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MYTHS OF VOLUNTARY COMPLIANCE: LESSONS FROM THE STARLINK CORN FIASCO

REBECCA M. BRATSPIES*

*What do our consumers have to say when the FDA is not there and the EPA is not there, Agriculture's not there, but Friends of the Earth find this out?
What kind of regulatory scheme is that?*¹

On September 18, 2000, a coalition of consumer and environmental groups detected DNA fragments from StarLink corn in *Taco Bell* taco shells sold in grocery stores.² StarLink corn, a genetically modified ("GM") variety of corn patented by Aventis CropScience,³ had only been approved for use as animal feed, and not for human consumption.⁴ Days later, Kraft Foods recalled all *Taco Bell* taco shells.⁵ Kraft's action started a frenzy of recalls as

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¹ *The Future of Food: Biotechnology and Consumer Confidence Before the Senate Comm. on Health, Education, Labor and Pensions*, 107th Cong. (Sept. 26, 2000) (statement of Sen. Tom Harkin (D-Ia.)) (quoted in *GM Food on Senate Menu*, at <http://www.cbsnews.com/stories/2000/09/26/national/main236438.html> (last visited Mar. 23, 2003)).

² Marc Kaufman, *Biotech Critics Cite Unapproved Corn in Taco Shells; Gene-Modified Variety Allowed only for Animal Feed Because of Allergy Concerns*, WASH. POST, Sept. 18, 2000, at A2 [hereinafter *Unapproved Corn*]. A coalition of environmental groups purchased twenty-three corn-containing grocery products and sent the products for genetic testing. *StarLink Corn: How it Reached the Food Supply*, A.P., Dec. 4, 2002, available at <http://archive.showmenews.com/2000/dec/20001204busi011.asp>. On September 18, the groups convened a press conference and announced that the tests had found traces of StarLink corn. *Id.*

³ The patents for StarLink corn were first held by Plant Genomic Science, which was later acquired by AgrEvo and ultimately became Aventis Crop Science. As part of the fallout from the StarLink crisis, Aventis CropScience was later sold to Bayer AG. For convenience, all the relevant corporate entities will be referred to as Aventis. Information available at <http://www.bayercropscience.com/bayer/cropscience/cscms.nsf/id/BioScience>.

⁴ *Id.*

⁵ Press Release, Kraft Foods, Kraft Food Announces Voluntary Recall of All *Taco Bell* Taco Shell Products from Grocery Stores (Sept. 22, 2000), available at <http://www.kraft.com/newsroom/092200.html>.

other manufacturers discovered StarLink corn in their products.⁶ By November of 2000, the FDA exercised its enforcement authority to recall nearly three hundred types of adulterated snack chips, corn flour, and other corn foods.⁷ The cost of these recalls ran into the hundreds of millions of dollars.⁸ Complaints began pouring into the Food and Drug Administration ("FDA") and the Center for Disease Control ("CDC") about allergic reactions to corn products attributable to StarLink contamination.⁹ Overnight, StarLink became a "Frankenfood" posterchild—the incarnation of GM critics' worst nightmares.¹⁰ International corn exports plummeted.¹¹ The ensuing crisis paralyzed an entire sector of American agriculture and food production,¹² and badly shook consumer confidence.¹³ Even two years later, StarLink corn is

⁶ See, e.g., *Biotech Corn Recall Expands in Stores, Restaurants*, WASH. POST, Nov. 3, 2000, at A5; *50% of Corn May be Impure; Problem Could Cost Hundreds of Millions*, DES MOINES REG., Oct. 28, 2000, at 1A; Mark Kaufman, *Corn Woes Prompt Kellogg Plant Shutdown*, WASH. POST, Oct. 21, 2000 at A2; *Starlink Costs ADM 'Tens of Thousands'*, REUTERS, Oct. 26, 2000, summary at <http://www.pestlaw.com/x/news/2000/20001022.html>; *Western Family Recalls Products with Altered Corn*, THE OREGONIAN, Oct. 26, 2000, at A2, available at 2000 WL 27103380.

