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## Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals

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# GAPS, INEXPERIENCE, INCONSISTENCIES, AND OVERLAPS: CRISIS IN THE REGULATION OF GENETICALLY MODIFIED PLANTS AND ANIMALS

GREGORY N. MANDEL\*

## ABSTRACT

*The regulation of genetically modified products pursuant to statutes enacted decades prior to the advent of biotechnology has created a regulatory system that is passive rather than proactive about risks, has difficulty adapting to biotechnology advances, and is highly fractured and inefficient—transgenic plants and animals are governed by at least twelve different statutes and five different agencies or services. The deficiencies resulting from this piecemeal approach to regulation unnecessarily expose society and the environment to adverse risks of biotechnology and introduce numerous inefficiencies into the regulatory system. These risks and inefficiencies include gaps in regulation, duplicative and inconsistent regulation, unnecessary regulatory expense, agencies acting outside their areas of expertise, and unnecessary increases in the cost of and delay in the development and commercialization of new biotechnology products. These deficiencies also increase the risk of further unnecessary biotechnology scares, which may cause public overreaction against biotechnology products, preventing the maximization of social welfare.*

*With science and society poised to soar from first-generation biotechnology (focused on crops modified for agricultural benefit), to next-generation developments (including transgenic fish, insects, and livestock, and pharmaceutical-producing and industrial compound-producing plants and animals), it is necessary to establish a comprehensive, efficient, and scientifically rigorous*

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*regulatory system. This Article details how to achieve such a result through fixing the deficiencies in, and risks created by, the current regulatory structure. Ignoring many details, the solutions can be summarized in two categories. First, statutory and regulatory gaps that are identified must be closed with new legislation and regulation. Second, regulation of genetically modified products must be shifted from a haphazard model based on statutes not intended to cover biotechnology to a system based upon agency expertise in handling particular types of risks.*

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## INTRODUCTION

Biotechnology may help ameliorate some of the greatest crises currently facing the United States and the world, including hunger and malnutrition, environmental degradation, and widespread disease. Genetically modifying crops through the use of biotechnology potentially allows for greater agricultural efficiency, increased nutritional content of food, and reduced environmental impacts. Genetically engineering animals may create cheaper food, reduce pressures on wild animal populations, and provide organs or tissues for human transplant. Modifying plants and animals to produce pharmaceuticals could provide for widespread, inexpensive dissemination of critical pharmaceuticals and vaccines throughout the United States and the world.

On the other hand, biotechnology could have harmful consequences. Potential problems include human health impacts resulting from the introduction of new allergens or toxins, widespread environmental and ecological damage resulting from the introduction of invasive species or loss of biodiversity, and unforeseen injury arising from the unintentional release of pharmaceuticals or industrial compounds into the food supply.

Most discussion concerning biotechnology takes place in a polarized debate between biotechnology proponents who focus only on biotechnology's advantages and generally deny its risks, and biotechnology opponents who focus only on biotechnology's risks and generally deny its advantages. A review of the data and information available concerning genetically modified products demonstrates that both camps are right, and wrong. There is now strong evidence that genetic engineering can provide substantial health, environmental, and economic benefits. There is also strong evidence that some genetically modified products pose certain human health and environmental risks. This Article stakes out a middle ground in the polarized biotechnology debate: Society simultaneously should promote the development and use of biotechnology while instituting necessary protection against its risks.

Adequate federal regulation of biotechnology is the tool that can best achieve both results at once. Effective and efficient regulation is the mediator that will determine whether society reaps the

spectacular advantages of biotechnology or succumbs to its potential dangers. Without proper regulation, society will face unnecessary risks, the benefits of biotechnology will be slowed severely and made more expensive, and the public will lack confidence in biotechnology products.

Though the history of biotechnology is relatively short, it already is filled with numerous regulatory lapses. An examination reveals that most problems and concerns arising in this field are the result of a deficient statutory and regulatory structure. Considering that genetically modified products are regulated pursuant to statutes enacted decades prior to the advent of biotechnology itself, these deficiencies are not entirely surprising. This default system has led to a regulatory approach that is passive rather than proactive about risks, has difficulty adapting to biotechnology advances, and is highly fractured—genetically modified plants and animals are governed by at least twelve different statutes and five different agencies or services.

The deficiencies resulting from this piecemeal approach to regulation unnecessarily expose society and the environment to the adverse risks of biotechnology and introduce numerous inefficiencies into the regulatory system. These risks and inefficiencies include gaps in regulation and regulatory authority, duplicative and inconsistent regulation, unnecessary regulatory expense, regulatory agencies acting outside their areas of expertise, and unnecessary increases in the cost of and delay in the development and commercialization of new biotechnology products. These deficiencies also result in a further risk: the failure to properly regulate biotechnology has led to unnecessary scares (StarLink corn contamination is the most infamous example),<sup>1</sup> which in turn cause a public overreaction against biotechnology products, preventing society from fully utilizing their potential benefits. Thus far, biotechnology scares primarily are all that have occurred; deficient regulation, however, creates the risk of more serious consequences, ones that could retard the biotechnology industry and impair social welfare.

This Article provides solutions to the deficiencies in, and the risks created by, the current regulatory structure. Ignoring many details for the moment, the solutions can be summarized in two

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1. See *infra* Part III.A.

categories. First, numerous statutory and regulatory gaps that are identified in this Article must be closed with new legislation and regulation. Second, regulation of genetically modified products must be shifted from a haphazard model based on archaic statutes not intended to cover biotechnology to a regulatory system based on agency expertise in handling particular types of risks. This shift would remove from the current system numerous inefficient instances of regulatory overlap, regulatory inconsistency, and agencies acting outside their areas of expertise. This proposal also would result in a regulatory structure that is both more protective of human health and the environment and less expensive for industry and taxpayers.

Science and society are poised to soar from first-generation biotechnology, focused on crops genetically modified for agricultural benefits, to next-generation developments including: transgenic fish, insects, and livestock; nutrient-enriched foods; and pharmaceutical-producing and industrial compound-producing plants and animals. In order to maximize the social benefit from these advances it is necessary to establish a comprehensive, efficient, and scientifically rigorous regulatory system to ensure adequate protection of human health and the environment. It is critical at this juncture to get the regulatory house in order so that society can harvest the benefits of future biotechnological advances without unduly suffering their risks. This Article explains and analyzes the steps necessary to achieve this result.

Part I of this Article provides a short history of genetic modification and an overview of the current state of biotechnology with respect to plants and animals. Part II contains brief descriptions and analyses of the various benefits offered and risks posed by biotechnology. The Article turns, in Part III, to four case studies, which highlight genetically modified product scares that have been caused, at least in part, by regulatory deficiencies. Analyzing these case studies yields valuable information regarding problems with biotechnology regulation and how such problems may be cured. Part IV provides a short primer on the current state of biotechnology regulation by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA). With the case studies as background, and an understanding of genetically modified product regulation in



place, Part V identifies the regulatory gaps, overlaps, inconsistencies, areas of inexperience, and other problems that exist with respect to the regulation of biotechnology products. Part VI discusses the causes of these regulatory deficiencies, provides solutions for improving the current regulatory system, and demonstrates that improved regulation is the appropriate mechanism for maximizing social welfare from genetically modified products.

## I. OVERVIEW OF GENETIC MODIFICATION

In order to evaluate the regulatory system currently governing genetically modified products, problems with the system, and how the system should be changed, it is necessary first to become familiar with the current status of genetically modified products in the United States. This familiarity, in turn, requires a short history of genetically modified products and a brief scientific introduction to the topic.

### *A. The History and Science of Genetically Modified Products*

Genetically modified crops, in a literal sense, have been around for centuries, probably since the advent of agriculture. In ancient times, farmers saved seeds from crops that produced the highest yield, proved the hardiest, or were the most disease resistant.<sup>2</sup> Since at least the 1500s, farmers have bred crops in an effort to produce more durable, productive, or marketable varieties.<sup>3</sup> Control over genetic modification of crops took a leap forward in the late 1800s with Gregor Mendel's discoveries regarding heredity and the inheritance of genetic traits, in particular, his finding that characteristics are inherited in a logical, predictable manner.<sup>4</sup> Since these

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2. See NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS 37 (2002) [hereinafter NRC 2002 REPORT].

3. See John Henkel, *Genetic Engineering: Fast Forwarding to Future Foods*, FDA CONSUMER, April 1995, available at <http://www.fda.gov/bbs/topics/CONSUMER/geneng.html> (last visited Apr. 7, 2004) ("By the 1500s, farmers were improving plants by crossing, for example, a productive crop with a wild relative resistant to disease or pests."); see also NRC 2002 REPORT, *supra* note 2, at 37.

4. NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 22-23 (2000) [hereinafter NRC 2000 REPORT].

discoveries, scientists and farmers have been selectively breeding closely related plants and animals in an effort to create hybrids with superior characteristics. Today, there are virtually no food products in supermarkets that have not been improved in some manner by selective breeding.<sup>5</sup> Genetic modification through the breeding of plants and animals (which will be referred to as "conventional genetic modification"), however, is labor intensive (only one out of thousands of hybrids becomes a useful variety), can only be done among closely related species, takes a long time to produce desired results (usually a decade), and is often imprecise.<sup>6</sup>

Scientists now are able to take genetic material responsible for a particular trait in one living species (whether plant, animal, insect, bacterium, or virus), and insert it into another species. Because the DNA building blocks for all living things are similar, desirable genes from any living organism can be inserted into any other living organism. This allows for modification of organisms at the cellular level, as opposed to conventional modification via breeding of the entire organism.<sup>7</sup> If the genetic insertion is successful, the new genetic material in the host organism does what most genes do—it directs the production of specific proteins.<sup>8</sup> This method of modification uses recombinant DNA (rDNA) techniques, and is referred to as rDNA genetic modification. The modified rDNA organisms are commonly referred to as "genetically modified," "genetically engineered," "bioengineered," or "transgenic."<sup>9</sup>

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5. ROYAL SOC'Y OF CAN., ELEMENTS OF PRECAUTION: RECOMMENDATIONS FOR THE REGULATION OF FOOD BIOTECHNOLOGY IN CANADA 16 (2001). Wild blueberries are one of the few remaining unmodified plant products. *Id.* Examples of foods that have undergone particularly dramatic changes through conventional genetic modification include edible ears of corn (as opposed to corn with hard kernels that could not be eaten until ground into flour) and the kiwi (a fruit developed from a hard little berry). Henkel, *supra* note 3.

6. NRC 2002 REPORT, *supra* note 2, at 43; NRC 2000 REPORT, *supra* note 4, at 23.

7. MARGARET MELLON, BIOTECHNOLOGY AND THE ENVIRONMENT: A PRIMER ON THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 20 (1988).

8. BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 200 (4th ed. 2002); Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 407 (2002). The two most common methods of genetic engineering are splicing the gene to be transferred to a virus and infecting the host organism with the virus, and coating tiny metal particles with the gene to be transferred and then firing the particles into the host cells. See ROYAL SOC'Y OF CAN., *supra* note 5, at 16-17.

9. Except as otherwise stated, the terms "genetically modified," "genetically engineered," "bioengineered," and "transgenic" are used synonymously in this Article, each referring to the direct transfer or modification of genetic material using rDNA techniques.

rDNA genetic engineering offers many advantages over conventional breeding techniques. First, the organism being modified does not have to be sexually compatible with the organism from which the genetic material comes—one can take genes from bacteria and implant them into plants or animals, and vice versa.<sup>10</sup> Second, new varieties can be produced much faster through rDNA methods than through conventional breeding techniques.<sup>11</sup> Third, specific knowledge of the trait caused by the particular DNA being transferred can reduce variability in the offspring organisms.<sup>12</sup>

### *B. Current Status of Genetically Modified Products*

Many people are surprised to learn that genetically modified food is already pervasive in the United States. Almost everyone reading this Article already has eaten genetically modified food, and likely has done so today.<sup>13</sup>

The first genetically modified commercial food item, the Flavr Savr tomato (a slow-ripening tomato), was introduced in 1994.<sup>14</sup> Since that time, genetically modified foods have become widespread, as over fifty types of transgenic plants have been commercialized in the United States.<sup>15</sup> These plants include delayed-

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10. NRC 2002 REPORT, *supra* note 2, at 43.

11. NRC 2000 REPORT, *supra* note 4, at 23.

12. *Id.* at 23-24. Genetic engineering, however, also can be imprecise. MARTIN TEITEL & KIMBERLY A. WILSON, GENETICALLY ENGINEERED FOOD: CHANGING THE NATURE OF NATURE 10 (2001).

13. See *infra* notes 19-20 and accompanying text. Only one in four people are aware that they have eaten genetically modified food. Memorandum from The Mellon Group, Inc. and Public Opinion Strategies, Inc., to The Pew Initiative on Food and Biotechnology 2 (Sept. 15, 2003) (on file with author).

14. TEITEL & WILSON, *supra* note 12, at 21. The Flavr Savr was not a commercial success. *Id.* at 22. The first genetically engineered plant was created in 1983; genetically modified plants were first grown in the field in 1987. *Id.* at 18.

15. See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, OFFICE OF FOOD ADDITIVE SAFETY, U.S. FOOD & DRUG ADMIN., LIST OF COMPLETED CONSULTATIONS ON BIOENGINEERED FOODS (2002) [hereinafter BIOENGINEERED FOODS LIST], available at <http://www.cfsan.fda.gov/~lrd/biocon.html> (last visited Apr. 7, 2004) (listing fifty-five submissions completed between 1994 and 2002); see also INFO. SYS. FOR BIOTECHNOLOGY, TABLES FOR FIELD TEST RELEASES IN THE U.S. (last updated Mar. 26, 2004) [hereinafter TABLES FOR FIELD TEST RELEASES], at <http://www.isb.vt.edu/cfdocs/isbtables2.cfm?tvar=4> (last visited Apr. 7, 2004) (reporting that sixty genetically modified plants have been deregulated). The Animal and Plant Health Inspection Service (APHIS) section of the U.S. Department of Agriculture is responsible for issuing permits and approving or denying the application for the release of

ripening crops, pest-resistant crops, herbicide-tolerant crops, virus-resistant crops, bacteria-resistant crops, fungus-resistant crops, and nematode-resistant crops, among others.<sup>16</sup>

Genetically engineered plants were grown on over one hundred million acres of American farmland in 2003, up from a mere six million acres in 1996.<sup>17</sup> In 2003, 81% of soybeans, 40% of corn, and 73% of cotton grown in the United States were grown from genetically modified seeds; over half of the canola and papaya were genetically engineered as well.<sup>18</sup> The Grocery Manufacturers of America estimates that 70% of food on grocery store shelves contains ingredients from genetically modified crops,<sup>19</sup> in everything from cereals and crackers, to juice and soda, to salad dressing and sauces.<sup>20</sup>

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genetically modified organisms. See INFO. SYS. FOR BIOTECHNOLOGY, BACKGROUND ON THE ENVIRONMENTAL RELEASES DATABASE, at <http://www.isb.vt.edu/biomon/explain.cfm> (last visited Apr. 7, 2004).

16. See, e.g., INFO. SYS. FOR BIOTECHNOLOGY, CHARTS FOR FIELD TEST RELEASE IN THE U.S. (last updated Mar. 26, 2004), at <http://www.isb.vt.edu/cfdocs/biocharts1.cfm> (last visited Apr. 7, 2004).

17. NAT'L AGRIC. STATISTICS SERV., U.S. DEPT OF AGRIC., ACREAGE 24-25 (June 2003), available at <http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bba/acrg0603.pdf> (last visited Apr. 7, 2004); TEITEL & WILSON, *supra* note 12, at 18. Growth of genetically modified crops in the United States dominates the worldwide industry, accounting for two-thirds of the global transgenic crop. See PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, FACTSHEET: GENETICALLY MODIFIED CROPS IN THE UNITED STATES [hereinafter PEW INITIATIVE FACTSHEET], available at <http://pewagbiotech.org/resources/factsheets/display.php3?FactsheetID=2> (Aug. 2003). The United States, Argentina, Canada, and China combined account for 99% of genetically modified crop production. *Id.*

18. PEW INITIATIVE FACTSHEET, *supra* note 17.

19. David Barboza, *Modified Foods Put Companies in a Quandary: Science Is Called Sound but Public Is Not Sure*, N.Y. TIMES, June 4, 2000, at A1; see also Rick Weiss, *Biotech Food Raises a Crop of Questions*, WASH. POST, Aug. 15, 1999, at A1 ("[N]early everything made with soy, corn, or cotton in this country ends up containing at least some gene-altered ingredients.").

20. See NATURAL LIFE, SHOP TO AVOID GENETICALLY ENGINEERED FOOD, at <http://www.life.ca/nl/60/avoidbiotech.html> (last visited Mar. 16, 2004). Examples of common food items containing genetically modified components include Fritos corn chips, McDonald's french fries, Coca-Cola, and Nestle's chocolates. *Id.* Close to fifty different types of crops have been genetically modified (not all have been commercialized, some are still under development), including alfalfa, apple, barley, beet, broccoli, carrot, cassava, citrus, coffee, corn, cotton, cranberry, cucumber, eggplant, grape, grapefruit, lettuce, melon, oat, onion, papaya, pea, peanut, pear, pepper, peppermint, persimmon, pineapple, plum, potato, radicchio, rapeseed (canola), raspberry, rice, soybean, squash, stone fruit, strawberry, sugarbeet, sugarcane, sunflower, sweet potato, tomato, walnut, watermelon, and wheat. LEONARD P. GIANESSI ET AL., PLANT BIOTECHNOLOGY: CURRENT AND POTENTIAL IMPACT FOR

Genetically modified crops are likely to become more varied and pervasive. The first generation of crops was altered primarily to provide agricultural benefits, such as pest resistance and herbicide tolerance. Next-generation crops will be manipulated to create more nutritious foods, and to produce plants that grow nonfood products, such as pharmaceuticals, vaccines, vitamins, and industrial compounds.<sup>21</sup> Numerous companies are working on producing pharmaceuticals that grow in plants. Once grown, the pharmaceuticals can be extracted from the plant, or in some instances people may be able to eat the genetically engineered plant to obtain the benefit.<sup>22</sup> Relatedly, plants may be used to grow industrial compounds for uses such as detergent manufacturing, paper production, and mineral recovery.<sup>23</sup>

Various species of trees are being genetically engineered to grow faster, produce wood that is easier to process, or resist certain diseases and other problems.<sup>24</sup> Many laboratories are working on varieties of genetically modified fish, such as transgenic salmon, carp, catfish, and trout, in an effort to increase rates of growth and reproduction, improve disease resistance, enhance cold tolerance, or provide other benefits.<sup>25</sup> Proposals for the commercialization of these fish are currently under review.<sup>26</sup>

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IMPROVING PEST MANAGEMENT IN U.S. AGRICULTURE 4-8, 16 (2002); MICHAEL R. TAYLOR & JODY S. TICK, POST-MARKET OVERSIGHT OF BIOTECH FOODS: IS THE SYSTEM PREPARED? 20 n.19 (2003).

21. See Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants, 67 Fed. Reg. 50,578 (Aug. 2, 2002) (to be codified at 7 C.F.R. pt. 340) [hereinafter Proposed Field Test Requirements]; Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4714 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

22. Andrew Pollack, *New Ventures Aim To Put Farms in Vanguard of Drug Production*, N.Y. TIMES, May 14, 2000, at A1.

23. Field Testing of Plants Engineered To Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11,337, 11,338 (proposed Mar. 10, 2003) (to be codified at 7 C.F.R. pt. 340) [hereinafter Field Testing of Pharmaceutical Plants].

24. LUKE ANDERSON, GENETIC ENGINEERING, FOOD, AND OUR ENVIRONMENT 41-42 (2000); ROYAL SOC'Y OF CAN., *supra* note 5, at 28.

25. See, e.g., PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, FUTURE FISH: ISSUES IN SCIENCE AND REGULATION OF TRANSGENIC FISH 5-7 (2003) [hereinafter FUTURE FISH]. Other traits scientists are investigating include modification to allow marine fish to be raised in fresh water, improving tolerance to various environmental conditions, and enhancing nutritional qualities. See *id.* at 5; ROYAL SOC'Y OF CAN., *supra* note 5, at 27.

26. See, e.g., FUTURE FISH, *supra* note 25, at 5-6. On the novelty front, an aquarium fish

Transgenic cattle, sheep, pigs, chickens, goats, rabbits, rodents, shellfish, and insects also are being developed.<sup>27</sup> Goals here include increasing growth rates, reducing fat levels, and improving disease tolerance, among others.<sup>28</sup> Experimentation is under way to genetically engineer animals to produce human biologics and other products, including organs and tissues for human transplant.<sup>29</sup> Animals could be modified to produce human proteins in their milk, which could then be extracted and purified for therapeutic use in humans.<sup>30</sup>

In sum, genetically modified crops are already widely commercialized, and the commercialization of many next-generation biotechnology products is just around the corner. Further, developments in rDNA technology and genomics, including the genetic sequencing of plants, are expected to lead to the accelerated development of even more new biotechnology products, both in number and diversity.<sup>31</sup>

## II. BENEFITS AND RISKS OF GENETICALLY MODIFIED PLANTS AND ANIMALS

No decision regarding how to use and regulate genetically modified products can be made without an understanding of their potential benefits and possible risks. This Part provides an overview of current scientific knowledge regarding the benefits and risks of genetically modified products.<sup>32</sup>

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genetically modified to glow in the dark recently was commercialized. Andrew Pollack, *So, the Fish Glow, But Will They Sell?*, N.Y. TIMES, Jan. 25, 2004, at C5.

27. See NAT'L RESEARCH COUNCIL, ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS 76-83 (2002) [hereinafter ANIMAL BIOTECHNOLOGY].

28. ANDERSON, *supra* note 24, at 75.

29. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 16; see also *id.* at 51-54.

30. See, e.g., COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POLICY, CASE STUDY NO. IV: FARM ANIMAL (GOAT) THAT PRODUCES HUMAN DRUGS 1 (2001) [hereinafter CASE STUDY NO. IV: FARM ANIMAL THAT PRODUCES HUMAN DRUGS], available at [http://www.ostp.gov/html/ceq\\_ostp\\_study5.pdf](http://www.ostp.gov/html/ceq_ostp_study5.pdf) (last visited Apr. 7, 2004). Other biologic products, such as therapeutic, blood, and vaccine products may be developed in this manner as well. *Id.*

31. See NAT'L RESEARCH COUNCIL, EXPLORING HORIZONS FOR DOMESTIC ANIMAL GENOMICS 1-4 (2002); see also Proposed Field Test Requirements, *supra* note 21, 67 Fed. Reg. at 50,578; Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

32. Determining the potential benefits and risks of genetically modified products is a

### *A. Potential Benefits of Genetic Engineering*

The commercialization of genetically modified crops potentially has many great societal advantages, ranging from increased agricultural efficiency, to nutritional improvement, to environmental protection. Anticipated future developments in biotechnology promise even more benefits. Each category of benefits is discussed below.

#### *1. Agricultural Benefits*

The growth of genetically modified crops may allow for the production of greater quantities of food more easily and at cheaper cost than conventional plants. Approximately \$14 billion worth of crops are lost each year in the United States due to plant pests.<sup>33</sup> Part of this crop loss can be reduced through the use of crops genetically modified to include an internal pesticide (so-called “pest-

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daunting process because of the scientific uncertainty in this area and the highly polarized debate concerning these products. As discussed in the Introduction, the literature and scientific reports coming from biotechnology proponents describe far more benefits and fewer risks than those from biotechnology opponents, which describe many risks and few or no benefits. Each side routinely accuses the other of bias in their scientific results; both sides have numerous scientists with Ph.Ds in relevant fields in their camps. The issues of which information to rely on and of bias in scientific information are therefore critical to this analysis.

The description of the benefits and risks of genetically modified plants and animals that follows, therefore, necessarily contains much cautionary language, discussing, for instance, “possible” benefits and “potential” risks. The benefits and risks described here, to the greatest extent possible, are those on which there is a significant degree of scientific consensus and which are published in independent, peer-reviewed publications. Where there is not this level of agreement on a benefit or a risk, the text and footnotes note the disagreement.

Somewhat unexpectedly, and perhaps somewhat reassuringly, reliance on independent, peer-reviewed publications leads to a relatively uniform reporting and analysis of the potential benefits and risks of genetically modified plants and animals, as discussed in Part III, *infra*.

