPA found “that it was nontoxic to mammals, birds, and most other insects, and would reduce the need for conventional pesticides.” *See id.*

The review process for the NewLeaf A3 potato lasted five years, from 1991-1995, and included the following measures:

The potato was initially field tested in small-scale plots under a permit granted by the USDA, followed by testing on a larger scale under an experimental use permit from the EPA. Subsequently, the USDA reviewed data submitted by the developer and determined that the modified potato was not a plant pest and, therefore, was not considered a regulated article under the plant pest regulations. The potato’s developer then completed the consultation process with the FDA, having submitted information confirming that, other than the presence of the B.t. protein, the NewLeaf™ potato was not significantly different from any other Russet Burbank potato. These actions cleared the way for the review of health, safety, and environmental data and the eventual approval of applications for commercialization by the EPA. In addition to obtaining a registration of the B.t. protein as expressed in the potato under FIFRA, the applicant was also required to petition the EPA for a tolerance exemption for potential trace levels of the B.t. protein under the FFDCA.

*See id.* According to Abramson and Carrato, “Technology companies have estimated that the combined cost to develop the (Bt) products, conduct the appropriate scientific studies, and obtain the necessary clearances for the current B.t. crops exceeded \$3 billion.” *See id.*

The registrations for Bt crops are conditioned on the producers’ acceptance of specific conditions, and the EPA has in some cases “persuaded registrants to accept additional conditions years after the original product approval action.” *See id.* For example, the registrations for Bt corn and cotton were subject to an “ongoing reassessment” through the year 2001, at which point the EPA had the option of whether to extend the registrations, or allow them to terminate. In October, 2001, the EPA extended the registrations for both Bt cotton and corn. For cotton, the EPA found the protein expressed in the genetically modified seeds, Cry1Ac, does not “significantly increase the risk of unreasonable adverse effects on the environment” and that use of Bt cotton would not pose risks to human health or to non-target species. *See* The EPA Biopesticides Registration Action Document, *Bt Plant-Incorporated Protectants* at IV 4 (Sept. 29, 2001), available at [http://www.epa.gov/pesticides/biopesticides/otherdocs/bt\\_brad2/6%20cotton.pdf](http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_brad2/6%20cotton.pdf). However, because Cry1Ac raises concerns with respect to the risk of gene flow and insect resistance management, EPA conditioned the registration on specific terms and conditions.

StarLink™ corn was initially registered with the EPA in May 1998.<sup>121</sup> The registration was limited to animal feed or industrial use with a maximum 120,000 acres.<sup>122</sup> The EPA did not approve the corn for human consumption based on concerns that a protein contained in StarLink™ corn, known as Cry9C, may be a human allergen.<sup>123</sup> However, the EPA approved the corn for animal consumption, based on the EPA's determination that the effect of any residual Cry9C in animal products would not be harmful to humans.<sup>124</sup> When StarLink™ was re-registered in 1999,<sup>125</sup> the restrictions limiting it to

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The registration for Bt corn containing Cry1Ab or Cry1F proteins was also extended, subject to specific terms and conditions. *See id.* The EPA concluded that Cry1Ab and Cry1F, the proteins found in the corn products at issue, have significant economic benefits, result in "less human and environmental risk than chemical alternatives," and would not pose risks to human health or to non-target species. *See id.*

121. EPA Office of Pesticide Programs, Biopesticide Fact Sheet: *Bacillus thuringiensis* subspecies *tolworthi* Cry9C Protein and the Genetic Material Necessary for Its Production in Corn, Section A (Mar. 2001), available at <http://www.epa.gov/pesticides/biopesticides/factsheets/fs006466t.htm> (last visited Dec. 30, 2001).

122. *See id.*

123. The EPA was unable to determine that there was a "reasonable certainty of no harm" from use of StarLink™ corn in human food, because of the risk that Cry9C could be allergenic:

The Agency's assessment of Cry9C revealed that it has particular characteristics in common with known allergens: it is relatively heat stable and does not readily break down in simulated digestive fluids. This raises the possibility that it could be a human allergen. However, EPA determined that, notwithstanding its concern with respect to human ingestion of Cry9C, Cry9C was "safe" and when used as animal feed would not present unreasonable risks to human health. Because the protein does not transfer to meat and poultry products, use in animal feed would not result in human dietary exposure to the protein/potential allergen.

Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,825, 4,826 (Jan. 18, 2001).

124. The EPA stated:

Based on the toxicology data cited and the limited exposure expected with animal feed use, there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of . . . Cry9C protein and the genetic material necessary for its production in corn. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. *The Agency has arrived at this conclusion because, as discussed above, the temporary tolerance exemption is limited to feed use only.*

*Bacillus Thuringiensis* Subspecies *Tolworthi* Cry9C Protein and Genetic Material Necessary for Production in Corn, 63 Fed. Reg. 28,260 (May 22, 1998) (emphasis added).

125. The registration was transferred to AgrEvo USA Company, and then to Aventis Crop Science USA LP. "On October 29, 1998, the StarLink™ corn registration was conveyed from Plant Genetic Systems (America) to AgrEvo USA. AgrEvo USA and Rhone Poulenc Ag Company subsequently formed Aventis CropScience USA LP (Aventis). As of February 22,

domestic animal and industrial use only and the 660 foot buffer zone remained the same, but the total allowable acreage was increased to 2.5 million acres.<sup>126</sup> The registration, which expired May 30, 2000, imposed a condition requiring the then registrant, Aventis, to ensure that all growers signed an agreement to abide by the restrictions set forth in the registration.<sup>127</sup>

The EPA registration outlined precise language that was to be used in the directions accompanying the product.<sup>128</sup> It appears that, at some time, Aventis prepared a form, entitled “StarLink™ Bt Grower Agreement,” that listed restrictions on the use of StarLink™ corn, but

2000, the StarLink™ corn registration is now held by Aventis under registration number 264-669.” See *Premarket Notice Concerning Bioengineered Foods*, 66 Fed. Reg. 4825 (Jan. 18, 2001).

126. See EPA Office of Pesticide Programs, *supra* note 122, at Section B.

127. See *id.*

128. See Neil E. Harl et al., *The StarLink™ Situation*, at 2-4 (July 30, 2001), available at <http://www.exnet.iastate.edu/Pages/grain/publications/buspub/0100star.pdf> (last visited Jan. 5, 2002) (emphasis added):

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes. All field corn containing the plant-pesticide that is sold or distributed by Aventis CropScience USA LP or a cooperator or licensee of Aventis, must be accompanied by informational material that contains the following:

\* \* \*

\* \* \*

Feed or Non-food Industrial Uses: Seeds expressing the Cry9C protein should be planted at a maximum of 40,000 seeds per acre on the site. Any seeds, plants or plant materials in the StarLink™ field, or within 660 feet of the field, should be used domestically for animal feed or non-food industrial purposes. None of the seeds, plants or plant materials in the StarLink™ plot, or within 660 feet of the field, may be used for food uses or may enter international commerce.

\* \* \*

#### STORAGE AND DISPOSAL

Seed Storage: Store in a cool dry place separate from conventional corn seed.

Seed and Plant Disposal: Any seeds, plants or plant materials in the StarLink™ field, or within 660 feet of the field, may be used domestically for animal feed or industrial purposes, or destroyed. *None of the seeds, plants or plant materials in the StarLink™ field, or within 660 feet of the field, may be used for food uses or may enter international commerce . . . .*

“not all producers were asked to or did sign the agreement.”<sup>129</sup> It is not clear whether growers actually received the warning required by EPA as a condition of registration.<sup>130</sup> However, it is undeniable that, even if growers were adequately warned, StarLink™ corn did enter the human consumption food channels. This entry caused a significant disruption in the corn market, and some consumers alleged resulting personal injury.