⁷ FDA Enforcement Report for November 1, 2000, available at <http://www.fda.gov/bbs/topics/ENFORCE/ENF00666.html>.

⁸ Sarah Lueck et al., *Corn-Recall Cost Could Reach Hundreds of Millions Even as Some Firms Benefit*, WALL ST. J., Nov. 3, 2000, at A2. See also Mike Glover, *Biotech Corn Deal Reached*, SAN ANTONIO EXPRESS-NEWS, Jan. 24, 2001, at 3E, available at 2001 WL 5228144 (reporting that Aventis agreed to settle the class action lawsuit for an undisclosed amount estimated to be \$100 million to \$1 billion). See also *Sutter v. Aventis Cropscience USA Holding, Inc.*, 145 F.Supp. 2d 1050, 1053-54 (S.D. Ia. 2001); *Dupraz v. Aventis Cropscience USA Holding, Inc.*, 153 F. Supp. 2d 1102, 1103 (D.S.D. 2001).

⁹ See Report, ENVIRONMENTAL HEALTH DIVISION, CENTER FOR DISEASE CONTROL, INVESTIGATION OF HUMAN HEALTH EFFECTS ASSOCIATED WITH POTENTIAL EXPOSURE TO GENETICALLY MODIFIED CORN (2001) [hereinafter CDC REPORT], available at <http://www.cdc.gov/nceh/ehhe/Cry9cReport> (reporting technical assistance in assessing allergies related to Starlink corn was performed by CDC at the request of FDA).

¹⁰ See Troy Goodman, *Are Biotech Crops Sowing Seeds of Dispute?* (Jan. 24, 2001), at <http://www.cnn.com/2001/FOOD/news/01/24/biotech.hunger/?related>.

¹¹ See William Lin et al., *StarLink: Impacts on the U.S. Corn Market and World Trade*, USDA FEED, SITUATION AND OUTLOOK 46, 52 (Apr. 2001), available at <http://usda.mannlib.cornell.edu/reports/erssor/field/fds-bby/fds2001.pdf>.

¹² See *id.* at 46.

¹³ See *Aventis SA Sued for a Second Time Over Starlink Corn Scare*, FOOD & DRINK WKLY., Jan. 9, 2001, at 1.

still popping up in corn shipments and still has the power to roil international markets.¹⁴

One company, with one GM crop, managed to contaminate food for millions of households and brought an international commodities market to a standstill. Now that the dust has settled, it is time to consider why things went so disastrously awry. How did this happen? How do we prevent it from happening again? All eyes are on the United States: If these crops cannot be regulated effectively here, can we really envision their successful use in countries with less developed regulatory programs? StarLink corn exposed a gaping hole in the GM crop regulatory framework. More recently, ProdiGene¹⁵ fell through that same regulatory hole—providing further evidence of a regulatory system in crisis. Unless action is taken, StarLink will be only the harbinger of more troubles to come.

The United States' policies toward adoption of GM technology are more favorable than any other industrialized countries',¹⁶ and the United

¹⁴ *Gene-Altered Corn Hits Prices*, GLOBE & MAIL, Dec. 31, 2002, at B18; Tom Sellen, *Commodities Report: Corn Falls to Three Week Low on Shipment's Genetic Tainting*, WALL ST. J., Dec. 31, 2002, at C11, available at 2002 WL WSJ 103129959 (reporting on the effects of Japanese discovery of StarLink Contamination in a December 2002 corn shipment); *US Defends Safety of Its GM Foods*, ASIA PULSE, Jan. 7, 2003, available at 2003 WL 4231643 (reporting that in response to the Japanese announcement, India rejected a corn aid shipment on biosafety grounds).

¹⁵ ProdiGene is an ag-biotech company developing "biopharm" crops—agricultural crops that have been genetically modified to produce industrial or pharmaceutical products. For a discussion of ProdiGene's regulatory near-disaster, see *infra* Part III.