33. See David Pinentel, *Economic and Environmental Impacts of Invasive Species and Their Management*, 21 PESTICIDES AND YOU 10, 10 (2001), available at <http://www.beyondpesticides.org/info/services/pesticidesandyou> (last visited Apr. 7, 2004) (“It is estimated that introduced insect pests cause nearly \$14 billion in U.S. crop losses each year.”); cf. NRC 2000 Report, *supra* note 4, at 19 (“An estimated \$7 billion in crop losses per year in the United States are caused by nematodes ... and even greater losses are caused by arthropod pests.”) (citation omitted).

protected" plants), improving both the yield and the quality of the crop.<sup>34</sup> Certain pest-protected corn, for instance, may increase yields from 1.8% to 8.1%.<sup>35</sup> Use of pest-protected plants also may lower production costs because growers will not have to pay for the pesticides themselves, or for their transportation, application, and disposal.<sup>36</sup>

Crops also are being genetically engineered to be tolerant of certain herbicides. Growers then can use specific herbicides on their crops without injuring the herbicide-tolerant crops themselves, thus increasing yields.<sup>37</sup> Such uses also may reduce costs. One study found that use of a particular herbicide-tolerant soybean resulted in a total production cost reduction of 6%.<sup>38</sup> Other crops have been modified to be disease-resistant and drought-resistant, with obvious benefits for agricultural yield and quality.<sup>39</sup> In addition, crops may be modified to enable them to grow in temperatures, soils, weather, and climates that would normally prohibit cultivation.<sup>40</sup>

Data from the 2001 growing season indicate that genetically modified crops in the United States increased yields by four billion pounds, and at the same time saved growers \$1.2 billion by lowering production costs, resulting in total net savings of \$1.5 billion.<sup>41</sup> Analyses of transgenic crops under development indicate that such varieties could increase crop yields by an additional ten

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34. NRC 2000 REPORT, *supra* note 4, at 46.

35. GERALD C. NELSON ET AL., THE ECONOMICS AND POLITICS OF GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE: IMPLICATIONS FOR WTO 2000, at 27 (1999).

36. See COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POLICY, CASE STUDY NO. II: BT-MAIZE 22-23 (2001) [hereinafter CASE STUDY NO. II: BT-MAIZE], available at [http://www.ostp.gov/html/ceq\\_ostp\\_study3.pdf](http://www.ostp.gov/html/ceq_ostp_study3.pdf) (last visited Apr. 7, 2004).

37. McGarity, *supra* note 8, at 412.

38. NELSON ET AL., *supra* note 35, at 18.

39. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4727 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

40. McGarity, *supra* note 8, at 413.

41. GIANESSI ET AL., *supra* note 20, at 40, 55. A separate, earlier National Research Council study found that increased yields were reported by many, but not all, growers. See NRC 2000 REPORT, *supra* note 4, at 33 (describing a reduced need for chemical pesticides and increased yields among many growers using transgenic pest-protected crops). Another report found that the first generation of transgenic corn and soybeans, if adopted globally, "would increase production by only an estimated [two] percent or less." HENRY A. WALLACE CTR. FOR AGRIC. & ENVTL. POLICY, WINROCK INT'L, TRANSGENIC CROPS: AN ENVIRONMENTAL ASSESSMENT 8 (2000), available at <http://www.winrock.org/general/Publications/transgenic.pdf> (last visited Apr. 7, 2004).



billion pounds per year and result in net economic savings of \$1 billion per year.<sup>42</sup> All told, the net value of the existing genetically modified crops and those in development was estimated to be \$2.5 billion, based on the increased value of the crops plus reductions in grower costs.<sup>43</sup>

Increased agricultural yields and lower grower costs should make food less expensive for consumers, in turn helping to reduce national and international hunger problems and save lives.<sup>44</sup> Though the 5% reductions in cost or increases in yield mentioned earlier may not sound significant, estimates are that even a limited worldwide adoption of genetically modified products that increase productivity by 5% would result in economic welfare gains of tens of billions of dollars.<sup>45</sup>

With the world's population growing exponentially, estimates show that agricultural production will need to be doubled over the next fifty years to keep pace with population growth.<sup>46</sup> Genetically engineered crops offer a way to accomplish a portion of this task. The National Academy of Sciences, in concert with six foreign academies of science, has urged the increased use and development of biotechnology crops to solve problems of hunger and poverty in developing nations.<sup>47</sup>

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42. GIANESSI ET AL., *supra* note 20, at 55.

43. *Id.*

44. Some critics contend that a greater supply of inexpensive food would do little to ease worldwide hunger, as the problem is one of inadequate resources for the delivery of food, not inadequate supply. *See, e.g.*, TEITEL & WILSON, *supra* note 12, at 116-17; Ellen Messer, *Food Systems and Dietary Perspective: Are Genetically Modified Organisms the Best Way To Ensure Nutritionally Adequate Food?*, 9 IND. J. GLOBAL LEGAL STUD. 65, 68 (2001) (arguing that the food crisis results from insufficient markets, not insufficient production). Many experts dispute the absolute nature of this claim, noting that though delivery problems may be important, additional supply will certainly aid in the hunger crisis. *See, e.g., id.* at 69-70. Similarly, creating crops that can grow in a wider variety of environments will make food more available in many regions of the world.

45. KYM ANDERSON ET AL., ESTIMATING THE ECONOMIC EFFECTS OF GMOS: THE IMPORTANCE OF POLICY CHOICES AND PREFERENCES 15 (CIES, Adelaide Univ., Policy Discussion Paper No. 35, 2000), available at <http://www.adelaide.edu.au/cies0035.pdf> (last visited Apr. 7, 2004).

46. Lakshman D. Guruswamy, *Sustainable Agriculture: Do GMOs Imperil Biosafety?*, 9 IND. J. GLOBAL LEGAL STUD. 461, 466 (2002).

47. Carol Kaesuk Yoon, *Call for Use of New Crops*, N.Y. TIMES, July 11, 2000, at C4. This report was issued in conjunction with the Royal Society of London, the Brazilian Academy of Sciences, the Chinese Academy of Sciences, the Indian National Academy of Sciences, the Mexican Academy of Sciences, and the Third World Academy of Sciences. *See* ROYAL SOC'Y

## 2. Human Health and Consumer Benefits

In addition to making food less expensive, genetic modification of crops also may allow for the growth of more nutritious food and the consumption of food that tastes better. More nutritious foods could include plant products that are modified to contain higher-than-natural levels of vitamins, minerals, desirable dietary fats, and antioxidants.<sup>48</sup> In one commonly cited example, Monsanto Corporation has agreed to make available, free or at cost, genetically modified rice (called "golden rice") that is rich in beta carotene, a precursor to vitamin A.<sup>49</sup> This may aid in reducing health problems associated with vitamin A deficiencies, which contribute to illness and death for approximately ten million people globally each year.<sup>50</sup>

Pest-resistant crops and crops that stay fresh longer will yield fruits and vegetables that are better looking and have less damage.<sup>51</sup> In addition, the use of pest-resistant crops will result in marketed fruits and vegetables containing less spray-pesticide

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OF LONDON ET AL., *TRANSGENIC PLANTS AND WORLD AGRICULTURE* (July 2000), available at <http://books.nap.edu/html/transgenic/pdf/transgenic.pdf> (last visited Apr. 7, 2004). The report called for regulatory systems to be established to monitor health risks from genetically modified plants and for research into environmental and food-safety risks. *Id.* at 2. Scientists critical of the report contend that the scientists supporting the report are those who have made their career in the area of genetically modified food, and may be influenced by a personal interest in funding. Yoon, *supra*; see also Christopher Marquis, *Monsanto Plans To Offer Rights to its Altered-Rice Technology*, N.Y. TIMES, Aug. 4, 2000, at A11.

48. NRC 2002 REPORT, *supra* note 2, at 222; TAYLOR & TICK, *supra* note 20, at 8; TEITEL & WILSON, *supra* note 12, at 131-32.

49. COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POLICY, CEQ AND OSTP ASSESSMENT: CASE STUDIES OF ENVIRONMENTAL REGULATIONS FOR BIOTECHNOLOGY 2 (2001) [hereinafter CEQ AND OSTP ASSESSMENT], available at [http://www.ostp.gov/html/ceq\\_ostp\\_study1.pdf](http://www.ostp.gov/html/ceq_ostp_study1.pdf) (last visited Apr. 7, 2004); see also Marquis, *supra* note 47, at A11; Messer, *supra* note 44, at 67. Golden rice represents a particular scientific advance. Most genetically modified products have involved the insertion of a single gene or multiple single genes. Golden rice introduces four stacked genes, ushering in the generation of more complex multigene transfers. *Id.* at 77.

50. NRC 2002 REPORT, *supra* note 2, at 226-27; see also CEQ AND OSTP ASSESSMENT, *supra* note 49, at 2. There is scientific controversy regarding whether the additional beta carotene will be successfully transformed by malnourished people into vitamin A. NRC 2002 REPORT, *supra* note 2, at 226-27; TEITEL & WILSON, *supra* note 12, at 134.

51. See NRC 2002 REPORT, *supra* note 2, at 222 (describing how transgenic plants may have an improved shelf life); McGarity, *supra* note 8, at 415 (describing how biotechnology could lead to better looking crops that retain freshness for longer periods of time).

residue.<sup>52</sup> Though not commercially successful yet, scientists also are trying to engineer crops to stay fresh and firm for longer periods of time and to improve their flavor.<sup>53</sup>

Genetic engineering may improve food safety along other lines. It may be used to reduce the allergenic risks associated with certain foods,<sup>54</sup> and may allow scientists to remove the genes that cause some toxins to form in certain plants.<sup>55</sup>

### 3. *Environmental and Ecological Benefits*

A potentially great advantage of transgenic crops is the many indirect benefits they may provide for the environment. As over half the land in the United States is used for crop and animal production,<sup>56</sup> environmental benefits from bioengineering will be widespread.

Many genetically modified crops have been modified to include a natural pesticide. Growth of these pest-protected plants should reduce or eliminate the need for pesticide spraying, reducing the amount of harmful pesticide residue left in the environment.<sup>57</sup> In addition, genetically modified pest-protected plants have specific insect targets, whereas traditional pesticides are broad-spectrum

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52. "In the United States, approximately thirty-five percent of all foods in supermarkets have detectable pesticide residues, and at least one to three percent of all foods have residues above the Food and Drug Administration's acceptable tolerance level." David Pimentel, *Overview of the Use of Genetically Modified Organisms and Pesticides in Agriculture*, 9 IND. J. GLOBAL LEGAL STUD. 51, 58 (2001).

53. TAYLOR & TICK, *supra* note 20, at 8; McGarity, *supra* note 8, at 414.

54. NRC 2000 REPORT, *supra* note 4, at 36; *see also* Andrew Pollack, *Gene Jugglers Take to Fields for Food Allergy Vanishing Act*, N.Y. TIMES, Oct. 15, 2002, at F2. Projects are underway to reduce the allergenicity of soybeans, wheat, rice, peanuts, ryegrass, and castor plants. *Id.*

55. *See* NRC 2002 Report, *supra* note 2, at 44 (describing how tumor-producing genes are removed from the vectors used to genetically engineer crop plants).

56. NRC 2002 REPORT, *supra* note 2, at 22; *see also* ROYAL SOC'Y OF CAN., *supra* note 5, at 130 (explaining that 70% of U.K. land and 11% of Canadian land are under some form of agriculture).

57. CASE STUDY NO. II: BT-MAIZE, *supra* note 36, at 22-23; *see also* NRC 2000 REPORT, *supra* note 4, at 6, 63. One early study found that 3.5% less active pesticide ingredients were used in 1998 compared with 1997, a decrease which corresponded with increased adoption of transgenic crops. L. L. Wolfenbarger & P. R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088, 2090-91 (2000). About 1% of the decline was attributed to the use of the transgenic crops, as opposed to other fluctuating factors such as pest problems, weather, and cropping patterns. *Id.*

chemical insecticides that kill many nontarget insects indiscriminately.<sup>58</sup>

To cite one example, many crops have been engineered to contain genes from the bacterium *Bacillus thuringiensis* (Bt). Bt naturally produces several proteins that are toxic to certain insects when ingested. Mixtures of various subspecies of Bt, created in order to affect as many insect species as possible, have been used conventionally to spray crops for over fifty years. When used as a spray, however, applications have to be made frequently, with concomitant residue left in the environment. In genetically modified Bt crops, production of the insecticide occurs continuously, eliminating the need for spraying.<sup>59</sup>

Data appear to show that benefits are accruing. Information from the 2001 growing season indicates that the use of genetically modified crops reduced pesticide use by forty-six million pounds.<sup>60</sup> The introduction of additional transgenic crops under development is estimated potentially to cut pesticide use by an additional 117 million pounds.<sup>61</sup> Many of the transgenic pest-protected plants were found to be effective at controlling pests, and a reduced need for chemical pesticide application and increased yields were reported by many, though not all, genetically modified crop growers.<sup>62</sup>

Herbicide-tolerant crops similarly may have environmental benefits. Use of these crops should allow farmers to stop using or reduce their use of preemergent herbicides and rely instead on postemergent ones. Preemergent herbicides are incorporated into the soil, requiring more tillage, which in turn leads to greater soil erosion, water loss, and reduction in soil organic matter.<sup>63</sup> All of these detrimental effects would be reduced by a shift to postemergent herbicides.

Lastly, the greatest threat to biodiversity today is likely habitat loss.<sup>64</sup> Bioengineering plants may reduce habitat loss through

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58. NRC 2000 REPORT, *supra* note 4, at 37.

59. *Id.* at 27-28.

60. GIANESSI ET AL., *supra* note 20, at 55.

61. *Id.*

62. NRC 2000 REPORT, *supra* note 4, at 33. One report found that insecticide sprays used on cotton in 1998 were reduced from an average of 8.3 applications for conventional cotton to an average of 6.0 applications for Bt cotton. *Id.* at 33-34, 114.

63. Wolfenbarger & Phifer, *supra* note 57, at 2091.

64. John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle To*

increased crop yields. As noted above, it is estimated that agricultural production will need to double over the next fifty years.<sup>65</sup> There are only two ways to achieve greater agricultural production: increasing yield efficiency or devoting more land to agriculture.<sup>66</sup> Doubling the amount of land currently devoted to agriculture would have devastating environmental and ecological effects—recall that one-half of the United States' land is already used for plant and animal production.<sup>67</sup> Achieving greater crop yield from existing agricultural lands, on the other hand, would decrease the pressure to develop currently undeveloped natural habitats, offering many ecological and environmental benefits.<sup>68</sup>

#### 4. Next-Generation Biotechnology Benefits

The potential benefits of future biotechnology advances are as varied as the products themselves. These advantages include widespread health, environmental, and economic benefits.

Numerous advances are occurring with transgenic plants. Researchers are genetically engineering plants to remove toxic heavy metals from contaminated waters and soils.<sup>69</sup> Scientists are genetically engineering trees to make them resistant to insects and herbicides, and to increase their rate of growth.<sup>70</sup> Other modifications may make the use of trees in the paper production process more efficient and reduce environmental pollution from paper production.<sup>71</sup>

Scientists are well advanced in genetically modifying plants to produce drugs, including antibodies, vaccines, pharmaceuticals, and human proteins.<sup>72</sup> Such an achievement will make drug production

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*Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207, 225 (2001); Wolfenbarger & Phifer, *supra* note 57, at 2091.

65. See *supra* text accompanying note 46.

66. Guruswamy, *supra* note 46, at 466.

67. See *supra* text accompanying note 56.

68. See Applegate, *supra* note 64, at 224-25; see also Wolfenbarger & Phifer, *supra* note 57.

69. NRC 2002 REPORT, *supra* note 2, at 229; see also Wolfenbarger & Phifer, *supra* note 57, at 2091 (describing how the use of transgenic crops may reduce the need to use toxic chemicals to protect crops).

70. NRC 2002 REPORT, *supra* note 2, at 222.

71. *Id.* at 223.

72. TEITEL & WILSON, *supra* note 12, at 130.

cheaper and could make drugs, particularly vaccines, far more available in developing countries.<sup>73</sup> An example of one such attempt is the modification of tobacco plants to produce a drug that will stimulate the production of platelets in bone marrow. This drug could be extracted from tobacco plants, purified, and used in treating human cancer patients who have received chemotherapy.<sup>74</sup> Other plant-produced pharmaceuticals currently in, or soon to be in, clinical trials include those to treat *E.coli*, non-Hodgkins lymphoma, cystic fibrosis, and herpes.<sup>75</sup> Though plant-produced pharmaceuticals are not yet commercialized in the United States, in Canada an anticoagulant agent is now being produced commercially in transgenic plants.<sup>76</sup> With the cost of health care ranking as one of the United States' greatest concerns, the inexpensive production of pharmaceuticals would be greatly beneficial.

Plants also are being genetically modified to grow industrial compounds, such as enzymes and other proteins, oils, waxes, and plastics.<sup>77</sup> Such advances not only may produce economic benefits, but also may provide substantial environmental benefits, for instance, by replacing conventional plastics with biodegradable polymers.<sup>78</sup> Plants genetically engineered to store more carbon could have a role in combating global warming.<sup>79</sup>

Though genetically modified animals and the products they produce have not yet been commercialized, many developments are underway and offer myriad benefits.<sup>80</sup> Bioengineered fish could

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73. See Pollack, *supra* note 22, at A26; see also TEITEL & WILSON, *supra* note 12, at 130-31. An experiment involving a potato genetically engineered to provide an oral vaccine was successful. TEITEL & WILSON, *supra* note 12, at 134-35; COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POLICY, CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN 49 (2001) [hereinafter CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN], available at [http://www.ostp.gov/html/ceq\\_ostf\\_study4.pdf](http://www.ostp.gov/html/ceq_ostf_study4.pdf) (last visited Apr. 7, 2004).

74. CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN, *supra* note 73, at 47.

75. BIOTECHNOLOGY INDUS. ORG., PLANT-MADE PHARMACEUTICALS: FREQUENTLY ASKED QUESTIONS, at <http://www.bio.org/pmp/factsheet2.asp> (last visited Apr. 7, 2004).

76. TAYLOR & TICK, *supra* note 20, at 20.

77. *Id.* at 21.

78. *Id.*

79. See *Can Ag Biotech Help Solve Energy and Global Warming Problems?*, AGBIOTECH BUZZ, vol. 3, no. 4, July 22, 2003, available at <http://pewagbiotech.org/buzz/display.php3?StoryID=107> (last visited Mar. 16, 2004) (arguing that genomics could help to advance the creation of carbon-neutral fuels such as ethanol).

80. The process of genetically modifying animals is significantly more complicated than genetic modification of plants, though the goal is the same: inserting foreign DNA into a host

decrease harvest pressure on wild fisheries, many of which currently are endangered or threatened.<sup>81</sup> One version of genetically modified salmon at an advanced stage of development is modified to use feed more efficiently and to grow rapidly. These traits will reduce the resources needed to grow salmon and reduce the amount of waste generated, consequently lowering the market cost of the salmon and reducing the harm to the environment per salmon raised.<sup>82</sup>

Farm animals such as poultry, swine, goats, cattle, and other livestock are being genetically modified to improve growth rate, feed efficiency, and disease resistance.<sup>83</sup> There may be other benefits as well. For instance, genetic engineering may allow for the removal of a gene associated with mad cow disease from cattle.<sup>84</sup> Genetic modification of livestock also may improve the nutritional composition for the animals' use as human food and reduce pressure on the development of agricultural land.<sup>85</sup> Food products produced by transgenic animals could include milk lacking the most common allergenic protein, eggs lower in cholesterol, and meat with greater vitamin content or modified fat content.<sup>86</sup>

Animals including poultry, swine, rabbit, goats, sheep, and cattle are being modified to produce pharmaceuticals or other products and to serve as potential sources for replacement organs or tissues for humans.<sup>87</sup> The production of human proteins in the milk of transgenic animals could provide an efficient method for producing such proteins and reduce the cost of pharmaceutical manufactur-

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organism. For a brief discussion of the methods used to genetically modify animals, see ANIMAL BIOTECHNOLOGY, *supra* note 27, at 35-49.

81. COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POLICY, CASE STUDY NO. I: GROWTH-ENHANCED SALMON 9 (2001) [hereinafter CASE STUDY NO. I: GROWTH-ENHANCED SALMON], available at [http://www.ostp.gov/html/ceq\\_ostp\\_study2.pdf](http://www.ostp.gov/html/ceq_ostp_study2.pdf) (last visited Apr. 7, 2004); see also Carl Safina, *The World's Imperiled Fish*, SCI. AM., Nov. 1995, at 46, 48-50 (describing the collapse of many fisheries worldwide as a result of industrial overfishing).

82. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 89-90; FUTURE FISH, *supra* note 25, at 10, 15-16; CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 9.

83. ROYAL SOC'Y OF CAN., *supra* note 5, at 90; see also ANIMAL BIOTECHNOLOGY, *supra* note 27, at 34 (describing how genetically engineered animals can be produced to have useful novel properties for increased protein, for biomedical purposes, and for human consumption).

84. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 37.

85. *Id.* at 16; ROYAL SOC'Y OF CAN., *supra* note 5, at 90.

86. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 67.

87. *Id.* at 16, 51; see also CASE STUDY NO. IV: FARM ANIMAL THAT PRODUCES HUMAN DRUGS, *supra* note 30, at 1.

ing.<sup>88</sup> Such production also may provide environmental benefits by reducing the amount of energy and other manufacturing inputs consumed during the production of protein.<sup>89</sup> The growth of organs in animals for human transplant could have substantial human health benefits due to the enormous shortage of human organs currently available for transplant.<sup>90</sup>

Transgenic insects are being developed as well. Insects domesticated for farming, such as the honeybee and silkworm, are being genetically engineered for disease resistance, and in the silkworm's case, to produce proteins other than silk.<sup>91</sup> Other insects are being modified for the production of certain proteins in insect larvae.<sup>92</sup> Insects also may be modified for improved use in programs to try to control other pest insects or invasive plant species.<sup>93</sup> There will likely be attempts to replace or infiltrate native populations of insects with ones that have been genetically modified to be less of a pest or unable to transmit pathogens.<sup>94</sup> For instance, research is ongoing to genetically modify mosquitos to make them malaria-resistant.<sup>95</sup>

In sum, biotechnology-derived products hold enormous promise for protecting human health and the environment, increasing agricultural production, improving nutrition, and providing economic benefits. In a world with resources constantly under

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88. CASE STUDY NO. IV: FARM ANIMAL THAT PRODUCES HUMAN DRUGS, *supra* note 30, at 1; see also ANIMAL BIOTECHNOLOGY, *supra* note 27, at 16-17, 51-52 (discussing the production of proteins in transgenic animal milk, eggs, or blood).

89. CASE STUDY NO. IV: FARM ANIMAL THAT PRODUCES HUMAN DRUGS, *supra* note 30, at 3.

90. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 17. Transgenic pigs may prove a useful source for organ transplants in humans. Currently, transplantation of pig organs in humans is not possible in part because humans have a dramatic immune response to a carbohydrate on the surface of pig cells. Inactivation of this enzyme in pigs through genetic modification could solve this problem. *Id.* at 37.

91. *Id.* at 21; THE PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, BUGS IN THE SYSTEM?: ISSUES IN THE SCIENCE AND REGULATION OF GENETICALLY MODIFIED INSECTS (2004) [hereinafter BUGS IN THE SYSTEM], available at <http://pewagbiotech.org/research/bugs/bugs.pdf> (last visited Apr. 7, 2004).

92. See ANIMAL BIOTECHNOLOGY, *supra* note 27, at 21 (describing how private companies already have begun to farm recombinant proteins from insect larvae).

93. *Id.*; BUGS IN THE SYSTEM, *supra* note 91.

94. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 21, 81.

95. BUGS IN THE SYSTEM, *supra* note 91.



greater and greater pressure, these potential advantages are far too great to be ignored.

### *B. Potential Risks of Genetic Engineering*

Despite the many potential benefits of genetic engineering outlined in the preceding section, biotechnology does not come without attendant potential risks. The risks from genetically modified food generally can be divided into two categories: human health impacts and environmental or ecological concerns.<sup>96</sup> The risks within each of these categories are discussed below, followed by a section describing the potential new risks and concerns raised by anticipated biotechnological advances.

#### *1. Human Health Impacts*

At the outset, it is important to note that there is no confirmed case of human disease or illness caused by genetically modified food.<sup>97</sup> There are still several concerns about impacts related to genetically modified food. From the human health perspective, the main concerns are believed to be allergenicity and toxicity.<sup>98</sup>

Genes inserted into plants express proteins, and certain proteins cause allergic reactions in some people.<sup>99</sup> Allergic reactions can

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96. A third category of issues raised by genetically modified products involves social and ethical concerns that do not have human health or environmental consequences. These types of concerns present normative issues, as opposed to scientific or objectively demonstrable risks, and thus are outside the scope of this Article. Examples of such concerns include potential industrialization or monopolization of agricultural business, whether the insertion of certain genes violates religious or dietary restrictions, whether genetic engineering in the first instance violates ethical norms, and whether genetically modified products should be so labeled. On the last concern, note that the USDA's new National Organic Program food labeling requirements may create an implicit "non-genetically modified" label because products labeled "organic" cannot contain products produced through rDNA technology. See National Organic Program, 7 C.F.R. § 205 (2003) (stating the requirements for organic labeling).

97. See NRC 2000 REPORT, *supra* note 4, at 6-8 (discussing the potential human health impacts and research needs related to genetically modified food).