The presence of StarLink™ corn in human food was initially discovered in September, 2000 by the environmental group Friends of the Earth.<sup>131</sup> The group hired an independent laboratory to test Kraft taco shells, which were found to contain traces of StarLink™ corn.<sup>132</sup> Immediately after the release of the test results, the FDA

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129. The agreement states in part:

In accepting StarLink™ corn, Grower agrees to direct the harvested grain and grain grown within 660 feet of the StarLink™ grain towards domestic feed (e.g. animal feed) and/or non-food industrial purposes. *Grower agrees not to use this grain for food use or allow it to enter grain export channels.* Grower further agrees to either feed the grain obtained from StarLink™ corn hybrids on-farm or sell it for domestic (animal) feed, industrial or non-food uses only. Possible domestic off-farm use of the grain includes selling it to feed mills, neighbors with livestock operations or elevators that supply U.S. livestock feed operations. Aventis CropScience will provide Grower with a list of elevators or grain buyers that can provide this type of usage, prior to planting and/or prior to harvest.

*See id.* at 5 (emphasis added).

130. As one author observed:

Essentially, Aventis depended on a game of telephone to keep StarLink from getting misdirected into the human components of the agricultural machine.

For the plan to work, information about StarLink would be passed from Aventis to the seed companies; then the seed companies would communicate it to its dealers, who would in turn tell farmers who bought StarLink.

Sometimes, the message got through. Jeff Lacina, a spokesman for the Garst Seed Co., said it informed all 3,500 of its dealers about the rules governing StarLink. And Sharon Greif, a Garst dealer in Linn County, Iowa, said she received that information and would have passed it to any customers who purchased the seed.

But in many other cases, the message about StarLink did not get through.

*See* The Associated Press, *StarLink corn: How it reached the food supply* (Dec. 4, 2000), available at <http://archive.showmenews.com/2000/dec/20001204busi011.asp>.

131. *See* National Environmental Trust, *Genetically Engineered Corn Not Approved for Human consumption Found in Taco bell Brand Taco Shells* [sic] (Sept. 18, 2000), at [http://www.biotech-info.net/taco\\_bell.html](http://www.biotech-info.net/taco_bell.html).

132. *See id.*

began receiving reports from consumers alleging that they experienced adverse effects after consuming food containing StarLink™ corn.<sup>133</sup> Kraft Foods began a “voluntary” recall and, at the request of the FDA, other companies recalled corn products that were suspected or known to contain StarLink™.<sup>134</sup>

On September 29, 2000, after consulting with the USDA, the EPA, and the FDA, Aventis agreed to purchase that year’s crop of StarLink™ corn, which prevented the majority of the 2000 crop from being used in processed foods.<sup>135</sup> In addition to the “voluntary” buy-back program, in January of 2001, Aventis “voluntarily” signed an agreement, with seventeen state attorney generals, legally binding the company for four years to compensate not only farmers who grew StarLink™ corn, but also farmers who did not grow StarLink™ corn but whose corn was found to contain the Cry9C protein.<sup>136</sup>

The EPA confirmed that StarLink™ corn entered the human food supply.<sup>137</sup> It is unclear exactly how much of the corn is presently in the U.S. food supply, although current estimates are lower than previous ones.<sup>138</sup> The risk of new StarLink™ corn entering the food

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133. See Ctr. for Food Safety and Applied Nutrition, *FDA Evaluation of Consumer Complaints Linked to Foods Allegedly Containing StarLink™ Corn*, at 2 (June 13, 2001). From July 25, 2000 to April 20, 2001, the FDA received a total of sixty-three consumer complaints. See *id.* at 3.

134. See EPA Office of Pesticide Program, *supra* note 122, at Section C.

135. See *id.* The USDA’s Commodity Credit Corporation (CCC) would purchase from farmers any StarLink™ corn that they did not plan to use as animal feed, at a rate of \$0.25 per bushel over the CCC’s posted price for the relevant county, and Aventis would reimburse the CCC. Alternatively, farmers electing to use the corn as feed on their farms would be paid a premium of \$0.25 per bushel.

136. K.T. Arasu, *U.S. States Ink StarLink Bio-corn Pact with Aventis* (Jan. 23, 2001), at [http://www.extension.iastate.edu/Pages/grain/news/starlink/starlink\\_jan/usstatesink.html](http://www.extension.iastate.edu/Pages/grain/news/starlink/starlink_jan/usstatesink.html) (last visited Jan. 6, 2002).

137. The EPA stated:

Test data from several sources demonstrate that StarLink™ corn was diverted into human food. Data from Aventis, Kraft Corporation, and the Food and Drug Administration confirmed the presence of Aventis’ Cry9c DNA (the genetic material necessary for the production of Cry9C) in Taco Bell taco shells when tested. . . .

Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,825 (Jan. 18, 2001).

138. An EPA Scientific Advisory Panel estimated that the amount of StarLink corn currently in the food supply is lower than the EPA previously thought:

The revised Aventis dietary exposure assessment report assumes that 0.125% of corn in all corn-based foods, including those produced from white corn, is StarLink™ grain

supply also appears to be low.<sup>139</sup> To prevent the further inundation of

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. . . According to testimony by the North American Millers Association at the July, 2001 SAP meeting, only 1.2% of 85,000 truckloads of corn received by dry millers was found to test positive for StarLink™. There appears to be a high rate of compliance with recommendations for testing incoming grain in the food corn processing industry . . . . Loads of corn in which Cry9C protein is detected are likely to be rejected. For these reasons, the SAP believes that the assumption of 0.125% StarLink™ corn in the food supply is highly conservative.

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Assuming a consistent program of testing grain entering food processing plants and reductions of Cry9C protein due to processing . . . the Panel concluded that the levels of Cry9C protein entering the U.S. food corn supply are very low. EPA estimated current concentrations of Cry9C protein in food corn to be 0.34 ppb, using the Aventis estimate of 5% rejection rate at corn dry mills. . . . Based on the North American Millers Association (NAMA) industry data showing 1.2% rejection rate, the concentration in food corn samples could be as low as 0.1 ppb. Additionally, the concentrations of Cry9C protein in both general grain stocks and the [U.S.] food corn supply will decline rapidly after the 2001 crop is harvested and with each subsequent production year.

*See* FIFRA Scientific Advisory Panel (SAP), *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Assessment of Additional Scientific Information Concerning StarLink™ Corn*, SAP Rep. No. 2001-09, at 19-22 (July 25, 2001) [hereinafter FIFRA SAP Report].

139. Furthermore, the SAP estimates that the risk of new StarLink corn entering the food supply is “very small”:

The risk of new Cry9C corn entering the food corn supply from the 2001 and later harvests has been managed. The original estimate of EPA in the December 2000 SAP report (that U.S. corn stocks contain 0.4% uncontrolled StarLink™) now appears to be overstated, especially for corn offered for use in the food market. In fact, the Panel concludes that even Aventis’ estimate of 0.125% StarLink™ corn in loads delivered to food corn processors may be too high. The Panel believes that as long as direct food corn users (dry millers, masa processors) continue to rigorously test to the lowest available detection limits, there will be a very small and decreasing risk of producing corn based foods with detectable Cry9C protein.

*Id.* at 25-26. However, as noted, this estimate depends on continued vigilance by market actors, and will not be controlled by direct regulatory measures.