¹⁶ In 2001, the United States accounted for sixty-eight percent of the total acreage of biotech crops planted. Argentina and Canada both enthusiastic adopters of GM technology, accounted for twenty-two percent and six percent respectively. James Stamps, *Trade in Biotechnology Food Products*, INT'L. ECON. REV., Nov./Dec. 2002, at 5. The European Union ("EU"), by contrast, has maintained a *de facto* moratorium on any new regulatory approvals for GM crops or foods. See Council Directive 90/220/EEC, 1990 O.J. (L 117) 15-27 (repealed Oct. 10, 2002 by Council Directive 2001/18/EEC, 2001 O.J. (L 106) 1-39). Recently the EU replaced this *de facto* moratorium with new, extremely stringent GM regulatory law: Directive 2001/18/EEC. In the developing world, response to this new technology has varied widely. China has adopted and promoted an indigenous GM industry, while many African states (including most recently Zimbabwe and Zambia) have sharply rejected the technology as a new form of colonialism. India and much of the rest of the world display a deep ambivalence. See generally DAVID G. VICTOR & C. FORD RUNGE, *SUSTAINING A REVOLUTION: A POLICY FOR CROP ENGINEERING* 2,6 (2002).

States accounts for most of the world's GM harvest.¹⁷ Around the world, GM promoters offer the United States' regulatory system as a proxy for the safety of these crops in general, and as an example of how GM crops can be safely deployed.¹⁸ StarLink corn blasted the assertion that United States regulation equals safety, and it provides a cautionary tale about what happens when a regulatory scheme has no credible enforcement strategy. StarLink also undermines a cornerstone assumption of the United States' regulatory strategy: that voluntary self-policing can be a viable, long-term strategy for managing this revolution in agriculture.

This Article explores the StarLink crisis in some detail. After discussing a general overview of the regulatory framework implicated by the StarLink fiasco in Part I, Part II provides a detailed analysis of the regulatory approval process that vetted StarLink corn. Part III uses StarLink corn to explore the structural flaws in this process—flaws that made the StarLink fiasco inevitable from the beginning. Part IV uses the StarLink fiasco to draw lessons about how market forces can support or undercut regulatory regimes, and suggests that the deficiencies highlighted by the StarLink fiasco are part of a broader ideological struggle over the proper role of government in the marketplace. Finally, Part V proposes a new regulatory approach for GM crops, grounded in both science and in the realities of a market economy. Regulatory missteps can doom this promising new technology. Without public confidence in the regulatory system, successful adoption of ag-biotechnology is unlikely. Thus, the new approach proposed is aimed at

¹⁷ See Jorge Fernandez-Cornejo & William D. McBride, *Agricultural Biotechnology: Adoption of Biotechnology and its Production Impacts*, ERS Agricultural Economic Report No. AER810 (May 2002), available at <http://www.ers.usda.gov/publications/aer810> (last updated May 21, 2002).

¹⁸ See, e.g., *Evaluation of the U.S. Regulatory Process for Crops Developed Through Biotechnology*, 19 COUNCIL FOR AGRIC. SCI. & TECH. 1, 4-8 (Oct. 2001); Ben Lilliston, *Don't Ask, Don't Know: The Biotech Regulatory Vacuum*, MULTINAT'L MONITOR, Jan. 1, 2000, at 9, available at 2000 WL 16039144 (quoting Senator Kit Bond, R-Mo.); Monsanto Company, *Roundup Ready Corn—Alleged Detection By FOE Q & A Monsanto Company* (Nov. 7, 2000), available at <http://www.monsanto.com/monsanto/layout/media/00/11-07-00a.asp> (offering United States regulatory approval as evidence that corn unapproved by the EU was safe for human consumption.); Thomas P. Redick et al., *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, 4 ENVTL. L. 1, 17, 27 (1997).

providing the regulatory oversight needed to ensure public health and safety, while still permitting an exploration of biotechnology's promise.

I. BACKGROUND

A. *What is StarLink Corn—A Brief Introduction*

Farmers began genetically manipulating plants long before they knew about genes. For thousands of years, farmers have selectively bred plants to enhance desirable traits and to suppress undesirable ones. Selective breeding exploits natural variations within a species to develop new, more desirable strains.¹⁹ Over time, this process of selective breeding can produce a radically altered species. Unlike modern genetic engineering, however, selective breeding can enhance or suppress only those traits already present in a population.