98. *Id.* at 7.

99. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592); TEITEL & WILSON, *supra* note 12, at 49. Approximately 5% to 8% of children and 2% of adults in the United States suffer from food allergies. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 68; Pollack, *supra* note

range from relatively minor symptoms to serious harm, including anaphylactic shock and death.<sup>100</sup> The amount of allergen exposure necessary to cause a reaction, even a severe one, can be remarkably small.<sup>101</sup>

Because allergenic proteins can be transferred by genetic modification from one organism to another,<sup>102</sup> the introduction of novel genetic material creates the possibility of introducing an allergen into a genetically engineered product.<sup>103</sup> This introduction has occurred in at least one instance: a genetically modified soybean expressed a protein from its donor organism (a brazil nut) that was a known allergen.<sup>104</sup> Similarly, new allergens could arise in the pollen of genetically modified plants.<sup>105</sup>

As some of the genetic material transferred to create genetically modified foods has never before been in the human diet, it is impossible to know how humans will react.<sup>106</sup> The National Research Council has concluded that allergenicity is one of the most

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54, at F2. Proteins found in cow's milk, soy, egg, wheat, and peanuts commonly induce allergic responses in children; common adult allergens include fish, shellfish, tree nuts, corn, and tomatoes. Oscar L. Frick, *The Potential for Allergenicity in Transgenic Foods*, in GENETICALLY MODIFIED FOODS: SAFETY ISSUES 104 (Karl-Heinz Eagle et al., eds., 1995).

100. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4728; see also ROYAL SOC'Y OF CAN., *supra* note 5, at 53-54 (describing the human body's response to food allergies).

101. ROYAL SOC'Y OF CAN., *supra* note 5, at 56-57 (one seventy-thousandth of a peanut can cause a minor allergic reaction); TEITEL & WILSON, *supra* note 12, at 49.

102. ROYAL SOC'Y OF CAN., *supra* note 5, at 55.

103. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4709.

104. NRC 2000 REPORT, *supra* note 4, at 66; ROYAL SOC'Y OF CAN., *supra* note 5, at 55. This soybean was not commercialized. NRC 2000 REPORT, *supra* note 4, at 66; ROYAL SOC'Y OF CAN., *supra* note 5, at 55. Although animal tests for allergenicity of the modified soybean were negative, researchers found that humans allergic to brazil nuts also would be allergic to the genetically modified soybean. ROYAL SOC'Y OF CAN., *supra* note 5, at 55. Tests for allergenicity are not part of the standard testing of genetically modified products. Sheldon Krinsky, *Risk Assessment and Regulation of Bioengineered Food Products*, 2 INT'L J. BIOTECH. 231, 236 (2000).

105. NRC 2000 REPORT, *supra* note 4, at 62-63.

106. *Id.* Indirect assessments—based on the source of the donor gene, comparison of the donor protein with known allergens, immunologic analysis, and other factors—may be used to provide insight into the potential for allergenicity to transgenic proteins new to the human diet, but such assessments are not determinative. ROYAL SOC'Y OF CAN., *supra* note 5, at 60-61. The risk of allergenicity is particularly difficult to test, in part because prior exposure is a prerequisite to an allergic reaction. NRC 2000 REPORT, *supra* note 4, at 66. The National Research Council has recommended that priority be given to developing "improved methods for identifying potential allergens in pest-protected plants." *Id.* at 7.

difficult aspects in assessing the safety of transgenic products and that the existing methods for identifying potential food allergens are deficient.<sup>107</sup> Further, even for proteins already in the human diet, people who know they are allergic to certain foods may no longer be able to avoid them because they will not know which transgenic foods contain proteins that have been transferred.<sup>108</sup>

A second direct risk of human consumption of genetically modified food is the possible introduction of new toxins, or increases in the amounts of naturally occurring toxins.<sup>109</sup> For instance, certain conventionally bred crops have produced hybrids with toxins not present in either parental line.<sup>110</sup> Genetically modified foods also could contain less nutrients than their conventional counterparts.<sup>111</sup>

There is a potential risk of other types of health effects from the consumption of genetically modified plants. One controversial study found that rats fed genetically engineered potatoes had weakened immune systems and changes in the development of multiple organs.<sup>112</sup> The EPA has conducted fairly extensive short-term testing with respect to pest-protected plants, and it has found no adverse impact.<sup>113</sup> Some scientists still have concerns, however, and the National Research Council has determined that the EPA does not yet have enough data in this regard.<sup>114</sup>

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107. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 68; NRC 2000 REPORT, *supra* note 4, at 140.

108. Sophia Kolehmainen, *Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 VA. ENVTL. L.J. 267, 278 (2001); McGarity, *supra* note 8, at 419. Relatedly, it may be hard to determine what is triggering the allergic reaction if the genetic material causing it is present in a number of different foods. ROYAL SOC'Y OF CAN., *supra* note 5, at 56.

109. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4728 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592); NRC 2000 REPORT, *supra* note 4, at 61-62, 70-71; ROYAL SOC'Y OF CAN., *supra* note 5, at 46.

110. NRC 2000 REPORT, *supra* note 4, at 70; ROYAL SOC'Y OF CAN., *supra* note 5, at 16.

111. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4728. One study found that certain genetically modified soybeans contained less nutrients associated with protection against heart disease, osteoporosis, and breast cancer than their conventional counterparts; other studies have not confirmed these results. TEITEL & WILSON, *supra* note 12, at 12, 50-51.

112. TEITEL & WILSON, *supra* note 12, at 55. The commission that initially sponsored this study fired the scientist who conducted it and stated that the research was deficient; a later panel of independent scientists, however, confirmed the original findings. *Id.*

113. NRC 2000 REPORT, *supra* note 4, at 65-66.

114. McGarity, *supra* note 8, at 417-18.

The risks identified in the preceding paragraphs are all direct human health risks. There are also indirect risks. In order to determine whether genetically modified cells have successfully incorporated the desired donor gene, scientists often attach an additional DNA fragment to the donor gene before it is inserted into the target host cell. This additional fragment contains a gene that will render the host cell resistant to a particular antibiotic. The potential transgenic cells are then exposed to this antibiotic, and those that have not successfully incorporated the donor gene will die off, leaving only genetically modified cells.<sup>115</sup> The surviving, modified cells are grown into modified plants, which still will contain the antibiotic-resistant trait. There is a concern that this antibiotic-resistant gene could be transferred to other organisms, or carried up the food chain into animals or people who eat the plant product.<sup>116</sup> The result could be a strain of bacteria that is resistant to one or more antibiotics.<sup>117</sup> This is of particular concern because of the general growing problem of bacterial resistance to antibiotics.<sup>118</sup> Both the Canadian Royal Society and the British Medical Association have recommended the cessation of the use of antibiotic marker genes in genetically modified food.<sup>119</sup>

Finally, the last risk is one that transcends categorization: genetic modification of food has the potential for unintended genetic consequences. This can occur for two primary reasons. First, gene insertion into host cells is an inexact process. Scientists cannot yet determine or predict the position of the inserted genetic matter in the host gene, and it varies from one insertion to the next. As a result, identical genetic modifications can affect cellular function in different ways.<sup>120</sup> Second, one cannot know what pleiotropic<sup>121</sup> or

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115. TEITEL & WILSON, *supra* note 12, at 8-9.

116. NRC 2000 REPORT, *supra* note 4, at 63; TEITEL & WILSON, *supra* note 12, at 39; Julie Teel, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. ENVTL. L.J. 649, 659 (2000).

117. McGarity, *supra* note 8, at 403, 423.

118. Kolehmainen, *supra* note 108, at 277. Though antibiotic resistance is a general concern in society, the risk of antibiotic resistance arising out of genetically modified foods is likely far lower than the risks posed by the large uses of antibiotics to prevent disease in livestock and human medicine. ROYAL SOC'Y OF CAN., *supra* note 5, at 49.

119. ROYAL SOC'Y OF CAN., *supra* note 5, at 49; McGarity, *supra* note 8, at 403, 424.

120. Krinsky, *supra* note 104, at 233; *see also* NRC 2000 REPORT, *supra* note 4, at 61, 66.

121. "Pleiotropic" effects are unintended genetic changes that result from the inserted genetic material having an effect beyond that intended on traits of the host organism.

synergistic effects may be caused by combining genes.<sup>122</sup> For instance, there are many examples of conventional breeding projects that have resulted in hybrid offspring with traits that were unexpected based on knowledge of the parents' genes.<sup>123</sup>

In sum, genetic engineering of crops raises several direct and indirect potential human health concerns.

## *2. Environmental and Ecological Concerns*

Genetically modified plants may impact the environment negatively through several mechanisms.<sup>124</sup> First, newly introduced genetic material may move into environments or organisms beyond those intended. This gene flow could occur through the dispersal of genetically modified seeds; through the dispersal of the pollen of a genetically modified plant by wind, animals, bees, or insects; or through the nonsexual transfer of genetic material from one organism to another, for instance, by virus or bacteria ("horizontal transfer").<sup>125</sup> The risk of gene flow is considered a "major environmental concern."<sup>126</sup> According to the National Research Council, "the introduction of any type of biological novelty can have unintended and unpredicted effects on the recipient community and

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122. Krinsky, *supra* note 104, at 233, 235; *see also* NRC 2000 REPORT, *supra* note 4, at 61, 66; TEITEL & WILSON, *supra* note 12, at 12. Examples of the imprecision in genetic engineering to date include: (1) genes for the color red placed into petunias not only changed the petunias' color, but also decreased their fertility and altered their growth, and (2) salmon genetically engineered with a growth hormone gene not only grew too big too fast, but also turned green. TEITEL & WILSON, *supra* note 12, at 12.

123. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4710 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592); NRC 2002 REPORT, *supra* note 2, at 43. In one example, a cross between two potato species created a hybrid offspring that produced a novel steroidal alkaloid not produced by either parent. NRC 2002 REPORT, *supra* note 2, at 43.

124. Agriculture was not benign with respect to the environment prior to the advent of transgenic crops. Examples of substantial environmental impacts from conventional agriculture include the destruction of forests and natural habitats, contamination from pesticide and herbicide residues, and the loss of biodiversity. *See* Guruswamy, *supra* note 46, at 474.

125. NRC 2002 REPORT, *supra* note 2, at 66-67; NRC 2000 REPORT, *supra* note 4, at 80; TEITEL & WILSON, *supra* note 12, at 38-39. Organic farmers particularly are concerned about gene flow because the movement of genes from genetically modified plants into organic crops could render such crops nonorganic. NRC 2000 REPORT, *supra* note 4, at 90.

126. ROYAL SOC'Y OF CAN., *supra* note 5, at 124.

ecosystem.<sup>127</sup> The environmental risk from gene flow will increase as the quantity and variety of genetically modified plants expand.<sup>128</sup>

If, for instance, herbicide-tolerant genes spread from engineered crops to a weedy relative, "superweeds" not susceptible to herbicides may be created.<sup>129</sup> Long-distance pollen flow, and therefore long-distance gene flow, is poorly understood, but transgenic pollen has dispersed at least three or four kilometers from its source.<sup>130</sup> The National Research Council noted that "the potential for enhanced weediness is the major environmental risk perceived for introductions of genetically modified plants,"<sup>131</sup> and has called for more research in this area.<sup>132</sup> Relatedly, species that are not currently considered weeds could become more difficult to control if they acquire certain transgenic traits.<sup>133</sup>

The risk of gene flow is not merely theoretical. In Britain, an experimental field of transgenic herbicide-tolerant plants were found to have pollinated nearby conventional plants.<sup>134</sup> In Canada, a variety of canola found growing as a weed was discovered to have acquired resistance to three different herbicides through gene flow.<sup>135</sup> Similarly, conventional crop genes are known to have spread to wild populations, sometimes creating more robust and abundant weeds,<sup>136</sup> and some experiments have indicated that genetically engineered plants may be more likely to cross-pollinate than their conventionally bred counterparts.<sup>137</sup> Such a risk was

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127. NRC 2002 REPORT, *supra* note 2, at 29.

128. Proposed Field Test Requirements, *supra* note 21, 67 Fed. Reg. at 50,578.

129. See NRC 2002 REPORT, *supra* note 2, at 67.

130. ANDERSON, *supra* note 24, at 49; NRC 2000 REPORT, *supra* note 4, at 91. Most pollen is dispersed only a short distance from the plant. ROYAL SOC'Y OF CAN., *supra* note 5, at 124.

131. NAT'L RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 3 (1989).

132. NRC 2000 REPORT, *supra* note 4, at 141.

133. *Id.* at 81.

134. John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 817-18 (2001).

135. THE PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, HAVE TRANSGENES WILL TRAVEL: ISSUES RAISED BY GENE FLOW FROM GENETICALLY ENGINEERED CROPS (2003).

136. NRC 2002 REPORT, *supra* note 2, at 67; see also NRC 2000 REPORT, *supra* note 4, at 84.

137. Kolehmainen, *supra* note 108, at 276 (discussing these experiments with genetically engineered mustard plants).

determined to exist for a genetically modified virus-resistant squash approved by the USDA.<sup>138</sup>

A derivative risk of gene flow is the potential extinction of wild species through hybridization.<sup>139</sup> If genes from transgenic crops find their way into wild plant species through asexual transfer or interbreeding, and the wild transgenic plants then interbreed with unmodified plants, the result could be extinction of the unmodified wild species.

A second route of environmental impact from genetically engineered plants is through the spread of nonindigenous transgenic species into natural habitats, which also could cause the extinction of a wild species or other disruption of ecosystems.<sup>140</sup> The introduction of invasive species poses a serious threat to biodiversity.<sup>141</sup> Invasive species cost the United States an estimated \$137 billion annually,<sup>142</sup> and are second only to habitat destruction in threatening the extinction of native species.<sup>143</sup> It is anticipated that additional risks may arise as the frequency and scale of the introduction of transgenic species increase.<sup>144</sup>

Genetically modified herbicide-tolerant canola plants, for example, are beginning to develop into a major weed problem in

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138. NRC 2002 REPORT, *supra* note 2, at 130-35.

139. *Id.* at 67-68, 134-35. Extinction through hybridization has been implicated in the disappearance of wild coconuts and the contamination of California's wild walnut populations with genes from cultivated species. *Id.* at 68.

140. *Id.* at 68-70; Wolfenbarger & Phifer, *supra* note 57, at 2088.

141. Press Release, USDA, President Clinton Expands Federal Effort To Combat Invasive Species (Feb. 3, 1999) [hereinafter USDA Press Release], available at <http://www.usda.gov/news/releases/1999/02/0043> (last visited Apr. 7, 2004); see also Wolfenbarger & Phifer, *supra* note 57, at 2088 ("[I]nvasive species have been categorized as one of the three most pressing environmental problems, in addition to global climate change and habitat loss.").

142. Wolfenbarger & Phifer, *supra* note 57, at 2088 (explaining that these expenses result from "direct and indirect effects, and control or preventive measures" of invasive species).

143. See USDA Press Release, *supra* note 141 (stating that "the spread of exotic species constitutes one of the most serious, yet least appreciated, threats to biodiversity"). The factors that cause one nonindigenous species to be harmless or beneficial, but another one to become problematically invasive are not well known. NRC 2002 REPORT, *supra* note 2, at 207; see also Wolfenbarger & Phifer, *supra* note 57, at 2088-89. The majority of introduced species do not become established long term. About "10% of intentionally introduced species persist after introduction," and of these "roughly 10% become an obvious problem." NRC 2002 REPORT, *supra* note 2, at 32. Approximately one percent of introductions, thus, become problematic. "The small fraction ... that do cause environmental effects can be tremendously disruptive ...." *Id.*

144. Wolfenbarger & Phifer, *supra* note 57, at 2090.

some parts of Canada.<sup>145</sup> Further, some of these weed-plants have been found to have acquired multiple herbicide-tolerant transgenes from different genetically engineered plants.<sup>146</sup>

Relatedly, there is concern that widespread success of genetically modified plants will lead to greater uniformity, and conversely less biodiversity, in the farm crop. This in turn will make the country more susceptible to widespread crop failures and other crop disturbances.<sup>147</sup>

The third mechanism of environmental impact is hazards to nontarget species. For example, pest-protected plants may be toxic to insects and animals other than those targeted by the introduced pesticide.<sup>148</sup> One of the benefits of transgenic crops identified earlier is the reduction of pesticide residue in the environment.<sup>149</sup> The converse of this benefit is that rather than having the pesticide applied at limited intervals, it is now contained in the modified plant throughout the entire growing season. This may make the pesticide more persistent in the environment, particularly in soils, than sprayed pesticides that decay rapidly and are only used at times or during years when certain insects are particularly problematic.<sup>150</sup> Greater exposure to a pesticide

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145. ROYAL SOC'Y OF CAN., *supra* note 5, at 122.

146. *Id.* Overall, the likelihood of genetically modified crops becoming serious invasive problems may be remote because most major crop species are artificially selected over time for traits that have low survival value in natural conditions. *Id.* at 121. Crop plants, thus, rarely disturb natural plant communities. *Id.*

147. Holly Saigo, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 GEO. INT'L ENVTL. L. REV. 779, 793-96 (2000). The most familiar example of widespread crop failure is the Irish Potato Famine of 1845. One million people (12% of the population) died of starvation as a result of a potato blight that destroyed the genetically uniform (monoculture) Irish potato crop. *Id.* at 795-96; TEITEL & WILSON, *supra* note 12, at 17, 97-98. The risk of monoculture is demonstrated by the fact that the same potato blight also struck in the Andes, but only affected a few of the forty-six varieties of potato grown there, and thus was not as destructive. ANDERSON, *supra* note 24, at 53. Instances of modern impacts from genetic uniformity exist in the United States. In 1970, there was widespread failure of the American corn crop due to Southern Corn Leaf Blight, which affected multiple varieties of corn with an identical gene. Saigo, *supra*, at 796; *see also* TEITEL & WILSON, *supra* note 12, at 98-99.

148. CASE STUDY NO. II: BT-MAIZE, *supra* note 36, at 25. There is some evidence of impacts on lacewings and Monarch butterflies. *See* NRC 2002 REPORT, *supra* note 2, at 70-71 (discussing lacewings); *see also infra* Part III.C (discussing Monarch butterflies).

149. *See supra* Part II.A.3.

150. *See* NRC 2002 REPORT, *supra* note 2, at 71; NRC 2000 REPORT, *supra* note 4, at 101; TEITEL & WILSON, *supra* note 12, at 54; Wolfenbarger & Phifer, *supra* note 57, at 2089. This



increases the probability that pests will evolve to overcome the protection mechanism, rendering the pesticide useless.<sup>151</sup> On the other hand, this impact may be lower than the impacts of traditional insecticides because traditional insecticides are broad spectrum, and therefore the transgenic pest-protected plants could lead to greater biodiversity in agricultural ecosystems where they replace certain traditional insecticides.<sup>152</sup>

Use of herbicide-tolerant crops also could have negative environmental consequences, as growers may increase herbicide applications because the crops are not affected by the herbicide.<sup>153</sup> Not only would this increase contamination, but also increased applications appear to be leading to the development of herbicide-tolerant weeds, thus requiring application of more herbicides.<sup>154</sup> It is estimated that extra herbicide use may increase weed control costs as much as one hundred percent in some cases.<sup>155</sup> In addition to leaving greater herbicide residue in the environment, more effective control of weeds also could lead to reduced biodiversity and to lower food availability for seed-specializing animals, particularly certain birds.<sup>156</sup>

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route of pesticide exposure in the soil is new, and the effects on microorganisms are unknown. ROYAL SOC'Y OF CAN., *supra* note 5, at 110.

151. NRC 2000 REPORT, *supra* note 4, at 19, 28; ROYAL SOC'Y OF CAN., *supra* note 5, at 139; TEITEL & WILSON, *supra* note 12, at 27-28. Instances of pest adaptation to conventional Bt products have been documented, and insect resistance to Bt crops is considered inevitable. NRC 2002 REPORT, *supra* note 2, at 76; NRC 2000 REPORT, *supra* note 4, at 35. This is particularly problematic for organic farmers, as Bt pesticides represent one of the few effective organic means to control pests. NRC 2000 REPORT, *supra* note 4, at 101; ROYAL SOC'Y OF CAN., *supra* note 5, at 139. The EPA is attempting to inhibit the development of pest resistance to Bt pesticides through the use of refuge zones—plantings of non-Bt crops that are not sprayed with conventional Bt. Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297, 327 (2002). The integrity of this program and its likelihood of success are questionable. *See id.* at 327-47 (discussing numerous problems with the EPA's refuge plan); *see also* GREGORY JAFFE, PLANTING TROUBLE: ARE FARMERS SQUANDERING BT CORN TECHNOLOGY? 5 (2003), available at [http://www.cspinet.org/new/pdf/bt\\_corn\\_report.pdf](http://www.cspinet.org/new/pdf/bt_corn_report.pdf) (last visited Apr. 7, 2004) (reporting that 19% of growers do not comply with the EPA's refuge requirements and 13% of growers do not plant refuges at all).

152. NRC 2000 REPORT, *supra* note 4, at 9, 80.

153. Pimentel, *supra* note 52, at 57, 63.

154. *See* Andrew Pollack, *Widely Used Crop Herbicide Is Losing Weed Resistance*, N.Y. TIMES, Jan. 14, 2003, at C1.

155. Pimentel, *supra* note 52, at 63.

156. NRC 2002 REPORT, *supra* note 2, at 76; *see also* ANDERSON, *supra* note 24, at 27;

Overall, genetically modified products raise substantial environmental and ecological concerns due to potential gene flow, through the introduction of nonindigenous species, and from hazards to nontarget species.

### 3. Next-Generation Biotechnology Concerns

Not surprisingly, the future advances in biotechnology that promise spectacular benefits also bring additional potential risks. The National Research Council has determined that the environmental risks of future transgenic plant varieties and their novel traits cannot be predicted, and are of a "wholly different order" than those posed by currently commercialized transgenic crops.<sup>157</sup> The introduction of transgenic plants tolerant to extreme temperatures, soil conditions, or climates, for example, could have impacts on other plant communities.<sup>158</sup>

The growth of pharmaceuticals or industrial compounds in plants raises fresh concerns beyond those discussed with respect to genetically modified crop plants, including enhanced concerns about the need for confinement and protection of the food supply.<sup>159</sup> Pharmaceutical-producing or industrial compound-producing plants could get into the general food supply through multiple routes: the crops or seeds could be misrouted during processing, pollen from a transgenic crop could fertilize a nearby food crop, insects could eat the modified plants, or the drug or compound could leak from the roots into the soil.<sup>160</sup> Additional risks include a pharmaceutical

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Wolfenbarger & Phifer, *supra* note 57, at 2089.

157. NRC 2002 REPORT, *supra* note 2, at 229-30, 246.

158. *Id.* at 230-31.

159. No products from pharmaceutical plants have yet completed the regulatory process in the United States. CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN, *supra* note 73, at 47. Some conventional plants have pharmaceutical properties, but the anticipated level of expression and concentration of the pharmaceutical in, as well as the wide-spread production and planting of, genetically modified plants raises new levels of concern. *Id.*

160. NRC 2002 REPORT, *supra* note 2, at 66-67; *see also* CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN, *supra* note 73, at 47-49; Pollack, *supra* note 22. One advantage of using tobacco plants to grow pharmaceuticals is that few organisms feed on them, likely because of the production of nicotine. *Id.* at 52. In particular, no mammals or birds feed on tobacco plants, earthworm populations are low in tobacco fields, and the tobacco plants are deflowered or harvested before flowering so bees and other pollinators should not visit the plants and should not be affected. *Id.*

itself being contaminated by pesticides or chemicals naturally occurring in plants (such as nicotine impacting pharmaceuticals grown in tobacco plants), or allergic reactions being caused by the transfer of proteins from the plants into pharmaceuticals.<sup>161</sup> As the National Research Council has concluded, the "production of nonedible and potentially harmful compounds in crops ... that have traditionally been used for food creates serious regulatory issues."<sup>162</sup>

The development of genetically modified animals raises multiple new risks, the greatest of which is the potential impact on the environment from the escape or release of transgenic animals.<sup>163</sup> Escapes of transgenic fish and shellfish are considered inevitable, and could overwhelm and potentially cause the extinction of wild species through two routes.<sup>164</sup> First, escaped transgenic fish could out-compete wild fish for resources such as food, space, and mates, particularly if the transgenic fish have been modified to improve fitness, adaptability, or survival traits.<sup>165</sup> Escaped farmed fish, for example, have destroyed egg nests constructed by their wild counterparts.<sup>166</sup> Second, escaped transgenic fish may threaten wild fish populations through hybridization. Escapes of nontransgenic farmed fish have been known to spawn successfully with wild relatives,<sup>167</sup> and studies have shown that populations of wild fish can "be wiped out by mating with certain kinds of genetically engineered fish."<sup>168</sup> There is also the previously discussed risk of

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161. Pollack, *supra* note 22.