One observer has noted that there is an alternative method of regulating StarLink™:

There is another regulatory option available to Aventis, besides a tolerance exemption from EPA, that would allow commerce to proceed. Aventis could ask FDA to regulate low levels of Cry9C toxin in food as an unavoidable adulterant—a step that would not jeopardize the integrity of the EPA’s regulatory system for genetically engineered products.

*See* Testimony of Rebecca Goldberg, PhD, to EPA’s FIFRA Science Advisory Panel, Comments Regarding the U.S. Environmental Protection Agency’s (EPA’s) Assessment of Scientific Information Concerning Starlink Corn Cry9C Plant-Pesticide (Nov. 28, 2000), at

the U.S. corn crop with hybrids containing Cry9C protein, the USDA, through the CCC, offered to purchase non-StarLink™ brands of hybrid corn seed containing Cry9C.<sup>140</sup>

The negative effects of the StarLink™ event are far-reaching, with the total cost to date estimated at approximately \$1 billion.<sup>141</sup> The corn market experienced significant disruption, including the cost of testing for the presence of commingled StarLink™ corn, the cost of rerouting corn shipments rejected by processors because StarLink™ is detected, and the cost and effort of devising methods to segregate corn to avoid commingling.<sup>142</sup> These costs will continue to accrue as long as StarLink™ corn is present in the food supply.

In fact, cross-pollination may have affected the crops of farmers who did not plant StarLink™ corn, causing the controversial Cry9 protein to be found in their crops. Groups of such farmers filed class action suits against Aventis in Iowa and Illinois.<sup>143</sup>

In addition to the effect on the domestic market, the United States experienced a significant drop in its corn exports in late 2000 and early 2001 as foreign markets expressed concern over genetically modified corn.<sup>144</sup> The Japanese discovered StarLink™ corn in snacks and animal feed, leading the U.S. Department of Agriculture to negotiate an agreement with Japan to screen U.S. corn shipments.<sup>145</sup>

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<http://www.environmentaldefense.org/programs/Health/StarLinkCom.html> (last visited Jan. 2, 2002).

140. See EPA Office of Pesticide Programs, *supra* note 122, at Section C.

141. See David Barboza, *As Biotech Crops Multiply, Consumers Get Little Choice*, N.Y. TIMES, June 10, 2001, at A1. "Seed companies, farmers, processors and food makers have spent more than \$1 billion in the last six months trying to eradicate Starlink. But most experts agree that will take years." *Id.* It is not clear that this figure accounts for the impact on U.S. corn exports, discussed *infra* notes 144-45 and accompanying text.

142. William Lin et al., *Impacts on the U.S. Corn Market and World Trade*, in USDA'S FEED YEARBOOK 40-48 (2001), available at [http://www.biotech-info.net/corn\\_impacts.html](http://www.biotech-info.net/corn_impacts.html) (last visited Jan. 7, 2001).

143. Anthony Shadid, *Blown Profits: Genetic Drift Affects More Than Biology—U.S. Farmers Stand to Lose Millions*, BOSTON GLOBE, Apr. 8, 2001, at G1, available at 2001 WL 3928228.

144. The largest factor in declining exports was restrictions imposed on the use of Starlink™ corn in major U.S. export markets, particularly Japan and South Korea. See Lin et al., *supra* note 142. Between November 2000 and February 2001, Japan's imports of U.S. corn for starch manufacturing declined twenty-seven percent from the previous year, and Japan turned to countries such as South Africa and Brazil to supply its corn. See *id.*

145. See Philip Brasher, *Biotech Corn Hurting U.S. Exports*, Associated Press Online, Nov.

Despite the public concern over StarLink™ corn, it is uncertain whether the product actually poses a threat to human health. A report issued by a Scientific Advisory Panel (SAP) to the EPA on July 25, 2001 concluded:

The test [that FDA developed to determine whether individuals had experienced an allergic reaction], as conducted, does not eliminate StarLink™ Cry9C protein as a potential cause of allergic symptoms. The negative results decrease the probability that the Cry9C protein is the cause of allergic symptoms in the individuals examined.

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[The test used by the FDA] does not eliminate the possibility that the individuals . . . reacted to the StarLink™ corn.

*Additional studies are necessary to eliminate Cry9C proteins as a potential cause for the allergic symptoms reported.*<sup>146</sup>

Consumers who claimed to have adverse reactions to products containing StarLink™ corn filed a class action suit in the U.S. District Court for the Northern District of Illinois, but the court preliminarily approved a proposed settlement on November 29, 2001.<sup>147</sup>

Aventis “voluntarily” withdrew the product registration for StarLink™ in January, 2001. In accepting the cancellation, the EPA noted that:

[T]his cancellation is being proposed because Aventis has failed to ensure that StarLink™ corn will not be diverted to human food, [*sic*] it is incumbent on any proponent of further use to demonstrate either: (1) That further use will not be diverted to human food, or (2) that StarLink™ corn is safe for

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17, 2000, available at <http://www.connectotel.com/gmfood/ap171100.txt> (last visited Jan. 23, 2002).

146. See FIFRA SAP Report, *supra* note 138, at 29-30.

147. See The U.S. District Court for the Northern District of Illinois’ findings of November 29, 2001, available at <http://www.starlinkcorn.com/ConsumerClassActionSettlement/Findings.pdf> (last visited Jan. 8, 2002).

human consumption because it will not present an unreasonable allergenic risk.<sup>148</sup>

Currently, according to Aventis, StarLink corn has not been commercialized in any country other than the United States.<sup>149</sup>

It is not clear what standard the EPA will apply in determining whether Aventis sufficiently established that StarLink™ does not present an unreasonable risk. It is not clear whether the company must prove with one hundred percent certainty that there is no risk of an allergic reaction in humans or if some lesser standard should apply. Moreover, it is unclear whether the EPA should hold Aventis financially responsible for any injuries sustained in the event of an allergic reaction. Several aspects of the Starlink™ story constitute regulatory failures on the part of the federal government, particularly the EPA.<sup>150</sup>

First, the EPA's labeling requirements for Starlink™ corn seed, described above, ignored the realities of the agricultural growing and crop collection and distribution system. This system could not

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148. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,825 (Jan. 18, 2001).

149. Aventis states:

This technology is not currently being developed or commercialized anywhere in the world, including the USA. Furthermore, Aventis CropScience has committed that the Cry9C technology will not be commercialized unless and until the necessary scientific methodology is developed to demonstrate to the EPA that, indeed, Cry9C may be safely registered for any end use.

Aventis CropScience is continuing its efforts to identify, contain and redirect corn containing Cry9C protein to animal feed and non-food, industrial uses in the US. These uses are fully authorized by the US Environmental Protection Agency.

Aventis, *Current Status of StarLink Corn*, available at <http://www.starlinkcorn.com/Current%20Status/Current%20Status.htm> (last visited Jan. 6, 2002). In light of the voluntary withdrawal of the StarLink™ registration, the EPA will not consider extension of the original registration. See The EPA Biopesticides Registration Action Document, *supra* note 120, at 11, available at [http://www.epa.gov/pesticides/biopesticides/otherdocs/bt\\_brad2/1%20overview.pdf](http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_brad2/1%20overview.pdf) (last visited Jan. 11, 2002).