Modern genetic engineering (including such techniques as gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes) has freed the process of genetic modification from limitations imposed by the existing characteristics of a species. Functional genes can now be isolated and transferred to a food crop from any organism—across species, class, phylum and kingdom. In other words, genetic engineering enables breeders to recombine genes themselves. Genetic engineers thereby avoid the main constraint on selective breeding—the need to start with sexually compatible organisms. This technology can create organisms that do not, and could not, exist without such intervention. The new technology also radically alters the timescale of genetic modification. Developing a new strain through selective breeding can take years or decades.²⁰ With the tools of genetic engineering, new strains may be developed much more rapidly.

Commercial applications of this technology thus far have concentrated on bioengineering pest resistance and herbicide tolerance into widely planted crops like corn, soy, cotton and potatoes.²¹ Growers adopting

¹⁹ For a general explanation of these points, accessible to the non-scientist, see *Feeding the Five Billion*, ECONOMIST, Nov. 10, 2001, available at 2001 WL 7320818.

²⁰ See NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION, app. A (2000).

²¹ See VICTOR & RUNGE, *supra* note 16, at 16-17.

these “first generation” GM crops have been able to increase yields while significantly reducing costly inputs like chemical pesticides and fertilizers.²² StarLink corn was a typical first generation GM crop—a corn hybrid modified to make it more profitable to grow, rather than to change its nutritional content.²³ StarLink corn contained two added genes—one conveying herbicide tolerance and one conveying insect resistance.²⁴ The herbicide tolerance gene was the product of an earlier approval process.²⁵ It was the addition of a gene derived from the bacterial species *Bacillus thuringiensis* (Bt),²⁶ coding for an insecticidal protein called Cry9C, that triggered the StarLink crisis.

Certain varieties of the Bt bacteria naturally produce a number of pesticidal proteins that are toxic to some significant lepidopteran agricultural pests.²⁷ The Bt organism and its array of insecticidal proteins have been well-studied.²⁸ As a result, there is a substantial body of scientific information available on the use of Bt as a spray-on pesticide, particularly in the organic farming industry.²⁹ In crops that have been genetically modified to express Bt proteins, one of the Bt genes conveying pest resistance is introduced into the plant's DNA. This gene enables the plant itself to produce the Bt protein, thereby protecting the plant from insect damage. The gene most commonly

²² *Id.*

²³ For an overview of research findings related to the economic impacts of transgenic crops, see Michelle C. Marra et al., *The Payoffs to Transgenic Field Crops: An Assessment of the Evidence*, 5 *AGBIO FORUM* 43 (2003), available at <http://www.agbioforum.org>.

²⁴ USDA/APHIS Petition 97-265-01p for Determination of Non-Regulated Status for Bt Cry9C Insect Resistant and Glufosinate Tolerant Corn Transformation Event CBH-351, May 1998, at 6-9 [hereinafter *StarLink Non-Regulated Determination*], available at http://www.aphis.usda.gov/biotech/dec_docs/9726501p_ea.HTM.

²⁵ AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. 27,041 (May 15, 1998).

²⁶ *Id.* at 27,042.

²⁷ Lepidoptera is a large order of insects, comprised of butterflies and moths. For a description of the biological mechanism by which Bt kills Lepidopteran pests, see INT'L LIFE SCI. INST., AN EVALUATION OF INSECT RESISTANCE MANAGEMENT IN BT FIELD CORN: A SCIENCE BASED FRAMEWORK FOR RISK ASSESSMENT AND RISK MANAGEMENT 9-10 (1998) [hereinafter *ILSI Report*].

²⁸ *Id.* at 1.