162. NRC 2002 REPORT, *supra* note 2, at 229.

163. As this Article goes to press, the National Research Council is releasing a new report on biological techniques to prevent genetically modified organisms from escaping into natural ecosystems and breeding or competing with their wild relatives, or passing engineered traits on to other species. NAT'L RESEARCH COUNCIL, BIOLOGICAL CONFINEMENT OF GENETICALLY ENGINEERED ORGANISMS (2004).

164. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 30, 90-92; CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 6.

165. ROYAL SOC'Y OF CAN., *supra* note 5, at 154-56; *see also* ANIMAL BIOTECHNOLOGY, *supra* note 27, at 76-78.

166. ROYAL SOC'Y OF CAN., *supra* note 5, at 156.

167. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 5; ROYAL SOC'Y OF CAN., *supra* note 5, at 156.

168. Carol K. Yoon, *Altered Salmon Leading Way to Dinner Plates, but Rules Lag*, N.Y. TIMES, May 1, 2000, at A1; *see also* CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 6-7.

unpredictable environmental disruptions that can arise whenever nonindigenous species invade an ecosystem.<sup>169</sup>

Escapes of transgenic insects are almost inevitable. Insects used for biocontrol would be intentionally released into the environment to control insect pests or invasive plants. This raises concerns regarding the transfer of introduced genes to wild populations of the same or other insects, extinction or other impacts on native species, and disruption of ecosystems.<sup>170</sup> Escapes of genetically engineered farm animals could present similar concerns to those posed by fish and insects, but the likelihood of escape is considerably lower.<sup>171</sup>

Bioengineered farm animals create other novel hazards. Transplantation of animal organs into humans may allow for the transmission of infectious disease and the creation of new disease agents.<sup>172</sup> A pathogenic virus could be created in the transgenic animal from the combination of genetic material used to insert the transgene and nonpathogenic viruses already present in the host animal.<sup>173</sup> The development of disease-resistant animals could create future difficulties in disease control and transmission of disease to other species, including humans.<sup>174</sup>

Transgenic animals also cause concerns for the human food supply. As with plants, genetically modifying animals will result in the expression of new proteins, raising the risk of an allergic response by certain consumers or the creation of toxins in the animal meat.<sup>175</sup> Some scientists are concerned that genetically engineered fish may bioaccumulate higher levels of toxins in their

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169. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 6-7, 24. Transgenic animals in particular may have unexpected ecological impacts associated with their fitness, interaction with other animals, roles in ecosystem processes, or potential for dispersal and persistence. *Id.* at 22; *see also* ANIMAL BIOTECHNOLOGY, *supra* note 27, at 78.

170. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 21, 88; BUGS IN THE SYSTEM, *supra* note 91.

171. CASE STUDY NO. IV: FARM ANIMAL THAT PRODUCES HUMAN DRUGS, *supra* note 30, at 8.

172. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 56-60.

173. *Id.* at 52.

174. ROYAL SOC'Y OF CAN., *supra* note 5, at 93; *see also* ANIMAL BIOTECHNOLOGY, *supra* note 27, at 47.

175. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 68-69, 71.

tissues than conventional fish, posing a health concern for humans or animals that eat the fish.<sup>176</sup>

Animals genetically engineered for nonfood products present additional hazards.<sup>177</sup> For instance, animals modified to produce proteins or other products will not be intended for human consumption, and adequate control measures will need to be established to ensure that they do not end up in the food supply.<sup>178</sup>

Genetically engineering animals raises some concerns for the animals themselves. For instance, pleiotropic effects (such as changes in anatomy, behavior, and enzyme and hormonal activity), are quite common in genetically engineered fish, and have been observed in modified farm animals as well. These effects can lead to physical or psychological suffering for the animal.<sup>179</sup>

Next-generation biotechnology poses risks of both a different magnitude and a different kind than existing genetically modified food crops.

To summarize, genetic engineering holds the prospect of spectacular health, environmental, and economic benefits for society, but these benefits do not come risk-free. In order to maximize the social benefit from biotechnology, it is necessary to establish a comprehensive, efficient, scientifically rigorous regulatory system to ensure adequate protection of human health and the environment. To determine how to institute such a system, it is useful first to examine several situations in which the regulation of biotechnology products has proven deficient.

### III. GENETICALLY MODIFIED PRODUCT CASE STUDIES

Over the past several years, a number of incidents involving genetically modified products have occurred that highlight the need for proper regulation. First, proper regulation is necessary to limit the potential risks to human health and the environment resulting

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176. FUTURE FISH, *supra* note 25, at 31. There is a concern that genetically modified fish could produce novel toxins, but some scientists argue that this is unlikely. *Id.*

177. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 65.

178. *Id.* at 54, 65-67. For animals modified to produce proteins in milk or eggs, "[h]alf of the genetically engineered population will be male, and will not be directly useful in production," and producers therefore will seek other manners of use. *Id.* at 66.

179. ROYAL SOC'Y OF CAN., *supra* note 5, at 87, 91-92; see also ANIMAL BIOTECHNOLOGY, *supra* note 27, at 43-44, 98.

from the development and commercialization of genetically modified products. Second, the widespread media and popular attention paid to these incidents can cause or increase public distrust concerning genetically modified products, which in turn may limit society's ability to reap the full benefits of this still-nascent technology.<sup>180</sup>

### A. *StarLink* Corn

Probably the best known genetically modified food scare was the discovery of *StarLink* corn, a genetically engineered strain of corn not approved for human consumption, in human food in the fall of 2000.<sup>181</sup> *StarLink* corn was not approved for human consumption because it carried transgenic genes that expressed a protein containing some attributes of known human allergens.<sup>182</sup> Because these proteins were never a part of the human diet before, it was unknown whether they would cause severe and potentially life-threatening allergic reactions in some humans.<sup>183</sup>

In 1998 the EPA approved Aventis CropScience's registration of *StarLink* corn for commercial use as animal feed,<sup>184</sup> and for nonfood industrial uses, such as in ethanol production.<sup>185</sup> Aventis CropScience requested approval for use in human food, and resubmitted such a request to the EPA in 1999. A series of tests by the EPA found that it was not possible to determine whether *StarLink* might trigger food allergies. As a result, the EPA did not approve *StarLink* corn for human consumption.<sup>186</sup> An independent

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180. Gregory N. Mandel, *Building Confidence Through Teamwork on Regulatory Proposals: The Genetically Modified Product Model*, 44 JURIMETRICS J. 41, 50-54 (2003).

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

182. *Id.* at 834.

183. See Barnaby J. Feder, *Companies Act To Keep Bioengineered Corn Out of Food*, N.Y. TIMES, Sept. 27, 2000, at C2. Since Cry9C, the bacterial protein found in the *StarLink* corn, was never before a part of the human diet, there was no way to conduct a conclusive allergy test. Andrew Pollack, *Kraft Recalls Taco Shells That Contain Bioengineered Corn*, N.Y. TIMES, Sept. 23, 2000, at C1.

184. *Sutter v. Aventis CropScience USA Holding, Inc.*, 145 F. Supp. 2d 1050, 1052 (S.D. Iowa 2001).

185. *In re StarLink Corn*, 212 F. Supp. 2d at 834.

186. *Id.*; EPA, WHITE PAPER ON THE POSSIBLE PRESENCE OF CRY9C PROTEIN IN PROCESSED HUMAN FOODS MADE FROM FOOD FRACTIONS PRODUCED THROUGH THE WET MILLING OF CORN 1 (Mar. 7, 2001) [hereinafter WHITE PAPER: WET MILLING CORN], available at <http://www.epa.gov/opppbd1/biopesticides/pips/wetmill18.pdf> (last visited Apr. 7, 2004).

Scientific Advisory Panel later convened by the EPA concluded that StarLink was a potential food allergen, and that no safe threshold level could be established.<sup>187</sup>

Because of the limited approval, the EPA required special procedures for StarLink corn. These procedures included: "mandatory segregation methods to prevent StarLink from commingling with other corn"; a "buffer zone" around StarLink corn crops to prevent cross-pollination"; and requirements that Aventis inform growers of the EPA restrictions and have the growers sign an agreement outlining management requirements.<sup>188</sup>

In September 2000, StarLink corn was discovered in Kraft Foods' Taco Bell-brand taco shells.<sup>189</sup> As a result, Kraft Foods ordered a recall of more than 2.5 million boxes of taco shells and halted production of the Taco Bell-brand shells.<sup>190</sup> The recall cost Kraft Foods millions of dollars.<sup>191</sup> StarLink corn was later found in many other brands of taco shells and other human food products as well, resulting in the eventual recall of over three hundred products.<sup>192</sup>

Azteca Mills, the company that milled the Kraft Food shells, halted further shipments of certain corn products from the mills identified as the sources of corn meal in the Kraft shells.<sup>193</sup> The Taco Bell restaurant chain decided to replace the shells in all 7000 of its restaurants.<sup>194</sup> Kellogg, ConAgra, and Archer Daniels Midland were all forced to stop production at certain plants because of concerns about StarLink contamination.<sup>195</sup> Shipments of U.S. corn

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187. Press Release, EPA Scientific Advisory Panel, Scientific Report on StarLink Corn Available (July 27, 2001) [hereinafter EPA Scientific Report], available at <http://www.epa.gov/scipoly/sap/pressrelease72701.htm> (last visited Apr. 7, 2004); see also *In re StarLink Corn*, 212 F. Supp. 2d at 835.

188. *In re StarLink Corn*, 212 F. Supp. 2d at 834-35.

189. Feder, *supra* note 183, at C2. The StarLink corn was discovered by an anti-genetic engineering advocacy group; there is no postmarket monitoring of genetically modified products in food. TAYLOR & TICK, *supra* note 20, at 39.

190. Feder, *supra* note 183, at C2.

191. *Id.*

192. ALEJANDRO E. SEGARRA & JEAN M. RAWSON, CRS REPORT RS20732, STARLINK CORN CONTROVERSY: BACKGROUND (Jan. 10, 2001), available at <http://www.ncseonline.org/nle/crsreports/agriculture/ag-101.cfm> (last visited Apr. 7, 2004); TEITEL & WILSON, *supra* note 12, at 29, 159.

193. Feder, *supra* note 183.

194. Pollack, *supra* note 183.

195. TAYLOR & TICK, *supra* note 20, at 78; James Cox, *StarLink Fiasco Wreaks Havoc in the Heartland: Developer Wants EPA To Approve Seed for Food Supply*, USA TODAY, Oct. 27,

were turned away from Japan and South Korea after testing revealed contamination with StarLink corn, leading to a sharp reduction in corn exports from the United States and costing United States farmers tens of millions of dollars.<sup>196</sup> Grain elevators and transporters were forced to institute expensive tests on corn shipments to assure that they were not contaminated.<sup>197</sup>

Aventis CropScience agreed to buy back the year's entire crop of StarLink corn, at a cost of about \$100 million, in an effort to prevent the grain from further contaminating the food supply.<sup>198</sup> It was anticipated that StarLink-related costs could end up running as high as \$1 billion.<sup>199</sup>

At the urging of the EPA, Aventis CropScience voluntarily agreed to cancel its StarLink registration, thus prohibiting StarLink corn from being planted for any reason.<sup>200</sup> Aventis CropScience stated that "it would no longer market bioengineered products for any use until they had been cleared for use in human food."<sup>201</sup> The EPA stated that "it would no longer grant 'split' approvals for genetically modified crops."<sup>202</sup>

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2000, at 1B.

196. TAYLOR & TICK, *supra* note 20, at 78; *see also In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 835 (N.D. Ill. 2002); Dupraz v. Aventis CropScience Holding, Inc., 153 F. Supp. 2d 1102, 1103 (D.S.D. 2001); PAUL MCAULIFFE, WORLD COMMODITY ANALYSIS CORP. STARLINK CORN A PROBLEM FOR U.S. CORN EXPORTS? (2001), at <http://www.biotech-info.net/problem.html> (last visited Apr. 7, 2004); Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation*, 20 REV. LITIG. 589, 614 (2001).

197. *In re StarLink Corn*, 212 F. Supp. 2d at 835.

198. Andrew Pollack, *European Company Will Buy Entire Crop of Corn in Recall*, N.Y. TIMES, Sept. 30, 2000, at C14. Aventis CropScience later stated that it had "located 88% of the [2000] StarLink harvest and contained it on farms where it was grown," but that nine million bushels remained unaccounted for. Cox, *supra* note 195.

199. Cox, *supra* note 195.

200. *In re StarLink Corn*, 212 F. Supp. 2d at 835; WHITE PAPER: WET MILLING CORN, *supra* note 186, at 1; Andrew Pollack, *Aventis Gives Up License To Sell Bioengineered Corn*, N.Y. TIMES, Oct. 13, 2000, at C5. Aventis CropScience, backed by the food industry, asked the EPA to permit the use of StarLink corn in food for four years in order to prevent a widespread disruption of the food and grain industries, because that was how long it was expected for the existing StarLink corn to work its way through the system. Andrew Pollack, *Corn Developer Appeals to E.P.A.*, N.Y. TIMES, Oct. 26, 2000, at C4.

201. Feder, *supra* note 183. In the spring of 2001, Aventis announced that it was looking for buyers for Aventis CropScience, Aventis' agrochemicals subsidiary. Deacon & Paterson, *supra* note 196, at 615.

202. TAYLOR & TICK, *supra* note 20, at 78.



A number of people complained of adverse reactions from eating food products containing StarLink corn.<sup>203</sup> The Centers for Disease Control investigated some of these reports but “did not find any evidence that hypersensitivity to the [transgenic] Cry9C protein [in StarLink corn] was responsible for the self-reported allergic responses.”<sup>204</sup> A class action lawsuit was filed by citizens alleging allergic reactions to taco shells containing StarLink corn.<sup>205</sup>

Numerous class actions were filed against Aventis CropScience on behalf of growers alleging that their corn crop was contaminated by StarLink corn or that they were injured by the widespread decline in corn demand.<sup>206</sup> Nationwide and statewide class action lawsuits were consolidated into a multidistrict litigation in *In re StarLink Corn Products Liability Litigation*.<sup>207</sup> Certain of these lawsuits have been settled for over \$100 million.<sup>208</sup>

StarLink corn was planted in twenty-nine states in 2000.<sup>209</sup> In early 2001, the USDA announced that StarLink corn had been detected in non-StarLink seed intended for sale that year. It was anticipated that all StarLink corn would be removed from the corn

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203. Press Release, Centers for Disease Control and Prevention, Background: CDC Involvement in Investigating Adverse Health Effects Associated with Eating Corn Products Potentially Contaminated with the Cry9C Protein in StarLink Corn (June 13, 2001), available at <http://www.cdc.gov/od/oc/media/pressrel/r010613a.htm> (last visited Apr. 7, 2004).

204. *Id.*

205. Deacon & Paterson, *supra* note 196, at 614.

206. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 842-43 (N.D. Ill. 2002); Deacon & Paterson, *supra* note 196, at 614-15. The contamination class actions were based both on cross-pollination in the field and contamination by commingling in the distribution process. *In re StarLink Corn*, 212 F. Supp. 2d at 842-43.

207. *In re StarLink Corn*, 212 F. Supp. 2d at 833.

208. See Allison Beers, *Food, Biotech Firms Settle StarLink Consumer Lawsuit*, FOOD CHEM. NEWS, Mar. 11, 2002, at 1 (reporting approval of a \$9 million settlement in a consumer class action lawsuit against companies that produced and sold StarLink corn); *Biotech II: StarLink Creator, Distributor Agree to \$110M Settlement*, GREENWIRE Feb. 7, 2003 (reporting that the developer and distributor of StarLink corn agreed to pay farmers \$110 million to settle the farmers' claims that they had not been properly informed that StarLink corn had not been approved for human consumption); Stephen Clapp, *StarLink Settlement Approved by Judge*, FOOD CHEM. NEWS, Apr. 14, 2003, at 6 (reporting final approval of \$110 million settlement for farmers whose property was contaminated by StarLink corn or who were injured by a reduction in corn prices because of the StarLink corn contamination).

209. Cox, *supra* note 195.

grain supply by 2002.<sup>210</sup> On December 27, 2002, Japanese authorities found "traces of StarLink corn in a shipment from the U.S."<sup>211</sup>

Several final points should be noted on this case study. The harvesting, storage, shipping, and processing equipment are often the same for human and animal food. Corn from myriad farms is commingled as it is gathered, stored and transported.<sup>212</sup> Consequently, StarLink corn was commingled with human food corn in numerous grain elevators.<sup>213</sup> Due to recognized commingling, the agricultural industry accepts about 2-7% foreign matter in bulk shipments of corn in the United States.<sup>214</sup> The StarLink corn-contaminated taco shells contained only about 1% StarLink corn.<sup>215</sup> Further, it was later discovered that growers of StarLink corn had been inadequately warned about the need to keep it segregated from other corn.<sup>216</sup>

Someone with working knowledge of the country's agricultural system would have recognized from the outset that it was inevitable that once StarLink corn was grown, produced, and processed on a large-scale basis, some of it would make its way into the human food supply.<sup>217</sup> According to one agricultural expert, "Anyone who understands the grain handling system ... would know that it would be virtually impossible to keep StarLink corn separate from corn that is used to produce human food ...."<sup>218</sup>

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210. EPA Scientific Report, *supra* note 187.

211. TAYLOR & TICK, *supra* note 20, at 93.

212. *In re StarLink Corn*, 212 F. Supp. 2d at 834.

213. McGarity, *supra* note 8, at 486; D.L. Uchtmann, *StarLink—A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159, 193-95 (2002).

214. Andrew Pollack, *Labeling Genetically Altered Food Is Thorny Issue*, N.Y. TIMES, Sept. 26, 2000, at A1.

215. *Id.* The test that discovered the StarLink corn was a test for the genetically modified DNA, not the potential allergy-causing protein that the DNA might express. The test, thus, did not establish whether the protein of concern itself was even in the contaminated products. *Id.* A test to identify whether processed foods contained the protein of concern did not exist because the "protein typically is broken down by heating and other food processing." Feder, *supra* note 183.

216. See Barnaby J. Feder, *Farmers Cite Scarce Data In Corn Mixing: Companies' Warnings Are Called Inadequate*, N.Y. TIMES, Oct. 17, 2000, at C1; see also *In re StarLink Corn*, 212 F. Supp. 2d at 838.

217. George Anthan, *OK Sought for Corn in Food*, DES MOINES REG., Oct. 26, 2000, at 1D. The EPA later acknowledged "that the limited approval for StarLink was unworkable." *Id.*

218. *Id.*

*B. Genetically Modified Salmon*

A genetically modified version of Atlantic salmon is expected to be the first genetically modified animal approved for sale for human consumption in the United States.<sup>219</sup> These salmon are engineered to contain genes intended to make them grow faster and use feed more efficiently.<sup>220</sup> The main concern raised by genetically modified salmon is environmental: Studies have shown that wild fish populations could be eliminated through mating with genetically engineered fish.<sup>221</sup> In addition, there is the risk of unpredictable environmental impacts occurring as a result of the introduction of a nonnative species into an ecosystem.<sup>222</sup>

In an attempt to limit the potential for wild propagation of transgenic salmon, the salmon are treated in an effort to produce only reproductively sterile, all-female offspring.<sup>223</sup> In addition, the salmon will be grown in enclosed ocean net pens.<sup>224</sup> However, full sterility currently cannot be achieved and escape of pen fish into open waters is common.<sup>225</sup> Therefore, escape of fish from pens will occur and may include females capable of reproduction. As noted earlier, escaped nontransgenic net pen Atlantic salmon have been

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219. Yoon, *supra* note 168.

220. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 1.

221. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 6-7; Yoon, *supra* note 168, at A1.

222. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 6-7, 24; Yoon, *supra* note 168, at A1. Transgenic animals, in particular, "may have surprising ecological impacts associated with their degree of fitness, interaction with other organisms, role in ecosystem processes or potential for dispersal and persistence." *Id.* at 22.

223. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 1.

224. *Id.*

225. *Id.* at 1-3; CEQ AND OSTP ASSESSMENT, *supra* note 49, at 8; FUTURE FISH, *supra* note 25, at 18; ROYAL SOC'Y OF CAN., *supra* note 5, at 151. It is possible to test the treated fish for sterility, but testing each salmon would be prohibitively expensive. *Id.* at 161. To cite one statistic on net pen escape, between 32,000 and 86,000 farmed salmon escaped in British Columbia between January and September 2000. *Id.* at 151.

known to spawn successfully.<sup>226</sup> Only a few fertile individuals are necessary to change the genetic structure of a wild species.<sup>227</sup>

Despite these risks, there are no federal laws that directly regulate the use or release of genetically engineered fish or other transgenic animals.<sup>228</sup> Both the EPA and the USDA have determined that they do not have regulatory authority over the genetically modified Atlantic salmon.<sup>229</sup> The FDA is the only regulatory agency to have asserted authority over the transgenic salmon, which it has done pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA),<sup>230</sup> on the basis that the transgenic salmon are a “new animal drug.”<sup>231</sup> A difficulty with this regulatory basis is that the salmon have only been modified such that a growth hormone they naturally produce for half the year is now produced all year long.<sup>232</sup> The FDA’s authority on this basis, therefore, may be tenuous.<sup>233</sup>

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226. See *supra* note 167 and accompanying text. Initially, escape was not anticipated to be a significant risk for pen-raised Atlantic salmon, because it was believed that escapees would be few and that any escaped individuals would not be able to compete successfully with native stocks or form viable populations. Escapees, however, occur in substantial numbers, and can survive in the wild. Experts still believed that there was not a significant cause for concern as the salmon were not expected to reproduce successfully in the wild. It now appears that escaped fish do reproduce. Further, genetically modified salmon may be able to do so in a broader range of ecosystems than anticipated. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 6-8.

227. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 23.

228. Yoon, *supra* note 168.

229. *Id.* Some have argued that the EPA could assert regulatory authority over genetically modified fish by defining the products produced by the transgenes to be “new chemical substances” pursuant to the Toxic Substances Control Act (TSCA). FUTURE FISH, *supra* note 25, at 46. The EPA, however, has not exercised this authority and there is some question regarding whether such an interpretation would be upheld. *Id.*

Certain native Atlantic salmon population segments in Maine have been listed as endangered distinct population segments pursuant to the Endangered Species Act. Endangered and Threatened Wildlife, 50 C.F.R. § 17.11 (2002); Enumeration of Endangered Marine and Anadromous Species, 50 C.F.R. § 224.101 (2002). This listing creates certain protections for these population segments of wild Atlantic salmon, and would likely impact any discussion of net pen aquaculture of the genetically modified Atlantic salmon in the vicinity of the listed wild populations. The listing, however, will not impact net pen aquaculture of genetically modified fish generally, or of modified salmon in other areas.

230. 21 U.S.C. §§ 301-399 (2003).

231. *Id.* § 321(v); Yoon, *supra* note 168, at A20.

232. FUTURE FISH, *supra* note 25, at 6, 8; Yoon, *supra* note 168, at A20.

233. FUTURE FISH, *supra* note 25, at 47. The FDA also potentially could rely on the National Environmental Policy Act (NEPA) as authority to regulate the environmental impacts of genetically modified fish. See 42 U.S.C. § 4332 (2003).

The FDA bases its authority on the reasoning that the FFDCA defines a "drug" to include "articles ... intended to affect the structure or any function of the body of man or other animals."<sup>234</sup> The genetic modification of the salmon certainly qualifies as a "drug" under this statutory language, as the modification is intended to affect function. On the other hand, the FFDCA's definition of "new animal drug" refers to substances not generally recognized as safe (GRAS), and a growth hormone already present in the salmon likely does not fit this bill.<sup>235</sup> The FDA's reasoning, that the increased protein production is not GRAS, is particularly questionable considering the FDA's conclusion in the transgenic crop arena that inserted genetic material is GRAS because all that is produced as a result of the insertion are proteins and other substances already commonly found in food.<sup>236</sup> The FDA's guidance concerning food crops therefore may undermine its authority over genetically modified fish or other animals. It also is certain that Congress did not intend "article" to have this expanded interpretation when the FFDCA was enacted in 1958, since the field of biotechnology did not exist at that time.

Under the FFDCA, a new animal drug's safety is determined with "reference to the health of man or animal."<sup>237</sup> The FDA interprets this statutory language to include "environmental effects that directly or indirectly affect the health of humans or animals."<sup>238</sup> Thus, as a practical matter, many "environmental effects" come within the FDA's interpreted regulatory jurisdiction under the FFDCA. Certain environmental effects, however, such as aesthetic injuries or certain ecological ones, could not be considered by the

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Some commentators contend that even if the FDA's authority is improper, genetically modified fish producers would not challenge the FDA's authority out of fear that a successful challenge would result in new, potentially more restrictive, legislation and regulation. *FUTURE FISH*, *supra* note 25, at 49. On the other hand, it only takes one allegedly irrational actor to challenge the FDA's regulatory authority, and predicting congressional response is a risky enterprise at best.