150. To hold the EPA entirely responsible, though, would be to ignore what might be described as an inherent flaw of the Coordinated Framework and the “blindness on” approach taken by the federal agencies to regulation in this area: neither USDA, which regulates agriculture, nor FDA, which regulates food safety, seem to have played any meaningful part in reviewing the EPA's proposed efforts at the time of registration to control the distribution of Starlink™ corn products, despite the fact that in all likelihood the EPA knew less about the issues involved in meaningful regulation on this issue than they did.

realistically provide the segregation on which the EPA sought to insist, at least without substantial additional enforcement and administrative requirements. EPA's labeling requirements were therefore essentially "paper" requirements.<sup>151</sup>

Second, based on a review of the public record described above, none of the parties involved: Aventis; seed dealers; seed buyers; growers; crop collectors such as silos; or grain handling companies seem to have been sanctioned for failure to observe or impose the EPA labeling restrictions. The government's failure to impose sanctions, beyond Aventis' agreement to absorb various costs for predictable failures to observe restrictions imposed by its registration requirements, was tantamount to an admission that the requirements were unenforceable at the outset.

Third, the EPA failed to use its authority in permitting the use of Starlink™ seed to establish which parties within the agricultural production and distribution system were required to accept responsibility for failure to observe and/or enforce its regulatory restrictions. Although the EPA required Aventis to engage in labeling and to obligate contractually others to observe the labeling restrictions, this situation effectively permitted Aventis to disclaim liability for failures to observe the labeling restrictions and did not force observance of the restrictions. Given the structure of the agricultural production and distribution system in the United States, it is entirely possible that had the EPA insisted on establishing clear responsibility throughout the agricultural production and distribution system for failures to observe restrictions, and to require monitoring and enforcement of such responsibilities before permitting the use of Starlink™ seed, the marketplace would not have been willing to accept the use of the seed because of increased administrative costs and liability risks.<sup>152</sup>

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151. It is one thing to rely on this "paper" enforcement structure of labeling and contracts in the control of agricultural chemicals, which are likely to cause only localized damage if misused. It is quite another to employ the same system in the case of products that may enter the food supply that can actually cause demonstrable damage to other crops miles away from their site of use, or even possibly hundreds or thousands of miles away. See NRC Report, *supra* note 1, at 91; see also Mexican maize, *infra* notes 153-59 and accompanying text.

152. This result appears to be precisely what happened to another potential Aventis product for soybeans, Libertylink™, which was reportedly "voluntarily" withdrawn from the market—

Fourth, it should be a source of embarrassment to the EPA that an environmental group, rather than the EPA or Aventis, actually discovered the contamination of the food supply that resulted from the unlawful distribution in commerce of Starlink™ corn. If the EPA is going to establish a set of restrictions on the use of an agricultural biotechnology product, it has a responsibility to the public to make certain that those restrictions are being observed. There is no substantial evidence that the EPA met this responsibility here.

These regulatory failures with respect to Starlink™ corn were avoidable. The federal government had sufficient legal authority to design and impose more effective regulations for the control of Starlink™ corn. Effective regulations would have been able to achieve better results and perhaps to avoid large unnecessary costs for Aventis. These regulatory failures do not, alone, call into question either the utility of agricultural biotechnology or the safety of Starlink™ corn. It is unreasonable, nevertheless, to expect that the public will accept inadequate regulations like those imposed in the case of Starlink™ corn as a basis for public acceptance of agricultural biotechnology, particularly where food products are concerned.

*B. The “Surprising” Case of Mexican Maize Contaminated with Genetically Engineered Corn Genes*

On October 2, 2001, the *New York Times* reported that maize growing in fifteen different locations in Mexico contained genetically engineered genes.<sup>153</sup> The research leading to the discoveries was

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at the urging of trade groups representing crop producers—because the soybeans had not received import clearance in overseas markets. See American Soybean Association News, ASA Lands AgrEvo Decision to Protect U.S. Export Markets by Delaying Commercialization of LibertyLink® Soybeans (Mar. 10, 1999), available at [http://www.asa-hamburg\\_de/gen\\_n6.html](http://www.asa-hamburg_de/gen_n6.html).

153. Carol K. Yoon, *Genetic Modification Taints Corn in Mexico*, N.Y. TIMES, Oct. 2, 2001, at F7.

According to the report:

In a finding that has taken researchers by surprise and alarmed environmentalists, the Mexican government has discovered that some of the country’s native corn varieties have been contaminated with genetically engineered DNA. The contaminated seeds were collected from a region considered to be the world’s center of diversity for corn—exactly the kind of repository of genetic variation that environmentalists and many scientists had hoped to protect from contamination. The result was unexpected

conducted by researchers from the United States and the Mexican

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because genetically modified corn, the presumed source of the foreign genes, has not been approved for commercial planting in Mexico.

Scientists expressed concern that the foreign genes could act to reduce genetic diversity in the country's native corn varieties and in the wild progenitor of domesticated corn, known as teosinte. If any of the foreign genes are very advantageous, plants carrying those genes could begin to dominate the population. In such cases genetic variation will be lost as the diversity of plants not carrying the foreign genes decreases or disappears. Whether that will happen or has happened remains unknown.

In addition to being one of the world's most important crops, corn is viewed with a near religious reverence in Mexico, with seeds of native varieties passed down from generation to generation. Until now, scientists said researchers had assumed that these varieties, some of which are grown only by subsistence farmers in remote areas, were pristine.

"These are the extremes, the places where you would really not expect to find contamination," said Dr. Ignacio Chapela, a microbial ecologist at the University of California at Berkeley, saying the results are an indication of widespread contamination. "The only reason they found it there is because that's the only place they've looked."

Scientists said the results also indicated that crop genes might be able to spread across geographic areas and varieties more quickly than researchers had guessed.

"It shows in today's modern world how rapidly genetic material can move from one place to another," said Dr. Norman C. Ellstrand, evolutionary biologist at University of California at Riverside. He said the real worry was that other foreign genes—like pharmaceutical-producing genes being developed in crops—could also find their way quickly and unnoticed into distant food sources. Mexico's Ministry of the Environment and Natural Resources made the announcement on Sept. 18 that contaminated corn had been found in 15 different localities. The announcement credited Dr. Chapela with the initial discovery but described only the results from government-led research. Neither Dr. Chapela's team nor the Mexican teams' work has yet been published.

Scientists assume the native corn became contaminated through interbreeding with Bt corn, but how Bt corn may have come to be planted in Mexico remains a matter of speculation. While not approved for planting, biotech corn is legally imported into Mexico for use in food. The Mexican government has not disclosed exactly what genes were found.

Exequiel Ezcurra, the director of the National Institute of Ecology, which worked on the study, did not respond to requests for an interview. But Dr. Chapela, who is familiar with the Mexican work, said the researchers had identified the presence of DNA sequences from the cauliflower mosaic virus. This DNA is used nearly universally in genetically engineered plants and does not produce Bt insecticide. As a result, it is still unclear whether any of the contaminated corn has the ability to produce the Bt insecticide.