²⁹ *Id.* at 13.

used has been *cryIA*,³⁰ which is approved for use in human and animal food.³¹ StarLink corn was produced by inserting a different Bt gene, known as *cry9C*, into corn hybrids. The pesticidal protein produced by *cry9C* controls many of the same corn pests as those produced by *cryIA*, and kills those pests in the same way by destroying the insect's stomach cells.³² Unlike *cryIA*, however, *cry9C* codes for a protein that shares several unusual molecular properties with known food allergens.³³

B. *General Overview of the United States Regulatory System For GM Crops*

In theory, no genetically engineered organism is approved for commercial use until its proponent has demonstrated that the GM organism conforms with the standards set by federal law. These standards are intended to protect human health and the environment, while encouraging the development of new, potentially lucrative technologies. The United States' regulatory approach to controlling the new biotechnology of genetic engineering was developed during the Reagan administration under the aegis of the Office of Science and Technology Policy ("OSTP"). OSTP drafted a Coordinated Framework for the Regulation of Biotechnology (the "Framework"), with the identified goals of creating a "coordinated and sensible regulatory review process that will minimize the uncertainties and inefficiencies that can stifle innovation and impair the competitiveness of U.S. industry,"³⁴ and of "reducing barriers to trade in biotechnology."³⁵ With these goals in mind, OSTP began its analysis from the political stance that

³⁰ For clarity, this Article adopts scientific nomenclature. References to genes will be italicized in lower case (ex. *cry9C*) and references to proteins will be capitalized in normal typeface (ex. CRY9C).

³¹ *Bacillus thuringiensis* CryIA(b) Delta-Endotoxin and the Genetic Material Necessary for its Production (plasmid vector pCIB4431) in Corn; Exemption from the Requirement of a Tolerance, 40 C.F.R. § 180.1152 (2002); *Bacillus thuringiensis* subspecies *Kurstaki* CryIA© and the Genetic Material Necessary for its Production in All Plants; Exemption from the Requirement of a Tolerance, 40 C.F.R. § 180.1155 (2002).

³² ILSI Report, *supra* note 27, at 9-10.

³³ CDC Report, *supra* note 9, at 4.

³⁴ Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (proposed Dec. 31, 1984).

³⁵ *Id.*

additional regulation was largely unnecessary and from the premise that existing law could adequately address regulatory questions created by the new technologies.³⁶

Under the Framework, GM products are fit into an already-existing set of laws and regulations. As a result, no single agency considers the full range of problems posed by GM crops. Rather, each agency evaluates only its own narrow piece of the GM universe. No one is responsible for the unique problems posed by GM crops, or for overarching questions about safe use of this new technology. In fact, the StarLink corn fiasco revealed that these problems can fall entirely outside the purview of agencies applying pre-existing laws. Compounding this problem is the fact that the relevant agencies, EPA, FDA and USDA, share no unifying vision of how to answer the questions and challenges posed by GM crops. For these reasons, the Framework has been roundly criticized as inadequate.³⁷

Unfortunately, the Reagan and first Bush administrations focused almost exclusively on deregulation and gave no careful consideration to the rising chorus of voices (both scientific and public) suggesting that this approach was not working. Rather than engage in any serious reconsideration of the basic assumption that existing law could meet the challenges posed by biotechnology, Vice President Quayle announced reforms designed to "speed up and simplify" the GM regulatory process.³⁸ For most of the Clinton

³⁶ *Id.* at 50,858. As the OSTP concluded that "at the present time existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology," it thus recommended that no new legislation need be drafted to regulate biotechnology. *See also* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,306 (June 26, 1986).

³⁷ Doug Gurian-Sherman, *Plugging Holes in the Biotech Safety Net*, Center for Science in the Public Interest, at 1, at <http://www.cspinet.org/reports/> (Jan. 7, 2003); Thomas O. McGarity et al., *Breeding Distrust: An Assessment and Recommendations for Improving the Regulation of Plant Derived Genetically Modified Foods*, at 2, available at <http://www.consumerfed.org/gmsummary.pdf> (2001). For a scholarly critique, see Rebecca Bratspies, *The Illusion of Care: Regulation Uncertainty and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L. J. 297 (2002); Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403 (2002). *See also*, Gregory A. Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491, 528-43 (1987); Note, *Designer Genes That Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products*, 100 HARV. L. REV. 1086, 1087-92 (1987).