234. 21 U.S.C. § 321(g).

235. *Id.* § 321(v).

236. *See infra* notes 285-88 and accompanying text. The genetic modification in this instance also may produce a protein that can be considered a drug. This runs into the same regulatory authority concerns because the protein being produced is one that already occurs naturally in the salmon.

237. 21 U.S.C. § 321(u).

238. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 14.

FDA in determining whether to approve or regulate the salmon.<sup>239</sup> In addition, the FFDCA contains no provisions regarding how to handle environmental risk.

Thus, the best-case scenario, assuming the FDA's interpretation of "drug" is upheld, is that the FDA is still the only agency with authority over the introduction of a genetically modified animal that primarily raises environmental concerns. Even in such a scenario, the FDA would lack authority over certain environmental impacts.

### *C. Threat to Monarch Butterflies*

In 1999, a Cornell University study found that pollen from genetically modified corn containing Bt, a gene from the Bt bacterium that produces a protein toxic to the European corn borer,<sup>240</sup> was toxic to Monarch butterfly larvae.<sup>241</sup> In August 2000, scientists from Iowa State University published a study showing that "plants growing in and near the [Bt] corn fields are being dusted with enough toxic pollen to kill [M]onarch caterpillars that feed on them."<sup>242</sup>

At that time, over one-quarter of the seventy-three million acres of corn planted in the United States was genetically modified to include the Bt pesticide.<sup>243</sup> Approximately half of the Monarchs in

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239. FUTURE FISH, *supra* note 25, at 48-49. The approval of a new animal drug application is a federal action pursuant to NEPA, thus, the FDA also will have to comply with its strictures in carrying out the approval process. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 14. There are some problems for the FDA complying with NEPA's public participation requirements during the approval process, because both the FFDCA and the Trade Secret Act, 18 U.S.C. § 1905 (2002), "prohibit revealing any information that is acquired as part of the new animal drug approval process." CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 16; *see also* FUTURE FISH, *supra* note 25, at 52.

240. The European corn borer is a significant corn crop pest from the *Lepidoptera* family (e.g., moths, butterflies). The European Corn Borer Home Page, at <http://www.ent.iastate.edu/pest/cornborer> (last updated Oct. 28, 1998).

241. John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999).

242. Carol Kaesuk Yoon, *New Data in Duel of Biotech Corn vs. Butterflies*, N.Y. TIMES, Aug. 22, 2000, at F2. According to the Iowa State study, twenty percent of the Monarch caterpillars eating the leaves bearing the genetically modified pollen died, compared with a zero fatality rate for caterpillars eating leaves with regular corn pollen. *Id.*

243. Carol Kaesuk Yoon, *Biotech Corn Isn't Serious Threat to Monarchs, Draft U.S. Report Finds*, N.Y. TIMES, Sept. 26, 2000, at F4.

the United States pass through the corn belt every year.<sup>244</sup> Unsurprisingly, the combination of these reports and facts caused widespread concern among the public and led to cries for bans on Bt-modified plants.

The EPA had considered the potential impact of Bt-modified plants on Monarch butterflies prior to approving their registration. The EPA concluded that Bt crops posed an extremely low risk based on the expectations that (1) Monarchs did not occur in cornfields in significant numbers;<sup>245</sup> (2) there would be relatively few milkweed plants (the Monarch butterfly larvae's sole food source) near or in the transgenic fields;<sup>246</sup> and (3) the amount of Bt pollen that would land on adjacent milkweed plants would be below toxic levels.<sup>247</sup> The new reports, however, threw the EPA's conclusions into question.

The EPA responded quickly to the Monarch butterfly concern by issuing a data call-in, and a variety of field and laboratory data was collected.<sup>248</sup> Analysis of this data generally "confirmed [the] EPA's earlier finding that the risk to [adult M]onarch butterflies from Bt-maize is extremely low," and also found that Monarch larvae avoided detrimental amounts of pollen.<sup>249</sup> A collaborative research effort to conduct a formal risk assessment of the impact of Bt corn on Monarch butterfly populations concluded that the risk from current crops was low or negligible.<sup>250</sup>

On the other hand, that same risk assessment also found that Monarch populations inhabit corn ecosystems to a degree previously undocumented,<sup>251</sup> that milkweed plants were abundant throughout the corn growing region, and that milkweed pollen was shed during

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244. CASE STUDY NO. II: BT-MAIZE, *supra* note 36, at 26.

245. NRC 2002 REPORT, *supra* note 2, at 74.

246. CASE STUDY NO. II: BT-MAIZE, *supra* note 36, at 25.

247. *Id.*

248. See CASE STUDY NO. II: BT-MAIZE, *supra* note 36, at 25-26; NRC 2002 REPORT, *supra* note 2, at 73-75.

249. CASE STUDY NO. II: BT-MAIZE, *supra* note 36, at 26; see also NRC 2002 REPORT, *supra* note 2, at 37, 75-77.

250. Mark K. Sears et al., *Impact of Bt Corn Pollen on Monarch Butterfly Populations: A Risk Assessment*, PNAS vol. 98, No. 21, at 11,937, 11,942 (2001), available at <http://www.pnas.org/cgi/reprint/98/21/11937.pdf> (last visited Apr. 7, 2004).

251. *Id.* at 11,942. Throughout the northern Corn Belt more Monarchs are bred in cornfields than in any other habitat.

the same period that larvae develop and use the cornfields.<sup>252</sup> In addition, another study found that the “level of natural deposition of Bt pollen ... was sufficient to kill Monarch larvae.”<sup>253</sup> The EPA continues to “assess the potential risks [to Monarchs] and the need for possible mitigation measures.”<sup>254</sup>

The EPA’s rapid response to the reports that raised concern is commendable, and the end result appears to be that Bt crops present a low risk to Monarch butterfly populations. The assumptions that the EPA made in approving the Bt crop registration, however, were scientifically unsound.

#### *D. ProdiGene Pharmaceutical-Producing Corn*

In September 2002, the USDA discovered corn genetically engineered to produce a pharmaceutical growing in an Iowa soybean field in violation of regulations. This corn had sprouted from seed left over from an approved 2001 field test by ProdiGene, Inc., a pharmaceutical bioengineering company.<sup>255</sup> Because the corn had already matured, its pollen may have traveled into nearby fields. The USDA, therefore, ordered the harvest and destruction of 155 acres of crop surrounding the test site in case the ProdiGene corn had contaminated it.<sup>256</sup>

Almost identically, in October 2002, APHIS discovered transgenic ProdiGene pharmaceutical-producing corn in a Nebraska soybean field, which also had sprouted from seed left over from a 2001 field test.<sup>257</sup> Apparently, the grower had violated APHIS containment

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252. *Id.* at 11,938-39; NRC 2002 REPORT, *supra* note 2, at 75.

253. NRC 2002 REPORT, *supra* note 2, at 74. The levels of natural deposition were found to be too low to kill adult Monarch butterflies at distances greater than five meters from the corn field edge. *Id.*

254. CASE STUDY NO. II: BT-MAIZE, *supra* note 36, at 26.

255. Ann Thayer, *ProdiGene Woes: Biopharm Firm Faces USDA, FDA Actions over Corn Contamination*, CHEM. & ENG’G NEWS, Nov. 25, 2002, available at <http://pubs.acs.org/cen/topstory/8047/8047notw3.html> (last visited Apr. 7, 2004).

256. Randy Fabi, *USDA Orders ProdiGene Biocorn Destroyed in Iowa*, Rueters, Nov. 14, 2002, available at <http://www.connectotel.com/gmfood/re141102.txt> (last visited Apr. 7, 2004); Press Release, APHIS, *USDA Investigates Biotech Company for Possible Permit Violations* (Nov. 13, 2002), available at <http://www.aphis.usda.gov/lpa/news/2002/11/prodigene.html> (last visited Apr. 7, 2004).

257. Thayer, *supra* note 255. Not surprisingly, both the pro-genetically modified product industry and the anti-genetically modified product activists instantly issued press releases



requirements by not fully removing the old ProdiGene corn plants from the field.<sup>258</sup> About 500 bushels of soybeans had been harvested from the field, which had then been mixed with 500,000 bushels of soybeans in a grain elevator.<sup>259</sup> APHIS impounded and destroyed the 500,000 bushels of soybeans, worth an estimated \$2.7 million.<sup>260</sup> The ProdiGene corn had been modified to produce an experimental vaccine for use against viral disease in pigs.<sup>261</sup>

Following the two incidents, ProdiGene and the USDA entered a consent decision and order regarding violations of the Plant Protection Act (PPA).<sup>262</sup> ProdiGene agreed to pay a \$250,000 civil fine and to reimburse the USDA approximately \$3 million for the costs of acquiring and destroying the 500,000 bushels of soybeans in Nebraska.<sup>263</sup> ProdiGene did not admit or deny any violations of the PPA.<sup>264</sup>

Shortly after the ProdiGene incidents, the EPA levied fines against two other firms (Dow Agrosciences and Pioneer Hi-Bred) for

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contending, respectively, that this incident either demonstrated that the current regulatory system was functioning well, or that the biotechnology industry cannot be trusted. Compare Press Release, Biotechnology Industry Organization, Bio Statement on ProdiGene, Inc. (Nov. 15, 2002), available at [http://www.bio.org/newsroom/newsitem.asp?id=2002\\_1115\\_01](http://www.bio.org/newsroom/newsitem.asp?id=2002_1115_01) (last visited Apr. 7, 2004) ("The ProdiGene incident demonstrates that the regulatory framework governing plant-made pharmaceutical crops works."), with Press Release, Friends of the Earth, Coalition to File Legal Petition Demanding Immediate Halt of Experimental Biopharmaceuticals Grown on Farms (Nov. 14, 2002), at <http://www.foe.org/new/releases/1102biopharm1.html> (last visited Apr. 7, 2004) ("With this latest contamination the government should halt all experimental genetically engineered crops grown on farms ....") (internal citation omitted).

258. See APHIS, *supra* note 256.

259. See Philip Brasher, *Biotech Corn May Have Tainted Soybeans*, DES MOINES REG., Nov. 13, 2002, at A1.

260. Andrew Pollack, *U.S. Investigating Biotech Contamination Case*, N.Y. TIMES, Nov. 13, 2002, at C7; APHIS, *supra* note 256; Press Release, USDA, USDA Announces Actions Regarding Plant Protection Act Violations Involving ProdiGene, Inc. (Dec. 6, 2002), available at <http://www.usda.gov/news/releases/2002/12/0498.htm> (last visited Apr. 7, 2004).

261. TAYLOR & TICK, *supra* note 20, at 88.

262. USDA, *supra* note 260.

263. See *id.*; see also TAYLOR & TICK, *supra* note 20, at 89. "ProdiGene also agreed to a \$1 million bond and higher compliance standards, including additional approvals before field testing and harvesting genetically modified material," and to "develop a written compliance program with USDA to ensure that its employees, agents, cooperators and managers are aware of, and comply with, the [PPA], federal regulations and permit conditions." USDA, *supra* note 260.

264. TAYLOR & TICK, *supra* note 20, at 89.

failing to take proper measures to protect against experimental pharmaceutical-producing plants contaminating other crops.<sup>265</sup>

To guard against future incidents and to allay consumer and food industry concerns, the Biotechnology Industry Organization (BIO), a biotechnology trade organization, initially directed its members not to plant pharmaceutical-producing plants in the Midwest and Plains states.<sup>266</sup> This policy caused widespread concern among farmers in the corn belt who desired to plant these potentially highly profitable crops.<sup>267</sup> BIO later reversed its position because of political pressure from these farmers.<sup>268</sup>

Perhaps in response to the incidents identified above, the USDA recently proposed new guidelines for the field testing of pharmaceutical-producing and industrial compound-producing genetically modified plants. Among other changes, these proposed regulations would increase the number of field site inspections made by APHIS during the growing season.<sup>269</sup>

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These brief case studies simultaneously demonstrate the need to properly regulate genetically modified products and also provide valuable insight into the regulatory deficiencies that currently exist with respect to genetically modified products. To understand why these problems are occurring, to identify additional issues, and to provide background for improving the regulatory structure governing genetically modified products, the current statutory and regulatory structure governing genetically modified plants and animals is outlined in the following section.

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265. Justin Gillis, *EPA Fines Biotechs for Corn Violations*, WASH. POST, Dec. 13, 2002, at E3.

266. TAYLOR & TICK, *supra* note 20, at 89.

267. *Id.*

268. Sandra Guy, *Kraft Exec Wants Tougher Rules on Planting Crops for Drugs*, CHI. SUN-TIMES, Apr. 4, 2003, at 50.

269. Field Testing of Pharmaceutical Plants, *supra* note 23, at 11,338.

#### IV. CURRENT REGULATION OF GENETICALLY MODIFIED PLANTS AND ANIMALS

##### *A. The Coordinated Framework*

As the biotechnology industry developed in the early 1980s, it was recognized that regulation was necessary to protect human health and the environment from the potential deleterious effects of transgenic products. This recognition culminated in the promulgation of the federal government's Coordinated Framework for Regulation of Biotechnology by the White House Office of Science and Technology Policy in 1986.<sup>270</sup> The Coordinated Framework instituted a "comprehensive federal regulatory policy for ... biotechnology research and products."<sup>271</sup> It specified that bioengineered products generally would be regulated under the then-existing statutory and regulatory structure.<sup>272</sup> The foundation for this decision was a determination that the process of biotechnology was not inherently risky, and therefore, that only the products of biotechnology, not the process itself, required oversight. On this basis, the Coordinated Framework established that existing laws and regulations were sufficient to handle the products of biotechnology.<sup>273</sup> This decision was based in part on a desire not to impose regulatory restrictions that could hamper the development of a promising and fledgling industry.<sup>274</sup>

As a result of the Coordinated Framework, three administrative agencies are involved in the regulation of the genetically modified products discussed in this Article: The FDA is responsible for food safety issues for transgenic crop and food-animal varieties, and for drug safety issues for modified pharmaceutical-producing plants or animals; the EPA handles health and environmental effects of pest-protected plants; and the USDA regulates the effect of genetically modified plants on other plants and animals in both agricultural

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270. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

271. *Id.* at 23,302.

272. *Id.* at 23,302-08, 23,309, 23,313-14, 23,336.

273. *Id.* at 23,302-03; see NRC 2000 REPORT, *supra* note 4, at 25-26.

274. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302-03.

and nonagricultural environments.<sup>275</sup> Because the Coordinated Framework would result in multiple agencies acting in closely related areas, two basic principles were delineated to guide regulatory policy. First, “[a]gencies should seek to adopt consistent definitions of those genetically engineered organisms subject to review to the extent permitted by their respective statutory authorities.”<sup>276</sup> Second, the “agencies should utilize scientific reviews of comparable rigor.”<sup>277</sup>

Implicit in the decision to regulate genetically modified products under preexisting statutes was the belief that bioengineered plants and animals were not significantly different from their conventional counterparts. This view was explicitly reiterated in a 1987 National Academy of Sciences report that reached three conclusions:

- [1] There is no evidence that unique hazards exist either in the use of rDNA techniques or in the movement of genes between unrelated organisms.
- [2] The risks associated with the introduction of rDNA-engineered organisms are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods.
- [3] Assessment of the risks of introducing rDNA-engineered organisms into the environment should be based on the nature of the organism and the environment into which it is introduced, not on the method by which it was produced.<sup>278</sup>

With the Coordinated Framework in place, the regulation of biotechnology was left to the administrative agencies.

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275. NRC 2002 REPORT, *supra* note 2, at 19.

276. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303.

277. *Id.*

278. NAT'L ACAD. OF SCIENCES, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES (1987). This position was confirmed again in 1992 by the Office of Science and Technology Policy. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992).

*B. The Food and Drug Administration*

The FDA is responsible for insuring that all food products on the market in the United States, other than meat and poultry, are safe. In furtherance of this goal, the FDA provides voluntary premarket consultations with food companies, seed companies, and plant developers regarding the safety of transgenic foods.

The FDA's statutory authority is the FFDCA, enacted in 1938.<sup>279</sup> No statutory provisions or FDA regulations expressly cover genetically modified foods. Pursuant to FDA regulations, plants modified through modern rDNA techniques are not treated any differently from conventionally modified plants.<sup>280</sup>

Section 402(a)(1) of the FFDCA authorizes the FDA to regulate "adulterated foods," defined as food that "bears or contains any poisonous or deleterious substance which may render it injurious to health."<sup>281</sup> In addition, section 409 of the FFDCA provides for the regulation of "food additives," which are substances that are intended for use in food, that may reasonably be expected to become a component of food, or that otherwise may affect the characteristics of food.<sup>282</sup> A food additive must be approved by the FDA prior to being used in food.<sup>283</sup> Manufacturers, however, do not need approval for a food additive if such substance is generally recognized as safe (GRAS) by experts.<sup>284</sup>

Thus, both the inserted gene of a transgenic plant and the product that it expresses are food additives, unless they are GRAS.<sup>285</sup> With respect to genetically modified foods, the FDA has determined that "[i]n most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly

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279. See 21 U.S.C. §§ 301-399 (2003).

280. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

281. 21 U.S.C. § 342(a)(1). "Food" is defined 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." *Id.* § 321(f). This includes human food, animal food, pet food, and substances migrating to food from food-contact articles. Definitions, 21 C.F.R. § 170.3(m) (2003).

282. 21 U.S.C. §§ 321(s), 348.

283. *Id.* § 348.

284. *Id.* § 321(s).

285. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990.

found in food, such as proteins, fats and oils, and carbohydrates," and therefore will be GRAS.<sup>286</sup>

The food additive manufacturer determines whether a food additive is GRAS, not the FDA.<sup>287</sup> A manufacturer does not need to report to the FDA that it has made a GRAS determination, but it may do so and may receive from the FDA an affirmation that the particular substance is GRAS.<sup>288</sup> Thus, the FDA's regulatory requirements with respect to genetically modified food are primarily voluntary. This decision was explicitly made by the FDA based on its determination that "[a]ny genetic modification technique has the potential to alter the composition of food in a manner relevant to food safety, although, based on experience, the likelihood of a safety hazard is typically very low."<sup>289</sup>

In 1995, the FDA conducted a safety review of the first genetically modified food product to be commercialized, the Flav'r Savr tomato.<sup>290</sup> This review was conducted at the request of the manufacturer, who was attempting to build public confidence.<sup>291</sup> Since that time, the FDA has not conducted a safety review of any of the scores of other genetically modified food products that have been commercialized; however, the FDA believes that manufacturers have voluntarily consulted with it regarding each of these products.<sup>292</sup>

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286. *Id.* at 22,985. The primary exceptions, where foods would require special review, would be where the gene transfer produces unexpected genetic results, may cause allergic reactions, significantly increases the level of toxicants, or changes the nutrient composition of the food. *Id.* at 22,993 fig. 1.

287. *Id.* at 22,989.

288. Affirmation of Generally Recognized As Safe (GRAS) Status, 21 C.F.R. § 170.35 (2003). Such a determination will protect the product from enforcement actions. *Id.*

289. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,986. A challenge to the FDA's decision not to regulate genetically modified food differently from conventional food was dismissed. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000).

On January 18, 2001, the FDA published proposed revised regulations for genetically engineered food. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592). These regulations would require manufacturers and importers to provide the FDA with premarket notification of their intent to market genetically modified foods that have not been subject to a previous premarket notification. *Id.* at 4707. These proposals, made days before President George W. Bush took office, have not been finalized or acted upon since that time.

290. Henkel, *supra* note 3.

291. *Id.*

292. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4708; NRC 2000 REPORT, *supra* note 4, at 29; Press Release, FDA, FDA To Strengthen Premarket Review of

The FDA does not require that genetically modified foods be labeled as such. The basis for this determination is the FDA's conclusion that genetically modified products do not differ materially from, or create greater safety concerns than, their conventional counterparts.<sup>293</sup> To the extent that there are significant safety concerns or usage issues, such as substantial changes in composition or nutritive value, the FDA requires labeling.<sup>294</sup>

The FDA explicitly has waived its regulatory authority over genetically modified pest-protected plants, so long as the plants have not also been modified to express other, nonpesticidal proteins.<sup>295</sup> These plants are regulated by the EPA as pesticides, and are discussed below.<sup>296</sup>

As discussed in the genetically modified salmon case study, the FDA asserts regulatory authority over genetically modified fish and other animals pursuant to the "new animal drug" provisions of the FFDCA.<sup>297</sup> These provisions allow the FDA to evaluate the new animal drug's safety with "reference to the health of man or

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Bioengineered Foods (May 3, 2000), available at <http://www.fda.gov/bbs/topics/NEWS/NEW00726.html> (last visited Apr. 7, 2004). The FDA has been consulted on more than fifty bioengineered plants. BIOENGINEERED FOODS LIST, *supra* note 15. The FDA has not required any of the transgenic plants, or their expression products, to be reviewed as food additives. NRC 2000 REPORT, *supra* note 4, at 29.

293. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,991.

294. *Id.* In *Alliance for Bio-Integrity v. Shalala*, the court upheld the FDA's decision not to require labeling based on consumer interest. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 181. Proponents of genetically modified food labeling point out an apparent inconsistency in FDA regulations, as the FDA *does* require labeling based on processing differences and consumer interest in certain other areas. Examples include labeling requirements for juice made from concentrate and for food that has been frozen. See *Beverages that Contain Fruit or Vegetable Juice*, 21 C.F.R. § 102.33 (2003) (labeling requirements for juice from concentrate); *False or Misleading Labeling on Containers*, 9 C.F.R. § 381.129 (2003) (labeling requirements for previously frozen poultry).

295. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 23,005.

296. See *infra* Part IV.C; see also Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues Derived Through Conventional Breeding from Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,830, 37,835 (July 19, 2001) (to be codified at 40 C.F.R. pt. 174) [hereinafter Exemption for Residues Derived Through Conventional Breeding]; Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772, 37,775 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174) [hereinafter Regulations Under FIFRA] (EPA regulations for pest-protected plants).

297. See *supra* notes 230-39 and accompanying text.

animal,<sup>298</sup> which the FDA interprets to include environmental effects that directly or indirectly affect the health of humans or animals other than those intended to receive the new drug.<sup>299</sup>

The FDA has regulatory authority over pharmaceuticals grown in genetically modified plants that are intended for use in humans pursuant to the Public Health Service Act<sup>300</sup> and the FFDCA. A full discussion of FDA regulations governing the approval of pharmaceuticals for human use is beyond the scope of this Article. It is sufficient to note that FDA regulations are similar to those governing transgenic plants used for food. In both cases, the FDA regulates the use of plants that might express an allergenic or toxic compound in the pharmaceutical, and protects against the introduction of nonfood material into food or feed.<sup>301</sup> The FDA regulations governing human drugs and biologics and animal drugs do not specifically address biotechnology.<sup>302</sup> The USDA shares regulatory authority over the growth of the genetically engineered pharmaceutical-producing plants, as discussed below.<sup>303</sup>

### C. The Environmental Protection Agency

The EPA regulates genetically modified products through its authority to regulate pesticide use and pesticide residue in food products. All pesticides must be registered with the EPA prior to their distribution, sale, or use, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), originally enacted in 1947.<sup>304</sup> "Pesticide" is defined under FIFRA to include any sub-

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298. 21 U.S.C. § 321(u) (2000).

299. CASE STUDY NO. I: GROWTH-ENHANCED SALMON, *supra* note 81, at 14.

300. 42 U.S.C. § 262-262a (2003).

301. See FDA, GUIDANCE FOR INDUSTRY: DRUGS, BIOLOGICS, AND MEDICAL DEVICES DERIVED FROM BIOENGINEERED PLANTS FOR USE IN HUMANS AND ANIMALS (DRAFT GUIDANCE) (Sept. 2002), available at <http://www.fda.gov/cber/gdlns/bioplant.pdf> (last visited Apr. 7, 2004).

302. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 164.

303. See *infra* Part IV.D.

304. 7 U.S.C. § 136-36a (2000). The EPA has the authority to regulate chemical substances under the TSCA, 15 U.S.C. §§ 2601-2629 (2000), but has determined that transgenic plants are not chemical substances. Statement of Policy, Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,324 (June 26, 1986). The EPA regulates genetically modified microorganisms pursuant to TSCA, defining microorganisms as chemical substances. Coverage of this Part, 40 C.F.R. § 725.8(c)(1) (2001).



stance "intended for preventing, destroying, repelling, or mitigating any pest."<sup>305</sup> To register a pesticide, one must demonstrate that the pesticide will not cause "unreasonable adverse risk to man or to the environment."<sup>306</sup> The EPA has authority to exempt pesticides from registration requirements if it determines them "to be of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of [FIFRA]."<sup>307</sup>

FIFRA was enacted to regulate chemical substances, not biotechnological products (it was enacted prior to Watson and Crick's discovery of the DNA molecule). Based on FIFRA's statutory definition of "pesticide," however, the EPA regulates the genetic material inserted into transgenic plants to express pesticidal products, as well as the expression products themselves, as pesticides.<sup>308</sup> Thus, manufacturers of transgenic pest-protected plants must receive registration of the plants from the EPA prior to commercialization. Certain congressional members and professional societies have contended that the EPA does not have authority to regulate transgenic pest-protected plants as pesticides under FIFRA, but the regulations have not been challenged in court.<sup>309</sup>

In 1988, just prior to the widespread development of genetically engineered pest-protected plants, the EPA exempted plants and

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305. 7 U.S.C. § 136(u).