*Id.*

government.<sup>154</sup> Mexican maize was thought to be a relatively pure strain of corn that was grown using conventional techniques in Mexico for thousands of years.<sup>155</sup> Virtually all of the permitting regulatory risk analysis for the use of Bt corn assumes that the pollen generated by that corn, containing Bt-produced endotoxins as well as the ability to reproduce such Bt corn, will travel only a few hundred feet from the plants.<sup>156</sup> It was regarded as “surprising” that genetically engineered corn genes would be found in maize growing in Mexico only five years after the planting of such corn was first permitted in the United States.<sup>157</sup>

The point of the Mexican maize mystery is not that it necessarily indicates that any particularly harmful result occurred.<sup>158</sup> What is at stake instead is a regulatory quality issue. If the genetic contamination occurred through planting, the lesson to be drawn is that genetically modified corn should not be planted in Mexico. If such planting occurred in a number of different locations, this result indicates a lack of necessary controls on either the part of the U.S. government, the Mexican government, or both. Alternatively, the genetic contamination occurred as a result of pollen spread from U.S. planted crops, this result would suggest that current regulatory assumptions about pollen travel and transfer may be seriously mistaken. In either event, it is incumbent upon U.S. regulators to determine conclusively the source of the genetically engineered material, which is very likely of U.S. origin. This determination will

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154. *Id.* More recent news reports indicate that there is a question about the accuracy of the original test data demonstrating genetic contamination of Mexican maize. On April 5, 2002, the *New York Times* reported that the scientific journal *Nature* had stated that based on its further review of criticisms of the original data, the “evidence available is not sufficient to justify publication of the original paper” that reported the contamination results. Carol K. Yoon, *Journal Raises Doubts on Biotech Study*, N.Y. TIMES, Apr. 5, 2002, at A19. The *New York Times* continued, however: “The conclusion of contamination [in Mexican maize] has largely remained unchallenged. Instead, scientists have focused their criticism on data suggesting that genetically engineered DNA might behave in unexpected ways, scattering around the genome . . .” *Id.*

155. *Id.*

156. *Id.*

157. *Id.*

158. However, an invasion of an ecosystem by an exotic should always be of management concern because ecosystems often lack defenses against exotics, and so can be destroyed by them.

make it possible to impose better controls or to improve regulatory assumptions made in permitting genetically altered products to be made and sold. Information regarding the origin of genetically engineered material in crops grown in other countries is information the U.S. regulatory system should have already obtained through the permitting, monitoring, and enforcement process. Its failure to obtain such information is a form of regulatory failure.<sup>159</sup> The U.S. regulatory system and U.S. agriculture, including agricultural exporters, can ill afford to be “surprised” in this manner if they are to achieve public acceptance for their products. As a matter of U.S. foreign policy, the United States can ill afford the loss of international credibility resulting from such surprises, and U.S. taxpayers should not be expected to bear any of the resulting costs or damages.

### *C. Lessons from the Transgenic Salmon Case Study*

Salmon are unusual fish. Salmon have an unusual life history that adapted them well to the demands of several rigorous environments. This exceptional adaptation to particularly harsh environments suggests that the genetic makeup of salmon is distinctive but, unfortunately, it is not well understood.<sup>160</sup> Salmon populations are in decline in most of the lower forty-eight United States because of a

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159. In the same vein, the NRC Report sharply criticized the fact that federal regulators do not have accurate information about the impact of Bt corn on nontarget organisms. The NRC Report stated:

Given that Bt corn is already planted over millions of acres in the United States, it seems appropriate for EPA, USDA, or registrants to sponsor careful field tests to determine whether lacewings or other natural enemies of crop pests are adversely affected by Bt corn.

NRC Report, *supra* note 1, at 113. The NRC Report therefore recommended that the “EPA should provide guidelines for determining the most ecologically relevant test organisms and test procedures for assessing nontarget effects in specific cropping systems.” *Id.*

160. The uncertainty regarding salmon biology is evident in the resources expended by the federal government to study the conditions necessary for salmon survival. *See, e.g.*, Statement of Jamie Rappaport Clark, Director, U.S. Fish and Wildlife Service, Department of the Interior, Before the Subcommittee on Fisheries Conservation, Wildlife and Oceans of the House Resources Committee, Regarding the Agency’s Fiscal Year 2001 Budget Request (Mar. 23, 2000), available at <http://laws.fws.gov/testimon/2000test/budgetma.htm>.

combination of habitat and demand pressure.<sup>161</sup> Recently, the federal government declared certain salmon populations to be either threatened or endangered species.<sup>162</sup>

The federal government has not yet agreed to permit the release of genetically modified or “transgenic” salmon into the environment.<sup>163</sup> However, it is well known that such transgenic salmon are under development, and it probably will be necessary for the government to grant a permit for their release into the environment.<sup>164</sup> In anticipation of such a request, federal government agencies responsible for such permitting undertook a case study to analyze the issues that would be presented by a request to permit such transgenic salmon farming.<sup>165</sup> Ironically, this case study discloses that the government’s efforts to regulate existing conventional salmon fish farming, when it approved permits for such farming, constitute a form of regulatory failure. Unless the government fully addresses the failure of the regulatory process, unfortunate and potentially irreversible results are likely to occur.

### 1. Conventional Salmon Fish Farming

Conventional salmon fish farming is a substantial and growing industry. In salmon fish farming, salmon are first bred in a manner intended to make them sterile, and then confined in pens in the ocean during the growing cycle.<sup>166</sup> The purpose of sterile breeding is to avoid interbreeding with other salmon populations, including wild

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161. See, e.g., National Wildlife Federation, Case Study: Salmon, available at [www.nwf.org/population/Salmon.htm](http://www.nwf.org/population/Salmon.htm) (last visited Apr. 8, 2002) (noting that commercial fishing and habitat degradation have contributed to the decline of wild salmon populations).

162. See Case Studies, *supra* note 35, Case Study One, at 1; Deskbook, *supra* note 35, at 113.

163. See Case Studies, *supra* note 35, Case Study One, at 1-2; Deskbook, *supra* note 35, at 113-14.

164. See Case Study, *supra* note 35, Case Study One, at 30; Deskbook, *supra* note 35, at 142. The regulatory structure for this permitting is different than that described above for plant products, and will involve additional federal agencies, including the U.S. Army Corps of Engineers and the Department of the Interior. Case Studies, *supra* note 35, Case Study One, at 1; Deskbook, *supra* note 35, at 113.

165. See Case Studies, *supra* note 35, at Case Study One, at 1; Deskbook, *supra* note 35, at 113.

166. See Case Studies, *supra* note 35, at Case Study One, at 4; Deskbook, *supra* note 35, at 116.

salmon, in the event of an escape from the pens.<sup>167</sup> The purpose of confinement in pens is to permit the fish to be easily recaptured at the end of the growing cycle when they are to be harvested, but this confinement also has the effect of limiting interbreeding.<sup>168</sup> The federal agencies that permit fish farming to occur assumed that sterile breeding would be successful, and that even in those cases where sterile breeding was not successful, escape from pens would not occur.<sup>169</sup> In the event that escape of a nonsterile fish did occur, it was assumed that the nonsterile fish would be unlikely to survive and interbreed due to environmental factors, including predation and geographic separation.<sup>170</sup> In short, the regulatory agencies took comfort from the idea that there were multiple barriers to the interbreeding of farmed and wild species of salmon.

The federal agency case study on transgenic salmon discloses that each of the assumptions that supported the idea that the salmon fish farms could indeed prevent farmed and wild salmon species interbreeding were to some extent contrary to reality. First, the techniques used to ensure sterility of the farmed salmon are not one hundred percent reliable.<sup>171</sup> Second, fish escape from salmon pens with reasonable frequency because the ocean is a harsh environment and pens are not an especially robust containment system for economic reasons.<sup>172</sup> Third, the escaped fish survive outside the pens and reproduce with reasonable frequency.<sup>173</sup> In other words, not one of the “containment system” assumptions made by federal regulatory authorities proved wholly accurate when judged against real world experience. Nor is this situation the first time that authorities

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167. See Case Studies, *supra* note 35, at Case Study One, at 4; Deskbook, *supra* note 35, at 116.