³⁸ Kurt Eichenwald, *Biotechnology Food: From the Lab to a Debacle*, N.Y. TIMES, Jan. 25,

administration, this laissez-faire Framework was left intact. Changes proposed toward the end of the Clinton administration, some in response to the StarLink crisis, were immediately repudiated by the incoming Bush Administration, for whom voluntary compliance is something of a mantra.³⁹ Thus, the Reagan Administration policy, which strictly limited regulatory oversight of GM foods headed for the market, survives to this day. That regulatory scheme is outlined below.

1. USDA's Regulatory Authority

In theory, USDA's regulatory authority extends to the import, interstate movement, and environmental release of any organism that poses a potential threat to United States agriculture.⁴⁰ To that end, USDA regulates the interstate movement of genetically engineered crops under the Federal Plant Protection Act ("FPPA").⁴¹ The FPPA gives USDA authority to regulate the movement of organisms that may endanger plant life, and to prevent the introduction, dissemination or establishment of such organisms.⁴² This Act could have given USDA wide authority to regulate GM plants. However, under the Framework, USDA interprets its regulatory duty with

2001, at A1 (quoting a May 26, 1992 speech).

³⁹ In regulatory areas as diverse as OSHA ergonomic standards, cybersecurity, and the reduction of greenhouse gases, the Bush administration has consistently rejected concrete regulatory standards in favor of voluntary compliance programs. *See, e.g.*, Statement of John L. Henshaw, Assistant Secretary of Labor for Occupational Health and Safety before the Subcommittee on Workforce Protections Committee on Education and the Workforce, United States House of Representatives (explaining the administration's reliance on voluntary compliance after rejecting the ergonomic standards established during Clinton Administration); Telecommunication Reports, *Bush Cybersecurity Proposal Stresses Voluntary Compliance*, Sept. 30, 2002, available at 2002 WL 20134690.

⁴⁰ *See e.g.*, Agricultural Biotechnology: Permitting, Notification and Deregulation, available at <http://www.aphis.usda.gov/ppq/biotech> (last visited April 15, 2003).

⁴¹ 7 U.S.C. § 7712 (2000). The FPPA succeeds two earlier statutes: the Federal Plant Pest Act, U.S.C. §§ 150aa-jj (1957) (repealed 2000), and the Plant Quarantine Act, 7 U.S.C. §§ 151-154(a) (1912) (repealed 2000). Within USDA, APHIS has primary regulatory responsibility over GM crops. *See* Restrictions on the Introduction of Regulated Articles, 7 C.F.R. § 340.0(a) (2003); Definitions, 7 C.F.R. § 340.1 (2003) (restricting the introduction of genetically altered organisms without authorization of APHIS). For the sake of clarity, I will refer to the USDA and APHIS collectively as USDA.

⁴² 7 U.S.C. § 7712(a).

regard to GM crops extremely narrowly. USDA limits its regulatory oversight to considering whether a GM crop will itself pose a conventional plant pest risk when introduced into the environment and/or interstate commerce.⁴³

To conduct this analysis, USDA uses the pre-existing definition of a plant pest as any living organism that directly or indirectly injures, or causes disease or damage, to a plant.⁴⁴ If USDA is satisfied that a GM plant does not pose a conventional plant pest risk, the agency views its regulatory inquiry as ended and will grant "nonregulated" status.⁴⁵ Once a crop obtains nonregulated status, USDA places no restrictions or reporting requirements on the distribution of the crop in the United States.⁴⁶ As of February 2003, USDA had granted more than fifty such petitions to GM crops.⁴⁷

In determining nonregulated status, USDA treats GM crops exactly like their conventional counterparts and evaluates them for exactly the same risks. While this plant pest inquiry might be sufficient for conventional crops, it is far too narrow to properly evaluate the risks posed by GM crops. Most GM crops currently on the market have been modified to produce pesticides or to be resistant to herbicides.⁴⁸ In addition to conventional plant pest risks, these GM crops may also pose risks based on the unique genes added through the process of genetic engineering.⁴⁹ Overuse or misuse of these crops might generate insect resistance, or might spread herbicide resistance to wild relatives.⁵⁰ Such an outcome would not only render the herbicide or pesticide

⁴³ See 7 C.F.R. § 340.0.