306. *Id.* § 136a(c)(8).

307. *Id.* § 136w(b). The EPA will exempt pesticides where there is "a low probability of risk to the environment, and [it] is not likely to cause unreasonable adverse effects [on] the environment even in the absence of regulatory oversight under FIFRA." Regulations Under FIFRA, *supra* note 296, 66 Fed. Reg. at 37,773. The EPA has exempted pest-protected plants that are derived through conventional breeding processes from pesticide registration requirements. Exemption for Residues Derived Through Conventional Breeding, *supra* note 296, 66 Fed. Reg. at 37,835. The EPA also has used this exemption process to exempt from the FFDCA tolerance requirements "residues of nucleic acids that are part of a plant-incorporated protectant." Exemption from the Requirement for a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids That are Part of Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,817, 37,820 (July 19, 2001).

308. Regulations Under FIFRA, *supra* note 296, 66 Fed. Reg. at 37,772-73.

309. NRC 2000 REPORT, *supra* note 4, at 38. In addition, they have raised concerns that the EPA regulation lacks "formal cost-benefit analysis," that it "could damage the [technological] progress ... by overburdening small biotechnology companies and public breeding programs," and could undermine "[public] confidence in the food supply." *Id.* Regarding the first issue, the lack of formal cost-benefit analysis, it is worth noting that the registration decision takes into account the "economic, social, and environmental costs and benefits" of the pesticide. 7 U.S.C. § 136(bb).

microorganisms with pesticidal properties from the requirements of FIFRA.<sup>310</sup> This exemption was intended for plants, such as chrysanthemums, that are naturally pest-protected.<sup>311</sup> Due to these regulations, the EPA does not regulate any plants themselves, including genetically modified ones.<sup>312</sup> As discussed above, the EPA does regulate the inserted genetic material and the products it expresses.

The EPA is responsible for regulating both the environmental and human health impacts of plants genetically modified to produce their own pesticides, as the FDA has ceded regulatory authority over pest-protected plants to the EPA.<sup>313</sup> Where use of a pesticide will result in any residue being left on food, the pesticide is subject to regulation by the EPA pursuant to the FFDCA. In these instances, the EPA establishes "tolerance" levels for the allowable amount of pesticide residue that can be left on food products.<sup>314</sup> Currently, all FIFRA-registered, pest-protected plants are exempt from tolerance level requirements because tests of these transgenic plants have not revealed a human health risk.<sup>315</sup>

The EPA does not regulate genetically engineered plants other than those modified to contain pesticides,<sup>316</sup> and it does not regulate the environmental impacts or potential impacts of genetically engineered animals.

#### *D. The U.S. Department of Agriculture*

The USDA is responsible for protecting and promoting American agriculture. On the principle that genetically modified plants could pose a risk to agricultural crops, the USDA oversees the agricul-

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310. Exemptions for Pesticides Regulated by Another Federal Agency, 40 C.F.R. § 152.20 (2001); see Pesticide Registration Procedures, Pesticide Data Requirements, 53 Fed. Reg. 15,952, 15,975 (May 4, 1988) (to be codified at 40 C.F.R. pts. 152-53, 156, 158, 162).

311. NRC 2000 REPORT, *supra* note 4, at 150.

312. See 40 C.F.R. § 152.20a (2001); Regulations Under FIFRA, *supra* note 296, 66 Fed. Reg. at 37,774.

313. See 7 U.S.C. § 136(bb). The registration process requires submission of information on the potential beneficial or adverse effects of the pesticide on human health and the environment. *Id.* § 136a(c)(2).

314. 21 U.S.C. § 346a (2000).

315. See Exemption from the Requirement of a Tolerance, 40 C.F.R. § 180.1155 (2001).

316. For example, it does not regulate herbicide-resistant or disease-resistant plants.

tural safety of the movement, importation, and field testing of transgenic plants.

In order to grow transgenic plants outside of a laboratory, approval must be obtained from the Animal and Plant Health Inspection Service (APHIS) of the USDA. APHIS' authority to regulate genetically modified plants stems from the Plant Protection Act (PPA).<sup>317</sup> The PPA was enacted in 2000, and thus, at first glance, appears to deviate from the trend of regulating biotechnology under ancient statutes. The PPA, however, essentially consolidated authority from two previous statutes that APHIS had used to regulate genetically modified organisms: the Federal Plant Pest Act (FPPA),<sup>318</sup> enacted in 1957, and the Federal Plant Quarantine Act (PQA),<sup>319</sup> enacted in 1912. Both the FPPA and PQA were originally enacted to regulate the introduction of nonindigenous plant species.<sup>320</sup> APHIS regulations governing genetically modified plants under the PPA are simply those established pursuant to the FPPA and the PQA.<sup>321</sup> No modification to APHIS' regulation of biotechnology products has been made pursuant to the PPA.<sup>322</sup>

Pursuant to the PPA, APHIS has primary regulatory authority for all genetically modified plants except pest-protected ones.<sup>323</sup> As APHIS is supposed to carry out its mandate while not impeding the growth of the biotechnology industry,<sup>324</sup> critics have contended that an agency charged with promoting agriculture (including the

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317. 7 U.S.C. §§ 7701-7772 (2003).

318. 7 U.S.C. §§ 150aa-150jj (1994).

319. *Id.* §§ 151-164, 166-167.

320. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,342-43 (June 26, 1986).

321. *See* Plant Protection Act, Revisions to Authority Citations, 66 Fed. Reg. 21,049 (Apr. 27, 2001) (revising the genetically modified plant regulations to change authority citations to the PPA without substantively changing the regulations); TAYLOR & TICK, *supra* note 20, at 25. The PPA was enacted as part of the Agricultural Risk Protection Act of 2000, pursuant to H.R. 2559. There was no Senate or House debate on the PPA portions of H.R. 2559, and there is little legislative history to indicate what Congress' intent was with respect to genetically modified plants when it passed the PPA.

322. Where APHIS has promulgated new regulations subsequent to the enactment of the PPA, such regulations have not differed "from what [APHIS] would have proposed under the authority of th[e] applicable provisions of law that were repealed by the Plant Protection Act." Plant Pest Regulations, Update of Current Provisions, 66 Fed. Reg. 51,340 (Oct. 9, 2001); *see* TAYLOR & TICK, *supra* note 20, at 25.

323. NRC 2002 REPORT, *supra* note 2, at 101.

324. *Id.* at 49.

biotechnology industry), “may not be able to objectively assess the safety of new products of agricultural biotechnology.”<sup>325</sup>

Under the PPA, anyone seeking to introduce (i.e., import, transport interstate, or release into the environment)<sup>326</sup> a regulated article must receive authorization from APHIS.<sup>327</sup> “Regulated article” includes

[a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 [a list of known plant pests] and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which [APHIS] determines is a plant pest....<sup>328</sup>

A “plant pest” includes a wide variety of organisms “which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof.”<sup>329</sup> This definition is very broad—any species that interacts ecologically with a plant likely could be considered to indirectly injure or damage it.<sup>330</sup>

Prior to conducting a field trial of a new transgenic plant, a developer must perform a risk evaluation on the plant to determine whether the plant may be a plant pest. No consideration of any other risks, such as other human health or environmental risks, must be evaluated prior to the field test.<sup>331</sup>

Authorization from APHIS can come via a notification or permitting process, each of which is aimed at ensuring that the

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325. *Id.* at 19.

326. “Environmental release” is the use of a regulated article outside the physical constraints of a laboratory, contained greenhouse, or other contained structure. Definitions, 7 C.F.R. § 340.1 (2003).

327. Restrictions on the Introduction of Regulated Articles, 7 C.F.R. § 340.0 (2003).

328. 7 C.F.R. § 340.1. Note that this definition is explicitly based on the organism’s having been developed through genetic engineering; i.e., it regulates based on the process by which the article was produced, not based on the product. One result of the taxonomic list restriction is that vertebrates cannot be considered plant pests. Groups of Organisms Which Are or Contain Plant Pests, 7 C.F.R. § 340.2 (2003).

329. 7 C.F.R. § 340.1.

330. *Id.*

331. 7 C.F.R. § 340.0.

transgenic organisms are grown and handled in a manner to prevent their escape into the environment. For most genetically modified plants, under certain conditions, simple notification of APHIS prior to release (without the requirement of receiving a permit) is sufficient.<sup>332</sup> Nearly 99% of all field tests, importations, and interstate movement of genetically engineered plants take place under the notification system.<sup>333</sup>

Permits are required for the movement, importation, and field testing of transgenic plants that do not qualify for notification, such as pharmaceutical-producing plants, and for plants denied notification.<sup>334</sup> APHIS uses the permitting process to evaluate potential plant pest risk and to require prevention measures to reduce risk.<sup>335</sup> The primary emphasis of the permitting process is confinement.<sup>336</sup>

An applicant can petition APHIS to determine that a certain genetically modified plant is not a plant pest (essentially that the regulated article is free from the risks outlined above), and therefore should be given "nonregulated status."<sup>337</sup> Plants granted nonregulated status, as well as their progeny, are no longer subject to any APHIS oversight—they may be freely planted, transported, and sold.<sup>338</sup> This process is the sole manner in which transgenic plants can be commercialized, and the primary, though not sole, route through which the products of transgenic plants can be

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332. Notification for the Introduction of Certain Regulated Articles, 7 C.F.R. § 340.3 (2003). The notification process applies to a specified list of plants and characteristics. Requirements include: confinement; that the plant not be listed as a noxious weed or considered a weed in the area of release; that the inserted gene be stably integrated; that the function of the inserted gene be known; that the inserted gene's expression not result in plant disease; that the inserted gene be derived from human or animal viral pathogens; and that the inserted gene does not cause the production of an infectious entity, encode for substances likely to be toxic to nontarget species or to feed on the plant, or encode for products intended for pharmaceutical use. NRC 2002 REPORT, *supra* note 2, at 108-09.

The applicant must notify APHIS of its intent to release a regulated article. APHIS staff reviews the notification for qualification and completeness, and then sends a recommendation to state officials for concurrence. The entire process must be completed in ten days for interstate movement, and thirty days otherwise. 7 C.F.R. § 340.3.

333. CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN, *supra* note 73, at 4.

334. NRC 2002 REPORT, *supra* note 2, at 110.

335. *Id.*

336. *Id.*

337. Petition for Determination of Nonregulated Status, 7 C.F.R. § 340.6 (2003).

338. *Id.* Prior to receiving nonregulated status, APHIS must conduct an Environmental Assessment pursuant to NEPA. 42 U.S.C. § 4332 (2000); 40 C.F.R. §§ 1500-1508 (2003).

commercialized (e.g., sale of an industrial protein derived from a plant).<sup>339</sup>

APHIS regulates transgenic pharmaceutical-producing plants pursuant to the same authority under which it regulates other transgenic plants, such as "regulated articles" under the PPA.<sup>340</sup> Thus, applicants must acquire a permit prior to the field test of transgenic pharmaceutical-producing plants, as such plants are specifically excluded from the notification process.<sup>341</sup> Various measures must then be taken to confine the transgenic plants to the field site during the period of release, and to prevent the plants or their offspring from persisting in the environment subsequently.<sup>342</sup>

With respect to biotechnology developments beyond plants, the Food Safety and Inspection Service (FSIS) of the USDA is responsible for the safety of food products prepared from domestic livestock and poultry.<sup>343</sup> The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) require FSIS to inspect cattle, sheep, swine, goats, equines, poultry, and food products prepared from them, which are intended for use as human food.<sup>344</sup> Pursuant to these acts, the FSIS has regulatory authority over genetically modified domestic livestock and poultry.

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339. NRC 2002 REPORT, *supra* note 2, at 111. "[C]ommercial products have also been created from regulated transgenic [plants]." *Id.* at 120. APHIS has deregulated many genetically modified crops. For a list of the deregulated plants, as well as pending deregulation petitions, see APHIS, PETITIONS OF NONREGULATED STATUS GRANTED OR PENDING (last updated Mar. 30, 2004), at [http://www.aphis.usda.gov/brs/not\\_reg.html](http://www.aphis.usda.gov/brs/not_reg.html) (last visited Apr. 12, 2004).

340. Restrictions on the Introduction of Regulated Articles, 7 C.F.R. § 340.0 (2003)

341. Permits for the Introduction of a Regulated Article, 7 C.F.R. § 340.4 (2003).

342. Notification for the Introduction of Certain Regulated Articles, 7 C.F.R. § 340.3 (2003). Earlier regulations required that the pharmaceutical-producing plants be isolated by a 1320-foot buffer from other plants in order to prevent cross-pollination, a distance twice that used to assure purity of their seeds. Minimum Land, Isolation, Field, and Seed Standards, 7 C.F.R. § 201.76 (2003); Pollack, *supra* note 22, at A1. Regulations proposed by APHIS would increase the buffer zone to one-half to one mile depending on certain factors. Field Testing of Pharmaceutical Plants, *supra* note 23, 68 Fed. Reg. at 11,338.

Other protective techniques are being developed. These include implanting a gene to turn the pharmaceutical-producing plant a different color and harvesting the pharmaceutical-producing plants before sexual maturity. Pollack, *supra* note 22, at A1.

343. See 21 U.S.C. §§ 451, 601, 1031 (2003) (granting the FSIS administrator the authority to regulate the safety of domestic livestock, poultry, and poultry products); Purpose, 9 C.F.R. § 300.1 (2003); FSIS Responsibilities, 9 C.F.R. § 300.2 (2003); FSIS Organization, 9 C.F.R. § 300.3 (2003) (establishing the FSIS within the USDA).

344. 21 U.S.C. §§ 451, 601, 1031.

APHIS also has regulatory authority over the release of insects for pest management,<sup>345</sup> and presumably would regulate the release of transgenic insects in the same manner. No agency regulates research and commercialization of transgenic insects other than for their intentional release, and no guidelines exist that govern their containment or the potential ecological risks posed by their release.<sup>346</sup>

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As evidenced by the preceding analysis, the statutory structure under which biotechnological products are regulated in the United States is based on legislation enacted decades ago, long before transgenic products were scientifically conceivable. As a result of dated statutes, and decisions made in the Coordinated Framework and thereafter, the regulations governing genetically modified products have been developed in a piecemeal, haphazard manner. Genetically modified plants and animals are now governed by as many as twelve different statutes and five different agencies or services.<sup>347</sup>

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345. 7 U.S.C. § 7701 (2003); Authority of the Secretary to Delegate Authority, 7 C.F.R. § 2.3 (2003); Under Secretary for Marketing and Regulatory Programs, 7 C.F.R. § 2.22 (2003); Administrator, Animal and Plant Health Inspection Service, 7 C.F.R. § 2.80(a)(51) (2003).

346. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 21, 88-89, 114. For a discussion of how certain existing statutes could be applied to transgenic insects, see BUGS IN THE SYSTEM, *supra* note 91.

347. See Table 1, *infra*.

**Table 1**  
**Regulatory Authority over Transgenic**  
**Plants and Animals<sup>348</sup>**

USE	STATUTE	AGENCY
Food and food additives Meat, poultry, egg products Pesticide residues	FFDCA FMIA, <sup>349</sup> PPIA, <sup>350</sup> EPIA <sup>351</sup> FFDCA	FDA FSIS EPA
Production of pharmaceuticals Human drugs Human biologics Animal drugs Animal biologics	FFDCA PHS Act, <sup>352</sup> FFDCA FFDCA AQL, <sup>353</sup> VSTA <sup>354</sup>	FDA FDA FDA APHIS
Production of pesticidal substances in plants	FIFRA PPA	EPA APHIS
Production of plant herbicide- tolerance Herbicide usage on plants	PPA FIFRA	APHIS EPA
Biocontrol of plants	PPA FIFRA	APHIS EPA
Biocontrol of plant pests	PPA FIFRA	APHIS EPA
Biomedical research on animals	AWA <sup>355</sup> HREA <sup>356</sup>	APHIS NIH <sup>357</sup>

348. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 162-64; CEQ AND OSTP ASSESSMENT, *supra* note 49, at 6. This Table lists the common uses of genetically modified plant and animal products, the statutes under which they are regulated, and the regulating agency under each statute. A careful reader will note that this Table lists only eleven statutes. As discussed elsewhere in this Article, the Animal Health Protection Act (AHPA) (enacted in 2002) may represent the twelfth statutory authority concerning genetically modified plants and animals. *See infra* note 371.

349. Federal Meat Inspection Act, 21 U.S.C. §§ 601-691 (2003).

350. Poultry Products Inspection Act, 21 U.S.C. §§ 451-471 (2003).

351. Egg Products Inspection Act, 21 U.S.C. §§ 1031-1056 (2003).

352. Public Health Service Act, 42 U.S.C. §§ 262, 264 (2003).

353. Animal Quarantine Laws, 21 U.S.C. §§ 101-135 (2003).

354. Virus, Serums, and Toxins Act, 21 U.S.C. §§ 151-159 (2003).

355. Animal Welfare Act, 7 U.S.C. §§ 2131-2159 (2003).

356. Health Research Extension Act, 42 U.S.C. §§ 201-300gg-92 (2003).

357. National Institutes of Health.



The multiplicity of statutes and agencies regulating biotechnology has created confusion among the regulated industries and the public, reduced clarity regarding scientific standards and requirements, and retarded the efficiency of biotechnology development and regulation. Not surprisingly, this fractured approach to regulation has led to numerous problems. Some of these problems were made evident in the case studies, some are evident from the preceding analysis of agency authority, and others are revealed through additional investigation. These regulatory problems are discussed and categorized in the following section.

#### V. REGULATORY GAPS, INCONSISTENCIES, INEXPERIENCE, AND OVERLAPS

The statutory and regulatory regime for genetically modified products described in the preceding section only partially reveals how these products are actually regulated in practice. In practice, the quality of transgenic product regulation is affected by issues of agency financial and personnel resources, agency priorities, agency decision-making structures, the quality of and reliance on in-house and third-party research, agency capture, political pressure, and other factors. The case studies discussed in Part III provide insight into the actual application of genetically modified product regulation. The following section provides examples of additional regulatory issues that have arisen, and weaves this analysis into a framework for understanding the types of deficiencies that are present in the regulation of genetically modified products.

In order to better understand these deficiencies, and to work towards their cure, it is useful to categorize them. The following four categories cover most of the regulatory problems concerning transgenic products identified in this Article: gaps in regulation or regulatory authority; overlaps in regulation or regulatory authority; inconsistencies among agencies in their regulation of similarly situated or identical products; and instances of agencies acting outside of their areas of expertise.

Gaps are a problem because of the potential for harm to human health or the environment. Overlaps cause a dead-weight loss on multiple fronts: for the regulated industry which has to fulfill

uplicative requirements; for government and, therefore, taxpayers who must pay more than the necessary cost of regulation; and for society for whom the development and commercialization of transgenic products is inefficiently delayed. Inconsistencies are not only irrational, but they also create a dead-weight loss for industry trying to comply with the regulations, and they may delay the development of valuable products. Lastly, instances of agencies acting outside their areas of expertise are inefficient and unreasonably increase the risk posed to society by genetically modified products. Each of these categories of deficiencies is discussed in turn.

### *A. Regulatory Gaps*

#### *1. Gaps in Environmental Review*

The most striking incidence of regulatory gaps with regard to genetically modified products is the lack of EPA involvement in the review and approval of numerous products that could have a significant impact on the environment. As the salmon case study demonstrates, the most significant risks posed by the introduction of genetically modified fish are likely environmental. The EPA, however, has determined that it does not have regulatory authority over these products. The EPA also has no role in the approval or field-testing and widespread planting of genetically modified plants other than those modified to be pest-protected. Thus, the EPA is not evaluating the potential impact of transgenic pharmaceutical-producing, industrial compound-producing, herbicide-tolerant, drought-tolerant, salinity-tolerant, virus-resistant, temperature-tolerant, or disease-resistant plants on the environment.

That the majority of types of genetically modified plants are not subject to environmental evaluation by the agency charged with protecting the nation's environment is one problem. Whether the plants are subjected to any appropriate environmental review is another. APHIS does not conduct environmental assessments of transgenic plants submitted through the notification process,<sup>358</sup>

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358. NRC 2002 REPORT, *supra* note 2, at 123. APHIS assumes genetically modified plants released into the environment pursuant to the notification process to be environmentally safe based upon the notification criteria and efforts required to minimize the chance of escape in

which is currently the dominant route for the field-testing of new genetically engineered plants.<sup>359</sup>

Most troubling, the sufficiency of the environmental testing that APHIS does engage in is questionable. The National Research Council recently criticized certain APHIS environmental risk assessments for "lack[ing] scientific rigor, balance, and transparency,"<sup>360</sup> for containing an analysis that was "weak and inconsistent,"<sup>361</sup> for failing to evaluate potential impacts on nontarget organisms, for failing to consider the interactions between multiple transgenic traits, and for failing to utilize all available scientific data and information.<sup>362</sup> APHIS also has been criticized for "relying too heavily on existing scientific literature rather than requiring applicants [for notification] to develop new experimental data" relevant to the risks posed by the pertinent genetically modified plants being reviewed.<sup>363</sup> The EPA, with numerous experts trained in and routinely performing environmental risk assessments, almost assuredly would not have run into the same difficulties as APHIS.<sup>364</sup>

The concerns raised by the existing gaps in environmental review will be exacerbated with next-generation biotechnology developments. In addition to transgenic fish, the FDA, not EPA, has authority to review the environmental impacts of transgenic farm animals modified to produce human drugs.<sup>365</sup> The EPA also lacks

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the field. *Id.*

359. See *supra* text accompanying note 333.

360. NRC 2002 REPORT, *supra* note 2, at 148.

361. *Id.* at 149.

362. *Id.* at 148-53, 160-66, 235. These criticisms were based on concerns that APHIS had ignored certain scientific information it had reviewed, reached contradictory conclusions on related analyses, relied on explanatory information as predictive, assumed that a lack of reported problems was evidence that problems had not occurred, used data inconsistently, failed to consider alternate options, and failed to consider interactions between different traits. *Id.*

363. Kunich, *supra* note 134, at 840.

364. Nevertheless, the EPA has been criticized for environmental scientific failures of its own, such as that demonstrated in the Monarch Butterfly case study. See *supra* Part III.C.; see also EPA, REPORT: FIFRA SCIENTIFIC ADVISORY PANEL MEETING, SAP REPORT NO. 99-06 (2000), available at <http://www.epa.gov/scipoly/sap/1999/december/report.pdf> (last visited Oct. 29, 2003) (criticizing the EPA's nontarget insect data requirements for genetically modified pest-protected plants as being inadequate).

365. CASE STUDY NO. IV: FARM ANIMAL THAT PRODUCES HUMAN DRUGS, *supra* note 30, at 7.

authority over the environmental and ecological impacts of transgenic insects.<sup>366</sup> The FDA and APHIS, not the EPA, are the agencies that review the environmental impacts of pharmaceutical-producing and industrial compound-producing plants.<sup>367</sup> As discussed above, whether APHIS has the capacity to conduct sufficient environmental reviews is questionable. For similar reasons, it is also unclear whether the FDA has the expertise necessary to evaluate adequately the environmental risks posed by biotechnology.<sup>368</sup> The FDA is not an environmental agency and lacks expertise in critical areas concerning environmental impacts such as ecology and evolutionary biology.<sup>369</sup> Even if the FDA's environmental assessments are adequate, it is unclear whether the FDA possesses authority to deny certain applications on the basis of environmental risk.<sup>370</sup> With new biotechnological developments fast approaching, it is imperative that these environmental gaps be closed.

## 2. Gaps Beyond Environmental Review

Regulatory gaps exist with respect to various agencies' authority beyond the concerns raised by inadequate environmental review:

- It is unclear whether any agency has regulatory authority over transgenic animals not intended for human food or to produce human biologics.<sup>371</sup>

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366. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 21.

367. CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN, *supra* note 73, at 52-53.

368. FUTURE FISH, *supra* note 25, at 54-55.

369. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 114-15.