168. See generally Case Studies, *supra* note 35, at Case Study One, at 5; Deskbook, *supra* note 35, at 117.

169. See Case Studies, *supra* note 35, at Case Study One, at 6; Deskbook, *supra* note 35, at 118.

170. See Case Studies, *supra* note 35, at Case Study One, at 6; Deskbook, *supra* note 35, at 118.

171. See Case Studies, *supra* note 35, at Case Study One, at 4; Deskbook, *supra* note 35, at 116.

172. See Case Studies, *supra* note 35, at Case Study One, at 23; Deskbook, *supra* note 35, at 135.

173. See Case Studies, *supra* note 35, at Case Study One, at 5; Deskbook, *supra* note 35, at 117.

underestimated the ability of salmon as a species to survive. As the federal agency study acknowledges, because it was assumed that salmon would not survive in fresh water, more than 20,000 salmon fry were flushed into the Great Lakes in the early 1970s.<sup>174</sup> The result was an explosion of the population of salmon in the Great Lakes.<sup>175</sup>

The containment steps required by existing conventional salmon fish farming permittees will slow down, but will not eliminate, the transfer of genetic material between the farmed and wild salmon species. This result would not be significant if the wild and farmed species were essentially equivalent, so that genetic transfer between them was of no consequence. No one knows, however, whether this conclusion is reasonable. In fact, there is reason to believe, based on the quality of the adaptation made by the wild salmon to their environment, that they contain valuable genetic material that could prove very useful if isolated and properly understood. If the wild species is extinguished by interbreeding with farmed salmon, this genetic material may be irretrievably lost.

## 2. Transgenic Salmon Permitting

The transgenic salmon under development are apparently prized by their developers because they can grow substantially faster than conventional salmon as a result of added genetic material, thus cutting the cost of production by shortening the time to market.<sup>176</sup> Many of the same issues raised by the government's failure to properly regulate conventional salmon fish farming are raised by transgenic salmon farming.

Transgenic salmon permitting poses an additional risk. Transgenic salmon grow more quickly and may be better competitors for food supply, and thus may prove more successful in mating. In other words, if the transgenic salmon escape confinement, and can breed, they may decrease genetic variation when interbreeding with the wild

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174. See Case Studies, *supra* note 35, at Case Study One, at 8; Deskbook, *supra* note 35, at 120.

175. See Case Studies, *supra* note 35, at Case Study One, at 8; Deskbook, *supra* note 35, at 120.

176. See Case Studies, *supra* note 35, at Case Study One, at 1; Deskbook, *supra* note 35, at 113.

population.<sup>177</sup> Over time, the result would be a decline of the total population of wild-type salmon.

Thus, the past experience of the federal government with permits for conventional salmon fish farming shows that it is necessary to substantially improve its permitting process in the case of transgenic salmon. The result of regulatory failure in that respect might be the irreversible collapse of wild salmon populations, despite their status as threatened or endangered species.

### 3. Lessons from the Inadequacy of the Coordinated Framework with Respect to Pest-Protected Plants

In view of the prominence of pest-protected plants in agricultural biotechnology today, it is striking to note that such plants were not regulated by the Coordinated Framework.<sup>178</sup> The EPA's failure to promulgate scientifically justifiable final regulations to govern pest-protected plants until after it granted permits allowing the planting of millions of acres of such plants is, in itself, a significant form of regulatory failure.

Although the NRC Report on pest-protected plants can be fairly described as supportive of the use of agricultural biotechnology, careful reading discloses that it is also sharply critical of the quality of regulation that occurred to date. First, the NRC Report criticized the scientific basis of major exemptions from plant-pesticide regulation proposed by the EPA. Second, the NRC Report concluded that "[t]he scope of product reviews, as delineated by USDA and EPA, has the potential to result in gaps in regulatory coverage."<sup>179</sup> In particular, the NRC Report noted that the USDA regulates only

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177. See Case Studies, *supra* note 35, at Case Study One, at 23; Deskbook, *supra* note 35, at 135.

178. NRC Report, *supra* note 1, at 145:

What the framework left unresolved were jurisdictional issues that would have to be addressed before commercial introduction of a number of products, including transgenic plants that were modified to resist disease and ward off insect pests. In fact, plants modified to exhibit pesticidal traits were not specifically addressed by the coordinated framework.

179. *Id.* at 161.

GMOs that it thinks are produced using “plant pests.”<sup>180</sup> As the NRC Report noted, “[m]any plants do not automatically meet the definition of a ‘plant pest.’”<sup>181</sup> In other words, according to the NRC, the development of new techniques for genetically engineering crops means that “the scope of USDA’s regulations might now fail to encompass some genetically engineered crops that the agency wishes to regulate.”<sup>182</sup>

Third, the NRC Report notes that in the case of regulating Bt cotton, the EPA and the USDA reached significantly different conclusions on whether any regulation at all should be required.<sup>183</sup> The USDA concluded that such cotton could be permitted without restrictions, because of the USDA’s narrow regulatory focus limited to plant pests.<sup>184</sup> The EPA, on the other hand, placed “geographic restrictions on the planting of Bt cotton until additional information could be provided to adequately assess the potential for and consequences of transfer of the Bt gene to related species.”<sup>185</sup> Remarkably, even though the reviews of Bt cotton by the two agencies occurred within months of each other, “[t]he agencies indicated that they did not communicate with one another on this issue before making their regulatory determinations.”<sup>186</sup> According to the NRC, the complete failure of the agencies to communicate when making essentially the same regulatory decision, combined with their sharply differing regulatory conclusions, “may have resulted in stakeholder confusion and raised questions about the credibility of assessments.”<sup>187</sup>

In short, based on the NRC Report’s review of this part of the agricultural biotechnology regulatory system, it would be difficult to describe U.S. regulation of pest-protected plants as comprehensive, consistent, or thorough. This description does not mean that there are inherent dangers to the creation or use of genetically created pest-

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180. *Id.*

181. *See id.*

182. *See id.*

183. *See id.* at 165-66.

184. *See id.*

185. *Id.*

186. *Id.*

187. *Id.*

protected plants. What it does mean, however, is that the federal government needs to decide whether it is willing to make necessary improvements to its regulatory process or, alternatively, whether the tort liability system will be permitted to establish limitations on the use of such technology.<sup>188</sup>

## VII. ANALYSIS OF EXISTING AGRICULTURAL BIOTECHNOLOGY REGULATION IN LIGHT OF SUSTAINABILITY PRINCIPLES

The existing regulation of agricultural biotechnology has significant flaws, as described above. The question presented here is, essentially, whether the regulation of biotechnology demands distinctively better regulation than what presently exists for conventional agricultural products. This issue can be addressed by analyzing how well the regulatory system meets the sustainability criteria discussed above and considers marginal costs and benefits.

### *A. Sustainable Yield and Biodiversity Maintenance*

The need for sustainable yield management and biodiversity maintenance exists in both conventional agriculture and agricultural biotechnology. In both cases, there is a clear tension between the range of possible improvements in crop varieties, and weed and pest control, and adaptations that can rapidly defeat such improvements and even, in the worst case, cause major crop losses or severe resource losses such as soil erosion or soil damage. This tension requires the federal government to take seriously the need to diversify and protect available agricultural resources, especially soil quality, water quality, and crop diversity. During the twentieth century, the federal government appropriately sought to conserve soil resources,

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188. An example of the operation of the tort liability system would be informal compensation and/or litigation over the performance of Roundup Ready™ crop seed, which allegedly failed to perform properly when used. See Ronnie Cummins, Monsanto's "Roundup Ready" Cotton Bombs in the USA, MOTION MAG. (Oct. 21, 1997), available at <http://www.inmotionmagazine.com/cotton.html> (describing potential class action lawsuit against Monsanto on behalf of cotton growers who suffered crop losses when Roundup Ready Cotton failed to grow properly).