370. Gregory Jaffe, *Coordinated Framework: Structure Needs an Overhaul*, ENVTL. F., May/June 2002, at 24.

371. CASE STUDY NO. IV: FARM ANIMAL THAT PRODUCES HUMAN DRUGS, *supra* note 30, at 14. It is possible that APHIS could exercise authority pursuant to the Animal Health Protection Act of 2002 (AHPA), 7 U.S.C. §§ 8301-8320 (1999 & Supp. 2003), to regulate genetically modified animals, to the extent such animals may affect the health of livestock (in much the same manner as APHIS regulates genetically modified plants based on their plant pest threat). APHIS authority turns on the meaning of "disease" under AHPA, a term to be defined by the Secretary of Agriculture. *Id.* § 8302(3). The Secretary may be able to define disease in such a manner as to include genetic modification of animals, although this would not be consistent with how the Secretary has defined the term previously, so whether such a definition would survive judicial review is not clear. *See, e.g.*, Definitions, 7 C.F.R. § 319.59-1 (2003) (defining "disease" in another agricultural context to include "its common

- Once APHIS grants a petition for nonregulated status for a transgenic plant, it no longer has any authority over the plant or its progeny, for instance to monitor for unexpected impacts.<sup>372</sup>
- There is no requirement that a manufacturer notify the FDA prior to the commercial introduction of a new genetically modified product.<sup>373</sup> The FDA's promulgation two years ago of a proposed regulation that would require notification recognized that this gap was a problem.<sup>374</sup>
- EPA lacks regulatory authority over the growers of pest-protected plants (its authority extends only to the producers of such plants).<sup>375</sup>
- Many APHIS requirements pertaining to preventing the environmental release of transgenic plants do not cover the release or movement of pollen.<sup>376</sup>
- Some genetically modified plants are not regulated on the basis that their modified trait has been conventionally bred into plants as well; this decision lacks scientific justification as the genetic modification may cause different effects than those caused by conventional breeding.<sup>377</sup>
- APHIS lacks the statutory authority to regulate genetically modified vertebrate plant pests and all organisms free of genetic material from plant pests.<sup>378</sup>

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meaning [and] a disease agent which incites a disease"). In addition, the legislative history of the AHPA is quite sparse and does not indicate that such a broad interpretation was intended.

372. NRC 2002 REPORT, *supra* note 2, at 111, 233. In addition, if these progeny are mated conventionally with other nonregulated transgenic plants carrying different transgenes, the offspring also will be considered nonregulated, even though they will contain combinations of transgenes never reviewed. These combinations could have pleiotropic effects. *Id.*

373. *See supra* Part IV.B.

374. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709-12 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592) (proposed rule requiring premarket notification of FDA of new genetically modified products).

375. TAYLOR & TICK, *supra* note 20, at 35.

376. NRC 2002 REPORT, *supra* note 2, at 109; APHIS, USER'S GUIDE FOR INTRODUCING GENETICALLY ENGINEERED PLANTS AND MICROORGANISMS (1997) [hereinafter APHIS, USER'S GUIDE], available at <http://www.aphis.usda.gov/bbep/bp/usergd.html> (last visited Apr. 7, 2004).

377. *See* NRC 2002 REPORT, *supra* note 2, at 86 (arguing that the failure to regulate crops conventionally bred to contain certain traits does not justify not regulating crops genetically engineered to contain the same trait).

378. Kunich, *supra* note 134, at 840.

A cross-agency deficiency results from agencies' reliance on the developer's planned use for their transgenic product as the trigger for regulation, as opposed to basing regulation on the actual characteristics of the product. For example, the EPA regulates a transgenic plant under its pest-protected plant rules only if the developer of the plant plans for it to be used for its pesticidal effects. Thus, the EPA does not regulate a transgenic corn variety modified to produce a known pesticide because the developer is developing the corn for purposes other than pest resistance, in this instance for medical diagnostic procedures.<sup>379</sup> Similarly, for purposes of determining whether field-testing of a transgenic plant meets APHIS's notification criteria, a modification is only considered to be for a pharmaceutical use if clinical testing of the product is proposed to the FDA.<sup>380</sup> Thus, the developer of the product, as opposed to APHIS, determines whether these types of transgenic plants may be prohibited from notification approval.

Other gaps exist in APHIS' notification and permitting processes. APHIS regulations state that a transgenic plant is not eligible for testing or commercialization under the notification process if the transgenes "[e]ncode substances that are known or likely to be toxic to nontarget organisms."<sup>381</sup> APHIS, however, defines "toxicity to nontarget species" to apply only to species that feed on the plant, not on dispersed plant parts, such as seeds, pollen, or plant residue.<sup>382</sup> Further, allergenicity is not one of the factors considered in approving a notification.<sup>383</sup> As discussed above, under the notification process, there is no limit to the amount of genetically modified product that can be planted or commercialized.<sup>384</sup> It therefore would be possible under the notification process to grow vast quantities of genetically engineered crops that have toxic plant

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379. NRC 2002 REPORT, *supra* note 2, at 180.

380. See APHIS, USER'S GUIDE, *supra* note 376.

381. Notification for the Introduction of Certain Regulated Articles, 7 C.F.R. § 340.3(b)(4)(ii) (2003).

382. NRC 2002 REPORT, *supra* note 2, at 180-81.

383. *Id.* at 181.

384. See *id.* at 180-81.

parts or may be allergenic.<sup>385</sup> This scenario appears to have occurred in at least one instance.<sup>386</sup>

Relatedly, under APHIS' permit process, APHIS can request additional information from applicants, but cannot require the requested information.<sup>387</sup> This deficiency may become critical as the permit process is expected to be the primary route for the commercial production of pharmaceutical-producing plants.

Regulatory gaps also exist with respect to the failure to properly inform growers regarding the proper manner for use and containment of genetically modified crops. This failure is a root cause of the contamination that occurred in both the ProdiGene and StarLink scenarios.<sup>388</sup> Critics also have noted it as a problem with regard to the proper planting of refuge areas so as to reduce the incidence of pesticide resistance.<sup>389</sup> Part of this deficiency stems from a failure of agencies to exercise their full regulatory authority, and part stems from regulators lacking authority over all entities involved in the use of biotechnological products.

The numerous regulatory gaps identified above unnecessarily increase the risk posed by genetically modified products. In addition, they increase the likelihood of future high-profile transgenic product scares that could both reduce public trust in the regulatory system and cause public opinion to coalesce against genetically modified products. In either case, this would prevent society from harvesting the optimum benefit of such products.

### *B. Regulatory Inconsistencies*

The Coordinated Framework in 1986 identified two primary priorities: that the agencies regulating genetically modified products "adopt consistent definitions" of genetically modified

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385. *See id.* at 181.

386. *See id.* at 180-81. This instance involves transgenic corn that produces the glycoprotein avidin. *Id.* Avidin is potentially toxic to a broad array of organisms, both in the field and after harvest. *Id.* The National Research Council "questions the wisdom of allowing such plants to be grown under the streamlined notification system." *Id.* at 182.

387. NRC 2002 REPORT, *supra* note 2, at 110; *see also* Permits for the Introduction of a Regulated Article, 7 C.F.R. § 340.4 (2003).

388. *See supra* Parts III.A, III.D.

389. *See* Bratspies, *supra* note 151, at 343-46 (discussing farmers' noncompliance with refuge requirements); JAFFE, *supra* note 151, at 5-6 (providing data on the number of farms out of compliance with refuge requirements in various states).

organisms and that the agencies implement scientific reviews of "comparable rigor" in their regulation of transgenic products.<sup>390</sup> Neither priority has been met.

As a result of constraints created by primary reliance on statutes that predate the advent of biotechnology, each of the three agencies involved in the regulation of genetically modified products defines identical regulatory constructs differently. Pest-protected plants provide an example of a genetically modified product over which all three agencies have regulatory authority. As Table 2 shows, each of the agencies identify the regulated product and define the regulated substance differently.

**Table 2**  
**Inconsistent Agency Definitions of**  
**Pest-Protected Plants**<sup>391</sup>

	<b>EPA</b>	<b>USDA</b>	<b>FDA</b>
<b>Regulated Product</b>	Plant-Incorporated protectant	Plant pest, regulated article	Food, feed, food additive
<b>Regulated Substance</b>	Pesticidal substance and genetic material necessary for its production	Organism engineered to contain sequences from plant pests	Human food (whole or processed), animal feed

With respect to the second priority, the National Research Council has specifically noted that the data on which the EPA and APHIS base their analyses, and the scientific stringency with which they conduct their analyses, are not comparably rigorous.<sup>392</sup> APHIS' risk assessment model may, in fact, bias it toward a finding of no

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390. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (June 26, 1986).

391. NRC 2000 REPORT, *supra* note 4, at 159 (the table reproduced above has been modified to reflect changes to agency definitions since the table was originally published). The Coordinated Framework recognized from the outset that achieving consistent definitions would not always be possible because of statutory constraints. *See, e.g.*, 51 Fed. Reg. at 23,303 (stating that as a result of existing law, some definitions between agencies may seem inconsistent). The failure to achieve this goal, therefore, is not necessarily the result of a lack of effort on the agencies' part. It does, however, demonstrate the difficulty of promulgating consistent regulations based on statutes enacted to handle different products.

392. *See* NRC 2000 REPORT, *supra* note 4, at 170-71.



significant risk.<sup>393</sup> Thus, close to two decades after the Coordinated Framework was established, neither of its priorities, both of which were aimed at consistency, have been achieved.

Other substantial regulatory inconsistencies exist. Genetically engineered pest-protected crops require premarket approval if they are intended to be used for their pest-protection properties, pursuant to EPA regulations;<sup>394</sup> all other genetically engineered food crops do not require premarket approval, including those crops modified to express a known pesticide, so long as the developer is producing the crop for another purpose, as they are subject to the FDA's voluntary consultation process.<sup>395</sup> This differentiation lacks a sound basis in science, logic, or public policy.

In another example, when APHIS granted nonregulated status to certain Bt crops, it did so on the basis that EPA regulations would adequately prevent Bt resistance from arising in plant pests.<sup>396</sup> APHIS, however, granted nonregulated status prior to the EPA's registration process, and did not follow-up to check that the EPA had promulgated the anticipated regulations.<sup>397</sup> Once APHIS granted nonregulated status, manufacturers and growers had no obligation to track or keep track of the genetically modified product, thereby limiting the EPA's ability to gather data and information on the impacts that APHIS expected the EPA to prevent through regulation in the first instance.<sup>398</sup>

The regulatory inconsistencies identified in this section are irrational and introduce substantial inefficiencies and unreasonable risks into genetically modified product regulation.<sup>399</sup>

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393. NRC 2002 REPORT, *supra* note 2, at 98.

394. *See supra* notes 313-16 and accompanying text.

395. *See supra* text accompanying notes 287-89; *see also* Affirmation of Generally Recognized As Safe (GRAS) Status, 21 C.F.R. § 170.35 (2003).

396. *See* Bratspies, *supra* note 151, at 324-25.

397. *See id.* at 325.

398. *See id.* at 325-26.

399. Instances in which agencies' regulatory authority overlap, but the agencies have reached different conclusions regarding the regulation of transgenic products, also demonstrate inconsistencies. *See infra* Part V.D.

*C. Regulatory Inexperience*

The StarLink corn case study highlights both an example of an agency acting outside of its area of expertise and the potentially disastrous effects of such action. Had the EPA, or likely the FDA, been familiar with the nation's agricultural system, it would have recognized that it was impossible for StarLink corn to be kept fully segregated from corn used for human food.<sup>400</sup> This lack of knowledge led to the most infamous transgenic food scare to date.

The numerous instances discussed above of agencies other than the EPA bearing responsibility for the environmental review of genetically modified products also present situations in which agencies are acting in areas outside of their expertise. These examples include: (1) the USDA and the FDA regulating the environmental impact of genetically modified plants other than those modified to produce their own pesticide,<sup>401</sup> (2) the FDA regulating the environmental impact of genetically modified fish and animals,<sup>402</sup> and (3) APHIS likely regulating the environmental impact of transgenic insects.<sup>403</sup> The salmon case study demonstrates the problems caused by the second deficiency. The first deficiency has led to difficulties of its own. For instance, APHIS' analysis of the likelihood of virus-resistant genes spreading from squash to weedy relatives has been criticized for not being well supported by scientific studies and for lacking necessary data.<sup>404</sup> In part, these deficiencies were perceived to come about as the result of "inadequate expertise [at APHIS] in population genetics."<sup>405</sup>

Lack of expertise and experience has led to other problems. The Monarch butterfly case study<sup>406</sup> reveals that agencies have failed to fully grasp the potential varied impact of genetically engineered products. In this instance, regardless of whether the Bt pollen

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400. See *supra* notes 217-18 and accompanying text.

401. See *supra* notes 295-96, 323 and accompanying text.

402. See *supra* notes 297-99 and accompanying text.

403. See *supra* notes 345-46 and accompanying text.

404. See NRC 2002 REPORT, *supra* note 2, at 134-35; NRC 2000 REPORT, *supra* note 4, at 122-25.

405. NRC 2002 REPORT, *supra* note 2, at 134.

406. See *supra* Part III.C.

actually poses a risk, the EPA's assumptions concerning the threat of transgenic pollen were scientifically unsound.<sup>407</sup>

Perhaps similarly stemming from inexperience, isolation distances required by APHIS for test plots of transgenic crops have been criticized as not being scientifically justifiable.<sup>408</sup> APHIS appears to have derived a required isolation distance, intended to establish a zero tolerance for contamination simply by doubling the isolation distance used by the USDA in another regulatory context in which a contamination level of 0.1% was acceptable.<sup>409</sup> There was no evidence that doubling the isolation distance would reduce the anticipated level of contamination from 0.1% to zero.<sup>410</sup> As discussed above, long distance pollen flow is poorly understood.<sup>411</sup> Pollen does appear to travel at least several kilometers, many times the isolation distance at issue.<sup>412</sup> Some have cited contamination by pollen flow as part of the cause of the StarLink fiasco.<sup>413</sup>

These problems of regulatory inexperience and agencies acting in areas beyond their expertise not only result in significant inefficiencies, but also dramatically and unnecessarily increase the risk posed by genetically modified products.

#### *D. Regulatory Overlaps*

Several types of regulatory overlap exist in the current regulatory structure. The first overlap concerns situations in which different agencies have authority over similar issues. For example, the EPA addresses food safety issues associated with plants genetically modified to produce their own pesticide,<sup>414</sup> whereas the FDA

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407. See *supra* notes 245-50 and accompanying text.

408. See NRC 2002 REPORT, *supra* note 2, at 125.

409. See *id.* at 125.

410. *Id.*

411. See *supra* note 125 and accompanying text.

412. Compare Minimum Land, Isolation, Field, and Seed Standards, 7 C.F.R. § 201.76 (2003) (stating the required isolation distances for various crops), with NRC 2000 REPORT, *supra* note 4, at 91 (discussing a study which found pollen dispersed as far as three kilometers from its source). Currently proposed regulations would increase the buffer zone for corn to between a half mile and one mile, depending on certain other factors. See *supra* note 342.

413. See, e.g., McGarity, *supra* note 8, at 487 ("Still others claimed that they had innocently sold elevators StarLink®-contaminated corn when the corn they planted became cross-fertilized by StarLink® corn from neighboring fields.").

414. See *supra* notes 313-16 and accompanying text.

addresses similar food safety issues for all other genetically modified plants.<sup>415</sup> There is no scientific rationale for this distinction. It is the result of the historical accident of transgenic pest-protected plants falling within FIFRA's statutory language.

Similarly, both the EPA and APHIS conduct overlapping reviews regarding the impact of pest-protected plants on nontarget species. The EPA studied the potential impact of Bt corn on butterflies to determine the effect of the pesticide on nontarget species, whereas APHIS studied the potential impact of Bt corn on butterflies to determine whether it would lead to a reduced butterfly population.<sup>416</sup> A reduced butterfly population was considered a potential plant pest risk as it could allow greater growth of weeds that the butterflies feed on.<sup>417</sup> In each instance, the result is that regulatory expertise and effort is inefficiently duplicated in multiple agencies.

A second type of regulatory overlap occurs where multiple agencies request the same information about the same biotechnological product, but do not share the information. For instance, though APHIS reviews genetically modified herbicide-tolerant plants and the EPA reviews the herbicide that will be applied, these reviews have not been coordinated.<sup>418</sup>

The worst case scenario for overlaps is for agencies to reach different conclusions concerning the same product. Such a result has occurred. Both APHIS and the EPA reviewed the potential for transgenic cotton to cross with wild cotton in parts of the United States. APHIS concluded that "[n]one of the relatives of cotton found in the United States ... show any definite weedy tenden-

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415. See *supra* notes 295-96 and accompanying text.

416. See CASE STUDY NO. II: BT-MAIZE, *supra* note 36, at 32 (presenting an example of overlap between the EPA and APHIS); NRC 2002 REPORT, *supra* note 2, at 72-74; NRC 2000 REPORT, *supra* note 4, at 163-65 (concluding that there is substantial overlap in this area); see also Regulations Under FIFRA, *supra* note 296, 66 Fed. Reg. at 37,775 (recognizing the potential for duplicative regulation in this area). In certain instances, it has been unclear whether APHIS was acting independently of the EPA, possibly producing differing levels of regulatory scrutiny, or whether APHIS lacked requisite expertise and was relying on the EPA's determinations. See NRC 2002 REPORT, *supra* note 2, at 157.

417. See NRC 2002 REPORT, *supra* note 2, at 72.

418. See CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN, *supra* note 73, at 17-18 (stating that although APHIS and the EPA are working on coordinating efforts, currently, there are no formal exchanges between the two agencies on this subject).

cies.”<sup>419</sup> EPA, conversely, found that there would be a risk of transgenic cotton crossing with species of wild cotton in southern Florida, southern Arizona, and Hawaii.<sup>420</sup>

Regulatory overlap in the area of genetically modified products has led to inefficient duplicative expertise and review, and to conflicting conclusions.

## VI. THE CAUSE AND THE CURE OF THE REGULATORY DEFICIENCIES

As demonstrated above, under the existing statutory and regulatory structure governing genetically modified products, administrative agencies lack the necessary and proper authority, act in areas outside their expertise, and regulate in conflicting and inconsistent manners. This section discusses the causes of these problems and provides proposals for curing them.

### *A. The Coordinated Framework Revisited*

The cause of many of the deficiencies identified can be traced to the 1986 Coordinated Framework for Regulation of Biotechnology. Specifically, the deficiencies can be traced to two problematic presumptions that formed the Coordinated Framework’s foundation: (1) that the techniques of biotechnology are not inherently risky, and (2) that biotechnology should not be regulated as a process—that is, that the products of biotechnology should be regulated in the same manner as conventionally created products.<sup>421</sup> Though both of these presumptions contain significant truthful elements, an absolutist statement of and belief in them has had long term deleterious effects.

The consequence of these presumptions is the existing statutory scheme in which bioengineered products are regulated under laws

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419. JOHN H. PAYNE, USDA/APHIS PETITION 97-013-01P FOR DETERMINATION OF NONREGULATED STATUS FOR EVENTS 31807 AND 31808 COTTON: ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT (1997), available at [http://www.aphis.usda.gov/brs/dec\\_docs/9701301p\\_ea.HTM](http://www.aphis.usda.gov/brs/dec_docs/9701301p_ea.HTM) (last visited Apr. 7, 2004).

420. EPA, BT PLANT-PESTICIDES BIOPESTICIDES REGISTRATION ACTION DOCUMENT IIC9-IIC10 (2000), available at [http://www.epa.gov/scipoly/sap/2000/October/brad3\\_enviroassessment.pdf](http://www.epa.gov/scipoly/sap/2000/October/brad3_enviroassessment.pdf) (last visited Apr. 7, 2003).

421. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303, 23,309, 23,336 (June 26, 1986).

enacted long before such products were considered possible. The decision to regulate transgenic products under archaic laws has led to many of the gaps, inconsistencies, inexperience, and overlaps discussed above. It has forced agencies to fit transgenic products into statutory and regulatory boxes that were not designed to handle them.<sup>422</sup> It has led agencies to assert regulatory authority over certain products where such agencies are not the most efficient regulators, either because they are not used to regulating a given type of product or because they lack the personnel, institutional knowledge, or capacity to regulate it.

Another result of the Coordinated Framework paradigm has been multiple failures on the part of regulatory agencies to recognize that genetically modified products sometimes do create new and different issues than those raised by the conventional products they routinely regulate. The Coordinated Framework's conclusions that genetically modified products should not be regulated based on the process by which they are created, and that no new statutory authority is necessary to regulate them, have led regulators to believe that there are no new risks posed by transgenic products, and perhaps to believe that they are not significantly risky at all.<sup>423</sup> These conclusions also have led to an agency culture of passivity in regulation. Agencies generally have appeared complacent with transgenic product risks, waiting for problems to occur before taking protective action. This complacency is likely due to a belief that these products do not cause any new or different risks. The StarLink corn and Monarch butterfly scenarios are prime examples of the danger of regulatory blinders in this regard.<sup>424</sup>

The Coordinated Framework's central precept, that the process of genetic modification is not itself inherently risky and therefore that the process should not serve as a trigger for regulation, was repeated explicitly in various federal reports, at least through 1992.<sup>425</sup> It has never been officially disavowed. Our current

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422. See, e.g., *supra* notes 308-09 and accompanying text (stating that FIFRA was enacted to regulate chemical substances, but is now being used to regulate genetic material in transgenic plants).

423. See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303, 23,309, 23,336 (asserting that the new regulations are not needed to address genetically modified products).

424. See *supra* Parts III.A, III.C.

425. See *supra* note 273 and accompanying text.

understanding of genetic modification and the actual manner in which it is now regulated, however, demonstrate that this perspective is flawed.

Each of the three main agencies charged with the regulation of genetically modified products now has determined independently that the assumptions of the Coordinated Framework are incorrect. These conclusions are demonstrated in each agency's current use of the process of genetic modification itself as a trigger for regulation.

APHIS regulation pursuant to the PPA is limited to "[a]ny organism which has been altered or produced through genetic engineering."<sup>426</sup> Thus, APHIS regulates organisms based on the process by which they were created, not based on the product. Similarly, the EPA's 2001 pest-protected plant regulations regulate plants based on whether they were derived through genetic engineering.<sup>427</sup> The regulations specifically apply only to those pest-protected plants created by genetic engineering, exempting similar, and theoretically even identical, plants derived through conventional breeding.<sup>428</sup>

Finally, in proposed biotechnology regulations in 2001, the FDA stated that, relative to traditional crop breeding, genetic modification increases the introduction of specific new substances into foods, increases the directed modification of the composition of foods, and increases the speed at which traits can be introduced into food.<sup>429</sup> The FDA concluded "that the products of [biotechnology] are likely in some cases to present more complex safety and regulatory issues than seen to date."<sup>430</sup> The FDA therefore proposed a premarket notification requirement for bioengineered food.<sup>431</sup> This proposed regulation is based on the biotechnology process, not the product. Echoing the three agencies' conclusions, the National Research Council also has determined that there is a logical scientific basis

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426. Definitions, 7 C.F.R. § 340.1 (2003).

427. Regulations Under FIFRA, *supra* note 296, 66 Fed. Reg. at 37,777-78; Exemption for Residues Derived Through Conventional Breeding, *supra* note 296, 66 Fed. Reg. at 37,830.

428. *See supra* note 427.

429. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

430. *Id.*

431. *See id.* at 4712-13.

for regulating all genetically engineered crops based on the process by which they were created.<sup>432</sup>

APHIS, the EPA, the FDA, and the National Research Council all have determined that certain genetically modified products should be regulated based on the process by which they were created. These determinations reveal that the foundational presumptions of the Coordinated Framework, and the basis for the current system of regulation, are unwarranted.

Other false presumptions in the Coordinated Framework further demonstrate that the regulatory system envisioned in 1986 and still in place today is unworkable. The FDA concluded in the Coordinated Framework that, "new marketing applications will be required for most products manufactured using new biotechnology."<sup>433</sup> As discussed above, the FDA has not required a new marketing application for a single one of the genetically modified food products introduced to date.<sup>434</sup> Similarly demonstrating limited foresight, the Coordinated Framework failed to prescribe how transgenic pest-protected plants would be regulated, apparently because such products were not yet on the regulators' radar.<sup>435</sup> Such products, however, were field tested just one year after the Coordinated Framework was promulgated and are now one of the dominant commercial genetically modified products.<sup>436</sup> Moreover, the Coordinated Framework failed to provide adequate regulatory structure for transgenic fish and shellfish.<sup>437</sup>

The governing paradigm of the Coordinated Framework has proven false and has been disavowed implicitly by the regulatory agencies charged with implementing it. The Coordinated Framework also has proven incapable of adapting to certain biotechnology advances. Despite these failures, the Coordinated Framework continues to serve as the operational basis for the regulation of genetically modified products today. That the current statutory and regulatory structure cannot effectively handle

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432. See NRC 2002 REPORT, *supra* note 2, at 52, 82-83.

433. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,309 (June 26, 1986).

434. See *supra* notes 288-89 and accompanying text.

435. See NRC 2000 REPORT, *supra* note 4, at 26.

436. See *id.*

437. FUTURE FISH, *supra* note 25, at 37 (noting that the Coordinated Framework failed to "specify the lead agency for transgenic fish and other [transgenic] aquatic organisms").



existing biotechnology products leaves little doubt that as biotechnology advances to next-generation products, introducing additional new issues and concerns, achieving proper regulation under the existing system and statutes will be even more problematic. Based on these recognitions, and on the numerous regulatory deficiencies cited in this Article, it is time to replace the Coordinated Framework and the current regulatory system with a substantially more efficient and reasonably protective structure.