protect food supply from contamination and monoculture, limit the use of pesticides, and prevent the spread of noxious weeds through various means including herbicides.<sup>189</sup> The federal government, however, has not taken its responsibility to manage resources for sustainable yield and biodiversity maintenance as seriously as it should have with respect to both the resources it owns and the way in which the private sector produces its agricultural products. The federal government recognizes only in general terms that these considerations should be substantial factors in making agricultural resource decisions of various kinds.<sup>190</sup>

One potentially significant difference between conventional and biotechnology agriculture is the speed and scale upon which change in crop composition, and hence habitat alteration, might occur. By markedly altering the economics of crop production, at least in the short run, biotechnology developments can potentially alter crop characteristics more widely and more quickly than can conventional agriculture. In addition, genetically modified plants and animals may, in some cases, not have natural predators in the ecosystems in which they are introduced, and may, as a result, have the same adverse impacts as a conventionally bred “exotic” species. Accordingly, although regulators may not generally need to treat sustainable yield and biodiversity maintenance issues fundamentally differently where conventional agriculture and agricultural biotechnology are concerned, there may be exceptions. In some cases, regulators may need to require more intensive premarket testing of some GMOs to provide additional scientific information on issues related to sustainable yield and biodiversity or to require physical limits on the extent of introduction of those new GMOs until they have a reasonable period of actual testing in commercial use. One such example is the limits the EPA imposed on the planting of Bt cotton. If an industry sponsor of a new GMO wishes to avoid such regulatory

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189. For example, FIFRA, 7 U.S.C. §§ 136-136y, controls the presence of pesticides on the market, and the FFDCA, 21 U.S.C. § 301 et seq., protects the safety of the food supply.

190. Improving the federal government’s capacity to manage resources for sustainable yield and biodiversity would need to be the subject of a different article. In fact, in the newly significant context of bioterrorism, which could be conducted both through conventional and genetic engineering technologies, the federal government would be well advised to reexamine its capabilities in these areas.

restrictions, perhaps the sponsor should be prepared to provide some form of reasonable financial compensation in the event that unanticipated damage occurs to the crops of other growers, or to other field organisms or conventionally bred competitors, or if an increased need for chemical control results from the expanded use of the GMO.<sup>191</sup>

### *B. Internalization of Costs*

As shown by the Starlink™ and other regulatory failure episodes described above, agricultural biotechnology is not yet being required to fully internalize its social costs.<sup>192</sup> All of the case studies considered above share the characteristics that unintended “escape” of GMO material from a containment system created through regulation occurred, or is likely to occur, with varying degrees of harm resulting from the escape. This type of unintended escape is a social cost that regulators must fully account for and control. This regulatory failure to require full cost internalization constitutes an important failure by U.S. agricultural biotechnology policy to meet sustainability criteria. It is a failure that must be rectified either by improvements in the regulatory process or by adjustments made through the tort liability system. This issue will be discussed further in the next section.

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191. For example, a GMO sponsor might purchase insurance coverage that would be able to be called on in the event that unanticipated damage of specified types occurred during the trial period. Such insurance might well be expensive, but there is no reason for the public to bear these unanticipated costs that result from premature introduction of a GMO.

192. There are assertions that biotechnology regulation involves excessive costs, or, at least, that costs should not be made higher. For example, industry sources claim that over \$3 billion were spent in permitting Bt plant products. *See* Abramson & Carrato, *supra* note 49, at 257. However, the proper standard for the appropriate cost of regulation is that it should cost no more than is needed to impose regulations that will force the full internalization of social cost, not that the cost of regulation should meet some arbitrary, predetermined standard. If regulation is excessive, industry should challenge it by demonstrating that various aspects of the regulation are unnecessary. Particularly in the area of biotechnology, the government has seemed to be willing to consider such assertions seriously and to modify regulatory requirements where such demonstrations could be persuasively made.

### *C. Public Participation and Transparency*

On both public participation and transparency dimensions, the process of agricultural biotechnology regulation has historically fallen below the standards set by the United States in other areas of environmental law. In virtually all other areas of environmental law, the United States is a world leader in public participation and transparency, often as a result of congressional authorization through statutory citizen action provisions, with fundamentally positive results.<sup>193</sup>

The major federal regulatory agencies appear to have belatedly recognized that they can improve both the transparency of decisionmaking and public participation in the regulation of agricultural biotechnology. Thus, for example, the FDA proposed to require premarket notification for biotechnology products that would be used as food.<sup>194</sup> Various regulatory agencies agreed to do a better job of policing the use of overbroad confidential business information claims that may prevent public scrutiny of the health and safety impacts of new biotechnology developments.<sup>195</sup> Although it is essential to safeguard industry rights to intellectual property in the regulatory process, it seems clear that better mechanisms can be developed to permit at least indirect public review of health and

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193. The right of citizens to participate in and to challenge government regulatory action in court is one of the most distinctive features of American environmental law. In many cases it is responsible for preventing “regulatory capture,” a phenomenon that limits the effectiveness of government regulation so often in other areas of American regulation, and is even more prominent in most other countries.

194. The FDA recently proposed to move from voluntary to mandatory premarket notification of biotechnology foods.

The proposed rule would require companies to provide notice of the intent to market a biotechnology food in the U.S. at least 120 days prior to commercial distribution through the submission of a Pre-market Biotechnology Notice (“PBN”). The PBN would include data and information about the food and a narrative discussing the data and information. The applicant must also agree to provide additional relevant data and information upon the Agency’s request. The public would have ready access to the PBN and the Agency’s response to it.

*See* Abramson & Carrato, *supra* note 49, at 252-53.

195. For example, the USDA has provided clarification on the type of submitted information that may be designated as confidential business information. *See* NRC Report, *supra* note 1, at 174.

safety issues in the regulatory process.<sup>196</sup>

All in all, the historical experience of other U.S. industries that employed controversial technologies, or were engaged in controversial business practices that had apparent potential for significant environmental and health effects, demonstrates that public support is an essential part of developing a successful new industry. Increased transparency and public participation in the regulatory process is an essential part of obtaining this public support and can actually avoid calls for more onerous public regulation either before or after development of new technology. Accordingly, Congress should consider imposing on the federal regulatory agencies requirements that they collect certain types of scientific data either before or after permitting various agricultural biotechnology products, such as the various studies recommended by the NRC Report, and that they make such data available for public review.

#### VIII. ALTERNATIVE FUTURE DIRECTIONS FOR SOCIAL CONTROL OF AGRICULTURAL BIOTECHNOLOGY

The EU seems to have embarked on a path toward more aggressive regulation of agricultural biotechnology. The EU proposed regulations that would require traceability of GMO food and feed products, regulations that would require additional labeling of such products, and regulations or international agreements that would permit countries to operate on the basis of the “precautionary principle” with respect to many GMOs, should they choose.<sup>197</sup> The U.S. agricultural biotechnology industry is opposed to all of these regulatory changes.<sup>198</sup>

It is certainly possible to view the proposed European changes as,

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196. For example, federal agencies might develop considerably more extensive networks of outside “peer reviewers” for such issues than presently exist. In principle, there is no reason that members of the public with the necessary technical backgrounds could not execute appropriate confidentiality undertakings that would permit them to engage in necessary technical reviews while safeguarding a project sponsor’s intellectual property.