### *B. Proposed Statutory and Regulatory Changes*

The problems identified throughout this Article point directly to many of the solutions that must be implemented in a new statutory and regulatory structure for regulating genetically modified products. These solutions fall into two broad categories: closing regulatory and statutory gaps, and overhauling the division of regulatory responsibility.

#### *1. Closing Regulatory and Statutory Gaps*

Numerous statutory and regulatory gaps must be closed to provide an adequate regulatory structure for genetically modified products. The most critical gaps exist with respect to environmental protection and next-generation biotechnology.<sup>438</sup> The EPA should be given statutory authority to evaluate the environmental risk posed by genetically modified products. The genetically modified salmon case study demonstrates the critical nature of this authority with respect to transgenic fish.<sup>439</sup> Transgenic insects similarly pose environmental concerns.<sup>440</sup> Although the environmental risk posed by livestock is lower because of the reduced risk of escape,<sup>441</sup> the EPA still should have authority over all genetically modified animals. The EPA also should be able to consider the environmental impact of transgenic plants other than those modified to be pest protected because of the risks of gene flow and invasiveness.<sup>442</sup>

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438. See *supra* Part V.A.1.

439. See *supra* Part III.B.

440. See *supra* note 170 and accompanying text.

441. See *supra* note 171 and accompanying text.

442. Examples of these types of plants would include, for example, pharmaceutical-producing, industrial compound-producing, herbicide-tolerant, drought-tolerant, salinity-

Currently, APHIS' review of releases, which focuses on impacts to agriculture, is the only review of the environmental impact of these plants. The vast majority of this review consists of the notification process.<sup>443</sup>

Expanded EPA environmental review does not mean that industry expenses will significantly increase, which could slow or otherwise impede biotechnology growth. First, EPA review will likely indicate that many types of transgenic products are not significant environmental threats and can be handled through some sort of notification process.<sup>444</sup> It should be the EPA that makes this environmental determination, however, not an agency that lacks environmental expertise or resources, or no agency at all. Second, for products of greater concern, EPA expertise should allow it to reach final determinations faster and more predictably than the current arrangement, with concomitant benefits for biotechnology developers.

The second major gap area, concerning next-generation biotechnology, also must be addressed. Regulations governing genetically modified animals for uses other than as human food or to produce human biologics must be promulgated. This is particularly important, as several animals modified to produce animal or veterinary biological products are anticipated in the near future.<sup>445</sup> As discussed above, the AHPA may provide APHIS with a basis for regulatory authority over such transgenic animals, but such authority is both unclear and has not been asserted.<sup>446</sup> Similarly, statutory authority for and regulations governing the research and commercialization of transgenic insects also needs to be developed. The lack of a clear regulatory structure in these next-generation areas may impede scientific progress.

Additional regulatory gaps must be filled within each of the three agencies. All agencies should regulate based on the potential risks of a given product, not based on how a developer classifies the product. APHIS should be given authority to monitor transgenic

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tolerant, virus-resistant, temperature-tolerant, and disease-resistant plants.

443. See *supra* notes 332-39 and accompanying text.

444. See, e.g., NRC 2002 REPORT, *supra* note 2, at 83 (stating that most genetic introductions will not pose a threat to the environment).

445. See CASE STUDY NO. IV: FARM ANIMAL THAT PRODUCES HUMAN DRUGS, *supra* note 30, at 14.

446. See *supra* note 371.

plants after they have been granted nonregulated status to provide for postmarket monitoring or oversight in order to be able to detect and correct any unanticipated problems.<sup>447</sup>

The FDA should implement its 2001 proposed regulations to make notification of the commercialization of new genetically modified food products mandatory. Though the FDA believes it has been voluntarily notified of all such products introduced to date,<sup>448</sup> as the role of biotechnology expands, not all developers will necessarily take this step. Absent knowledge of a particular genetic modification, the FDA has no method for monitoring whether food products have been genetically modified or contain any genetically modified component.<sup>449</sup>

Growers of genetically modified pest-protected plants should be made accountable to the EPA for the manner of use and containment of the transgenic plants. Currently, only product developers are accountable to the EPA, and grower accountability is attempted through contractual agreements between the producer and the grower required by the EPA.<sup>450</sup> The StarLink<sup>451</sup> and ProdiGene<sup>452</sup> cases, as well as recent surveys of grower compliance,<sup>453</sup> amply demonstrate that such informal control is not sufficient.

Most of the other statutory and regulatory gaps identified above have clear fixes and will not be discussed further.<sup>454</sup> A final point with respect to regulatory gaps should be made. Some gaps are not the result of statutory or regulatory deficiencies but result in part from a lack of scientific knowledge. Long-distance pollen flow is a prime example. It is a poorly understood phenomenon, but it has a significant effect on how numerous genetically modified crops and pharmaceutical-producing and industrial compound-producing

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447. See TAYLOR & TICK, *supra* note 20, at 44 (stating that the need for postmarket oversight is likely to change with genetic products).

448. See *supra* note 292 and accompanying text.

449. See TAYLOR & TICK, *supra* note 20, at 54 (stating that agencies today only respond to specific safety concerns that arise, rather than knowing which products are genetically modified).

450. See *id.* at 34-36. The grower is therefore under no legal obligation to the EPA to comply with any planting restrictions. See *id.*

451. See *supra* Part III.A.

452. See *supra* Part III.D.

453. JAFFE, *supra* note 151, at 5-6 (presenting data on refuge requirement compliance deficiencies on corn farms).

454. See *supra* Part V.A.

plants should be handled. One solution in these instances is to create a market for the missing scientific data. If, for instance, agencies began to require data on pollen flow in relation to regulatory approval for planting transgenic plants under certain conditions, understanding of this critical parameter would improve rapidly.<sup>455</sup> Improved scientific understanding will allow for more finely tuned regulation, which in turn will result in savings for industry, as it will not have to comply with regulations that are inefficiently overprotective due to a lack of information.

## *2. Overhauling the Division of Regulatory Responsibility*

In order to maximize the social welfare improvements provided by genetically modified products, instances of regulatory agencies acting outside their areas of expertise, regulatory overlap, and inconsistent and sometimes conflicting regulation must be remedied. All three of these problems can be substantially ameliorated by shifting the division of regulatory authority over genetically modified products from the current one, based haphazardly on preexisting statutes, to a division based upon each agency's expertise and general mandate. Thus, the FDA should bear responsibility for the human health risks posed by genetically modified plants or animals intended for use as human food or pharmaceuticals; the EPA should take responsibility for evaluating the environmental risks posed by transgenic products; and the USDA should regulate the impact of genetically engineered products on agricultural crops and livestock.

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455. For example, Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) liability and potential liability created a market for data on groundwater chemistry and hydrology. See James Salzman, *Valuing Ecosystem Services*, 24 *ECOLOGY* L.Q. 887, 898 (1997) (reviewing *NATURE'S SERVICES: SOCIETAL DEPENDENCE ON NATURAL ECOSYSTEMS* (Gretchen C. Daily ed., 1997)). Wetlands regulations created a market for data on wetlands vegetation and hydrology. *Id.* Both of these needs led to a much better understanding of the respective scientific issues.

Requiring industry to provide scientific information raises concerns about potential industry bias in the reporting of data. The experience with hazardous and toxic waste site cleanup, wetlands protection, endangered species surveys, and other types of environmental assessment requirements has demonstrated that regulatory agency review of industry-provided data can help to ensure accuracy and lead to greater scientific knowledge in the long run. See *id.* (discussing the improvement in the understanding of scientific matters due to CERCLA and wetlands regulation).

This division of regulatory authority not only is inherently logical, but also provides the added benefits of increased efficiency, greater human health and environmental protection, and economic savings. Placing regulatory authority for particular risks in the hands of the agency with the most expertise, experience, and relevant resources will best guarantee that the risk is properly evaluated and protected against. It will do so as quickly and inexpensively as possible. Such action also will clear up instances of regulatory inconsistency and overlap because a given risk will only be evaluated by a single agency.

One concern with such a solution may be that a single transgenic product could be regulated by multiple agencies if it presents multiple types of risks; that is, there will be certain types of overlap even under the proposed changes to the regulatory system. Because genetically modified products raise varied types of risk, it is inevitable that there will be some overlap in agency responsibility under any regulatory system. The nature of legislation and regulation themselves necessarily create overlaps and gaps, as well as overregulation and underregulation. Legislation and regulation require the categorization of problems or concerns in some manner. Inevitably certain issues will arise that do not fit neatly into the regulatory boxes created. Where these issues fall through the cracks, there will be a regulatory gap; where they fall within multiple boxes, there will be regulatory overlap. For efficiency and economic purposes, one goal of regulation should be to minimize these regulatory problems, while still maintaining adequate protection. The proposals contained in this Article seek to minimize regulatory gaps and greatly reduce the existing amount of regulatory overlap.

In addition, the expense of any overlap that results from this proposal can be reduced by requiring the agencies to coordinate their actions; for instance, by designating a lead agency based on the most significant risk and requiring only a single developer submission covering all pertinent information for a given product. Under the existing regulatory system, a lead agency is usually, but not always, designated for transgenic products that fall within multiple agencies' authority. Such designation, however, is not necessarily based on the type of risk presented and generally has

not resulted in coordinated information submission requirements.<sup>456</sup> For instance, both the EPA and the USDA require similar information submissions on pest-protected plants.

The requirements proposed here also would force better communication among the various agencies, a problem that has plagued biotechnology regulation since its inception,<sup>457</sup> with resulting increases in efficiency for industry and savings for taxpayers. Most importantly, placing responsibility for a given risk with the agency best equipped to regulate it removes the cost of paying for unnecessary, duplicative areas of expertise in multiple agencies, significantly reducing the expense of regulation.

It is worth noting that in most areas of regulation in the United States, the agency that has regulatory authority over a given product is usually the agency with the most expertise in handling the type of risk presented by the product. Genetically modified product regulation, however, is a product of the historical accident of transgenic products being squeezed into statutory definitions not intended for them. Numerous inefficiencies could be cleared up and numerous risks protected against by shifting regulatory authority to a risk-based approach.

### *C. Debunking Common Critiques of Regulatory Change*

Optimizing social welfare through improving the regulation of genetically modified products is not a universally accepted solution. Many commentators contend that the current statutory and regulatory structure governing genetically modified products should not be changed. Most critiques of more efficient and reasonably protective regulation fall into one of several camps: that biotechnology products are not different than, or do not present different risks

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456. See Wilson Huhn, *Three Legal Frameworks for Regulating Genetic Technology*, J. CONTEMP. HEALTH L. & POL'Y, 1, 29 (2002) ("Despite its name, the [Coordinated Framework] has often lacked coordination.").

457. See, e.g., Recommendations and Statement of the Administrative Conference Regarding Administrative Practice and Procedure, 54 Fed. Reg. 53,493 (Dec. 29, 1989) (recommending numerous steps to improve interagency coordination in the regulation of biotechnology); CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN, *supra* note 73, at 17-18 (noting that the EPA and APHIS have not coordinated herbicide-tolerant plant review); NRC 2000 REPORT, *supra* note 4, at 16 (recommending improving interagency coordination in the regulation of biotechnology).

than, conventional products; that regulation based on process would treat like products differently; or that market forces will adequately protect society from the risks of genetically modified products. Though each of these contentions contains grains of truth, none withstand rigorous analysis, as discussed below.

*1. Are Genetically Modified Product Risks New?*

The most common critique of the need to regulate genetically modified products differently is likely that the risks posed to human health and the environment by such products are no different than those posed by conventionally bred crops, and therefore no special regulation is necessary. Supporting this contention, in 1987 the National Research Council stated, "[t]here is no strict dichotomy between, or new categories of, the health and environmental risks that might be posed by transgenic and conventional pest-protected plants."<sup>458</sup> The argument against specific genetically modified product regulation, however, relies on loose terminology and takes the National Research Council findings out of context.

In a limited sense, it is true that certain risks from genetically engineered products are not different in kind than those posed by conventional products. For instance, both types of modification can lead to undesirable traits in the final product, can create unexpected results, and can result in gene flow to other organisms.<sup>459</sup> Just like genetically modified products, some people have allergic reactions to conventional crops and conventional species can be an invasive threat to native species. The quality and quantity of risks posed by genetically modified products, however, are different in certain critical respects from those posed by conventional products, and it is these differences that require special attention.

The differences between transgenic and conventional product risks occur primarily because biotechnology allows a much broader array of genetic traits to be incorporated into a new organism than

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458. NRC 2000 REPORT, *supra* note 4, at 43; *see also* NRC 2002 REPORT, *supra* note 2, at 29, 52 (noting that "[t]ransgenic crops do not pose unique categories or kinds of environmental hazards," and, "it is not possible to qualitatively differentiate the general environmental risk associated with the release of conventionally bred crop cultivars and the introduction of new species").

459. NRC 2002 REPORT, *supra* note 2, at 48-49; ROYAL SOC'Y OF CAN., *supra* note 5, at 124.

is possible through conventional breeding.<sup>460</sup> Conventional breeding is limited by the available genetic variability in the target organism and its sexually compatible relatives. "The great potential, as well as risk, of genetic engineering is that it removes those limits."<sup>461</sup> Genetic engineering allows the introduction of new traits that could never have been incorporated before.<sup>462</sup> Additionally, the highly domesticated characteristics of some conventional crops are believed to pose fewer environmental hazards than transgenic crops.<sup>463</sup> Initial experiences with genetically modified animals also demonstrate this difference. Naturally occurring mutations appear to place certain limitations on the amount of change in conventionally bred animals, while genetic engineering may not. For instance, naturally modified salmon appear to be limited to four times their normal size, while transgenic salmon have grown up to a mean size of eleven times normal at certain ages.<sup>464</sup>

The degree of change in genetic information resulting from modification, whether conventional or biotechnological, can be measured along two dimensions: by the number of genetic changes made and by the taxonomic distance between the donor and host organisms. Changes in the former manner will vary in extent for both biotechnological and conventional modification. Changes in the latter manner, however, are much greater for genetic engineering than for conventional hybridization. As a result, the National Research Council found, in its most recent report on the subject, that genetic engineering can "introduce specific traits or combinations of traits that pose unique risks."<sup>465</sup> For example, transgenes that introduce natural pesticides from nonplant sources create new exposures and therefore new concerns.<sup>466</sup> On this basis, the Council

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460. NRC 2002 REPORT, *supra* note 2, at 220; Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

461. Wolfenbarger & Phifer, *supra* note 57, at 2092; *see also* NRC 2002 REPORT, *supra* note 2, at 36-37 (noting this difference).

462. NRC 2002 REPORT, *supra* note 2, at 48 ("What makes the transgenic approach particularly new is the potential to incorporate novel traits.").

463. *Id.* at 36.

464. ANIMAL BIOTECHNOLOGY, *supra* note 27, at 79-80.

465. NRC 2002 REPORT, *supra* note 2, at 48.

466. NRC 2000 REPORT, *supra* note 4, at 57.



concluded, "there are good arguments for regulating all transgenic crops."<sup>467</sup>

Thus, while people are allergic to conventional foods and conventional foods contain toxins, genetic engineering may introduce a more diverse or far greater amount of different allergens and toxins. As genetically modified products become more pervasive, the number of these introductions and the speed with which they occur will increase. For similar reasons, though the categories of risk posed by potential antibiotic resistance, pesticide resistance, gene flow, or invasiveness may not be new, the risks in certain areas are significantly higher, and can be different in kind from those regulators have faced before.

The differences in risk between biotechnological and conventional modification are even more pronounced for next-generation biotechnology products. Consider first agricultural crops. The experience with the transgenic varieties commercialized to date are expected to provide only "a very limited basis for predicting" the environmental risks posed by future transgenic plants, which are considered to be on a "wholly different order" than those currently posed.<sup>468</sup> The new risks posed by potential widespread use of pharmaceutical-producing and industrial compound-producing plants, and by the future introduction of genetically modified fish, insects, and livestock discussed throughout this Article demonstrate the necessity of particularized transgenic product regulation.

## *2. Should Regulation Be Based upon the Product or the Process?*

A second common critique of the conclusion that genetically modified products should be regulated as such is that it could lead

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467. NRC 2002 REPORT, *supra* note 2, at 52; *see also* CEQ AND OSTP ASSESSMENT, *supra* note 49, at 3. As the National Research Council noted, this conclusion does not imply that all transgenic crops are dangerous. In fact, most may not need heavy oversight. But, regulation is necessary to weed those that need a second look from those that do not. NRC 2002 REPORT, *supra* note 2, at 52.

It is possible that a greater understanding of the risks posed by transgenic plants will indicate that conventional crops have not been regulated adequately. Admittedly, this would place governmental regulators in a difficult spot. *See id.* at 19. Inadequate regulation of earlier products, however, is a poor reason not to regulate later technologies adequately.

468. NRC 2002 REPORT, *supra* note 2, at 220, 246.

to the anomalous result of two identical products (one created though conventional breeding, one through genetic engineering) being regulated differently. Though this concern resonates in theory (identical products should be regulated identically), it fails to withstand a practical analysis.

First, genetic modification increases the introduction of new substances, increases the speed at which traits are introduced, and leads to the introduction of transgenes from taxonomically very different organisms. As a result, the probability of certain risks being created by the process of genetic engineering is substantially greater than by the process of conventional breeding. Regulation based on the process of creation is rational because certain genetically modified products are more likely to pose certain risks than conventional products.

Second, all three agencies regulating genetically modified plants and animals, based on their practical experience, as well as the National Research Council, have concluded that at least certain of their regulatory regimes should be based upon the process (genetic engineering) by which a given product was created.<sup>469</sup>

Third, many conventionally bred products, for example, most farm crops, have been unregulated since time immemorial. Instituting a regulatory regime to cover all crops would be far more difficult than instituting one to cover transgenic products, if not impossible. Faced with the choice between implementing a regulatory system that will better protect society from the risks posed by genetically modified products, even if it fails to regulate a small number of similarly risky conventional products, and no regulatory protection at all, the former is highly preferable.

### *3. Should Protection Be Left to the Market?*

The last category of critique of genetically modified product regulation is the contention that market forces will adequately protect society from the risks of these products, and will do so more efficiently than regulation. The existence of substantial market failures and inefficiencies in this area, however, demonstrates that such a critique is unsupportable.

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469. See *supra* notes 426-33 and accompanying text.

First, numerous externalities are inherent in the risks posed by genetically modified plants and animals. Under a market approach, transgenic product developers and growers would not take into account the full social cost of most environmental impacts caused by their products. For instance, absent widespread natural resource disasters, it is unlikely that product developers and growers would bear the burden of ecological damage caused by gene flow, invasive plants, reduction in biodiversity, or impacts on nontarget organisms. The tort system and other legal remedies may force developers and growers to bear the cost of certain human health impacts, but problems with scientific proof of causation would introduce externalities here as well.

Second, many of the risks posed by biotechnology would only result in latent harm, to the extent they cause harm, either to human health or the environment. In addition, causation will often be a matter of probability. Two issues that the American tort system has significant difficulty handling are harms not known until a long time after they were caused and issues of probability in causation.<sup>470</sup> Thus, injured parties would have a hard time recovering proper damages.

Third, in bad-case scenarios involving significant or widespread harm, the damage caused may be so great that the party responsible will have insufficient resources to compensate injured parties or society adequately. Relatedly, because many injuries caused would result only in latent harms, the party responsible may no longer be able to be located or may no longer be a going concern.

Market forces do not provide an efficient or adequate means of controlling or regulating biotechnology because of the market failures and externalities introduced by the potential harmful

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470. See generally JOSEPH SANDERS, *BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION* (1998) (discussing these tort system problems in connection with the Bendectin litigation); PETER H. SCHUCK, *AGENT ORANGE ON TRIAL: MASS TOXIC DISASTERS IN THE COURTS* (1986) (discussing these tort system problems in connection with various toxic tort litigation). That the tort system generally has a difficult time handling issues where causation is a matter of probability and the harm is latent does not mean that it has no role in the regulation of genetically modified products. Should transgenic products cause widespread harm, the tort system would play an essential part in assigning and apportioning liability, as has occurred in the StarLink corn case. Whether the tort system will do so efficiently, however, is a matter of much conjecture.

effects of genetically modified products. Revising the current federal statutory and regulatory framework is necessary.

### CONCLUSION

Since this country's creation, the federal government often has had to handle new legal and regulatory issues arising as the result of technological innovation. For example, the invention and introduction of the steamboat in the nineteenth century led to new issues regarding steam engine safety and liability for injury caused by exploding boilers,<sup>471</sup> and the development and use of new industrial substances in the twentieth century led to myriad new issues concerning the protection of human health and the environment from toxic substances and hazardous waste.<sup>472</sup> Each time a new technological advance creates new concerns, the issue arises of whether to govern the new technology under the existing system and rules or to create a new system and rules. This issue is significantly complicated by the fact that technological advances are often, almost by definition, at the forefront of scientific knowledge, and therefore not only are usually incomprehensible to the layperson, but may not be fully, or even well, understood by the most advanced experts in the relevant field. In the case of the steamboat, it took decades to determine whether boiler explosions were random or the result of negligence.<sup>473</sup> In the case of toxic substances, decades of research are ongoing concerning their risks and impacts.<sup>474</sup> In the face of limited knowledge, however, governmental actors must still establish how new technology will be regulated.

Due to this common scientific and technical uncertainty, and to a general human proclivity to analogize new experiences to existing knowledge,<sup>475</sup> reliance on the existing system and rules is often the most attractive solution at first glance. Using the existing system is usually the easiest and cheapest answer in the short run: it

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471. NAN GOODMAN, *SHIFTING THE BLAME: LITERATURE, LAW, AND THE THEORY OF ACCIDENTS IN NINETEENTH-CENTURY AMERICA* 68-69 (1998).

472. ROBERT V. PERCIVAL ET AL., *ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY* 374-538 (3d ed. 2000).

473. GOODMAN, *supra* note 471, at 68-69.

474. PERCIVAL ET AL., *supra* note 472, at 374-434.

475. See Mandel, *supra* note 180.

requires the least effort to implement and can be developed around existing and vested interests. Such a solution, however, often proves unworkable in the long term for the very reasons that it has in the area of genetically modified products: the new technology may create concerns and risks so different from previously experienced ones that the rules protecting against earlier risks are inadequate to handle the new technology. Unfortunately, once established, legal and regulatory regimes resist change, even as scientific knowledge and understanding evolve.

The Coordinated Framework was promulgated in 1986, at the dawn of the biotechnology era. It is not surprising that, in an area developing as rapidly as biotechnology, a regulatory structure proposed two decades ago and based on a patchwork of statutes and regulatory processes created even earlier, would prove fundamentally flawed and unable to adapt to current developments.

Though potentially difficult to implement politically in certain regards,<sup>476</sup> solutions to many of the regulatory deficiencies identified in this Article are not difficult to define. Solving them requires enacting certain additional legislation to close statutory gaps and promulgating certain new regulations to close regulatory ones. In addition, to remove the numerous regulatory inconsistencies and overlaps plaguing this area, and to eliminate the need for agencies to act outside of their areas of expertise, it is necessary to realign the regulation of genetically modified products to focus on the actual risks posed by the products. These risks are now far better understood than they were when the Coordinated Framework was promulgated.

Next-generation biotechnological advances are fast-approaching: the field-testing and production of pharmaceutical-producing and industrial compound-producing plants are expected to increase significantly in the coming years and several genetically modified fish are awaiting approval for commercial use.<sup>477</sup> The risks to human health and the environment presented by future genetically

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476. There are a variety of legal, political, social, psychological, and other practical phonema that will resist change. Without wading into this vast literature, it is worth noting one status quo bias of particular relevance here. Regulatory agencies may be expected to be territorial concerning their areas of oversight, and may try to avoid ceding authority to other agencies even where it would be more efficient. Mandel, *supra* note 180, at 44.

477. Field Testing of Pharmaceutical Plants, *supra* note 23, 68 Fed. Reg. at 11,338; FUTURE FISH, *supra* note 25, at 6.

modified plant varieties, by the production of nonedible and potentially harmful compounds in crops that have traditionally been used for food, and by genetically modified fish and other animals and insects, will include risks of different types than those posed by transgenic products to date.

The opportunity to optimally reap the potentially spectacular health, environmental, and economic benefits of these biotechnology advances will be severely hampered if they are not regulated properly. The opportunity will be hampered because society will face inefficient costs and delays and unnecessary risks, and also because distrust of the regulatory system or future high-profile problems caused by inadequate regulation could result in a public backlash against genetically modified products. As we stand at the portal between first-generation biotechnology and next-generation biotechnology advances, it is imperative that the statutory and regulatory structures be properly revised to provide for the effective and efficient regulation of genetically modified products.