197. See Commission on the European Communities, *supra* note 109.

198. For example, thirty-eight organizations in the agri-food industry, including the trade association Biotechnology Industry Organization, urged President Clinton not to change the current FDA policy regarding labeling of biotech foods. See Letter to President Clinton (Nov. 12, 1999), available at <http://www.bio.org/food&ag/1112letter.html>.

in many respects, little more than efforts to maintain trade barriers in favor of conventional European food producers. However, the European regulatory changes discussed above all involve efforts to subject GMO food and feed products to consumer and public choice and pressure. The changes also permit vetoes on the introduction of certain GMO products by European countries in the event of scientific uncertainty.<sup>199</sup> Taken together, they adopt a model for regulation similar, in some respects, to U.S. environmental law, if it were adapted to GMO food and feed products.

The American agricultural biotechnology industry prefers the U.S. food and drug regulation model instead of European-style regulation.<sup>200</sup> In order to make this position ultimately defensible to the public, industry must persuade policymakers and the public both that agricultural biotechnology has very limited risks and that federal agency regulators can be counted on to require *and enforce* regulation that will control any remaining risks. As has been shown, there is definite support for at least the first of these contentions, but the second contention ultimately has its limits in light of the history of agricultural biotechnology regulatory failure and the limits of existing scientific knowledge. Improvements in federal agency regulation are therefore clearly necessary if long term public acceptance of GMO plant, food, and feed products is to occur. At the same time, if the agricultural biotechnology industry wants to make certain that it does not eventually face public demands for European style regulation and a shift in the basic burden of proof for permitting new products akin to the “precautionary principle,” it is probably going to have to accept a reasonable degree of tort liability to provide both compensation for harm and deterrence against unduly risky conduct.

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199. See Francer, *supra* note 6, at 309-10.

200. Under the “food and drug” regulation model, individual states cannot set more stringent health and safety requirements for introduction of food and drugs into commerce than those set by the federal government because such state regulation is preempted by federal law. While this limitation means that industry is able to avoid local protectionism, it also means that members of the public are required to accept the idea that the federal government is better able to protect their health and safety than state authorities, which is not uniformly true. A “level playing field” argument is often made against European-style regulations, asserting that such regulations discriminate against biotechnology. This argument is quite correct, but is unlikely to change matters in terms of obtaining public support for biotechnology.

## IX. CLARIFYING THE TORT LIABILITY REGIME FOR AGRICULTURAL BIOTECHNOLOGY PRODUCTS

At present, it is uncertain what type of liability regime will be applied to harm caused by agricultural biotechnology products.<sup>201</sup> Because agricultural biotechnology products are potentially socially useful products, and agricultural biotechnology is not inherently dangerous, the higher the quality of federal regulatory review of agricultural biotechnology, the lower the level of tort liability for remaining harm the industry should be required to assume. Assuming that the regulatory system is indeed improved in the directions discussed above, there is a reasonable policy argument that agricultural biotechnology product tort liability should be limited in certain key respects sketched out below. It might be preferable for the industry to seek legislative clarification concerning the appropriate liability regime rather than waiting for the issue to be resolved in the courts.<sup>202</sup> Development of a consensus on appropriate liability rules through the legislative process or some other means should strengthen public confidence in agricultural biotechnology.

Broadly speaking, harm caused by agricultural biotechnology could theoretically be divided into four categories: harm caused by permit violations; harm caused to protected natural resources; harm caused to conventional crops and conventionally bred animals; and human health harms.

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201. Several articles surveyed the tort liability regime that may be applied to biotechnology products. For the reader's information, and without meaning to endorse any of their conclusions, see, e.g., Dan L. Burk & Barbara A. Boczar, *Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791 (1994); Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation*, 20 REV. LITIG. 589 (2001); Julie A. Davies & Lawrence C. Levine, *Biotechnology's Challenge to the Law of Torts*, 32 MCGEORGE L. REV. 221 (2000).

202. The reasons for this preference have to do with the inconsistency of results that may occur in litigation given the uncertainty regarding appropriate liability standards, and its very substantial costs. Moreover, a fair amount of litigation regarding damage allegedly done by agricultural biotechnology may occur in the context of class action lawsuits, which are often exceptionally time consuming and expensive. Finally, clear legislative standards governing industry liability may be necessary to make industry operations insurable by private insurers.

*A. Harm Caused as a Result of Permit Violations*

An improved regulatory system will be the foundation of social protection against the risks of agricultural biotechnology until there is sufficient scientific data to accurately and fully assess the risks of biotechnology products in advance. Accordingly, agricultural biotechnology products as to which there are significant scientific uncertainties should be subject to strict liability for harms caused, if such harms are caused by violations of regulatory permit conditions. Exemptions from this requirement can be made on a case-by-case basis as experience grows.

A rule of strict liability for such harms will ensure the enforceability of such regulatory permit conditions and limit the need for the government to add additional regulatory requirements or increase enforcement resources. In some cases where there are particularly large uncertainties about a particular biotechnology product and potential for large harms related to those uncertainties, regulatory authorities may need to consider a requirement for financial assurance to be provided by the project sponsor to ensure that if harm occurs as a result of a permit violation, a permit applicant will have the financial resources to pay the resulting costs. In any event, fine and penalty provisions of federal law relating to agricultural biotechnology permit violations should be strictly enforced; Congress should appropriate sufficient funds so that regulatory agencies and law enforcement entities have the necessary resources to ensure such enforcement occurs.

*B. Harm Caused to Protected Natural Resources*

There is substantial evidence that agricultural biotechnology products, such as transgenic salmon, can adversely affect natural resources, such as wild salmon populations, if not properly regulated. Agricultural biotechnology products should be subject to strict liability for harm caused at least to those natural resources that receive special statutory protection, such as the Migratory Bird Treaty Act or the Endangered Species Act, in the same manner and

on the same basis as would be true for harm to such resources caused by products of conventional agriculture or its operations. Consideration may also need to be given to requiring financial assurance for both conventional agriculture and agricultural biotechnology products with respect to certain types of federally permitted environmental releases that may cause irreversible environmental damage, such as extinction of a species.

*C. Harm Caused to Conventional Crops and Conventionally Bred Animals*

Absent a regulatory permit violation, agricultural biotechnology products should generally be subject to liability for harm caused to crops and conventionally bred animals only on the basis of fault, such as negligence.<sup>203</sup> However, the government should develop a low cost means, such as internet publication, of providing information regarding the use of agricultural biotechnology products and avoidance of unintended consequences of such use to producers of conventional crops and conventionally bred animals and to agricultural biotechnology product users.

*D. Human Health Harms*

The protection of human health is a fundamental requirement for a successful agricultural biotechnology regulatory system. Because conventional agriculture and agricultural biotechnology may pose comparable risks to health, assuming an improved regulatory system (including provision for additional testing for potential human health harms such as allergenicity and toxicity) and absent a permit violation that caused the harm, agricultural biotechnology products should be subject to liability for harm caused to human health only under the same liability scheme and in those circumstances where a conventional food producer would be subject to such liability. Punitive damages should only be available for intentional or grossly

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203. Consideration should be given, however, to whether in certain exceptional types of cases traditional common law principles such as nuisance or trespass might continue to apply even where only permitted releases occurred.

negligent violations of regulatory requirements that cause significant harm or in circumstances where such damages would be available against a conventional agricultural food or feed producer.

#### X. CONCLUSION

Although agricultural biotechnology has the potential to provide useful products, it also poses some new environmental and safety risks in addition to some of the same risks posed by conventional agriculture. The U.S. federal regulatory system clearly needs improvement as a result of regulatory failures in the federal government's control of agricultural biotechnology. If needed regulatory improvements are made, tort liability for agricultural biotechnology products should, in certain key respects, parallel the rules governing tort liability for conventional agriculture, but may, in specific cases, require more stringent liability standards. Taken together, these reforms should be sufficient to permit the rational development of agricultural biotechnology while ensuring agricultural sustainability.