⁴⁴ 7 C.F.R. § 340.1.

⁴⁵ Starlink NonRegulated Determination, *supra* note 24, at 2-4.

⁴⁶ United States Regulatory Oversight in Biotechnology, *available at* <http://www.aphis.usda.gov/biotech/OECD/usregs.htm> (last visited Apr. 5, 2003).

⁴⁷ See National Biotechnology Information Assessment Program/Information Systems for Biotechnology, *Tables for Field Test Releases*, at <http://www.isb.vt.edu/cfdocs/isbtables.cfm> (last updated Feb. 27, 2003) [hereinafter *Tables for Field Test Releases*].

⁴⁸ Rachel Massey, *Biotech: The Basics-Part 1*, RACHEL'S ENVT. & HEALTH NEWS (Jan. 17, 2001), at http://www.rachel.org/bulletin/pdf/Rachels.Environment_Health_News_1931.pdf.

⁴⁹ To identify these risks is not to discount the very real and meaningful environmental benefits that these crops potentially offer. Experience in China, for example, suggests that use of these Bt crops can dramatically reduce reliance on pesticides. Leslie Ryan, *GM Crops—Savior or Saboteur? Agricultural Biotechnology in China Today*, 2001 COLO. J. INT'L ENVTL. L. & POL'Y 203, 205-206 (2001). Considering that pesticide contamination is a major public health and ecological threat, these crops will likely provide significant benefits if properly managed.

⁵⁰ See, e.g., L.L. Wolfenbarger & P. R. Phifer, *The Ecological Risks and Benefits of*

useless (of particular concern because, to date, the largest class of GM crops have been modified to express Bt—a unique natural pesticide critical to organic farming) but might also ripple through the ecosystem in unpredictable and unknown ways.⁵¹ Moreover, contamination from pollen drift threatens to create an adventitious presence of GM genes in non-GM crops, permanently altering the gene pool of the crops with foreign genes not approved for consumption in many parts of the world,⁵² and possibly threatening the traditional right of farmers to save seeds for future planting.⁵³ These

Genetically Engineered Plants, SCIENCE, Dec. 15, 2000, at 2088, available at <http://www.sciencemag.org>.

⁵¹ *Id.* See also John Harte, *Land Use, Biodiversity, and Ecosystem Integrity: The Challenge of Preserving Earth's Life Support System*, 27 ECOLOGY L.Q. 929, 958 (2001); Deepak Saxena et al., *Insecticidal Toxin in Root Exudates from Bt Corn*, 402 NATURE 480, 480 (Dec. 2 1999), available at <http://www.nature.com/nature/> (expressing concern that a released GMO might alter the natural ecosystem and have enormous effects on natural biodiversity).

⁵² Bruce Barcott, *Seeds of Discord*, LEGAL AFF., Jan./Feb. 2003, at 60, available at <http://www.legalaffairs.org>; Norman C. Ellstrand, *When Transgenes Wander, Should We Worry?*, 125 PLANT PHYSIOLOGY 1543, 1545 (2001), available at <http://www.plantphysiol.org>; Neil E. Harl, *Genetically Modified Food Crops: Guidelines for Producers*, available at <http://www.extension.iastate.edu/Pages/grain/publications/buspub/0010harll.pdf> (last visited April 15, 2003); Carol Norris & Jeremy Sweet, *Monitoring Large Scale Releases of Genetically Modified Crops (EPG1/5/84) Incorporating Report on Project EPG 1/5/30: Monitoring Releases of Genetically Modified Crop Plants* (final report of monitoring studies of field scale releases of GM oilseed rape crops in England from 1994-2000), available at <http://www.defra.gov.uk/environment/gm/research/epg-1-5-84.htm> (Dec. 24, 2002). One frightening report of GM contamination involved a native variety of corn in Mexico—a country that had not even approved commercial planting of the GM variety detected. Carol Kaesuk Yoon, *Genetic Modification Taints Corn in Mexico*, N.Y. TIMES, Oct. 2, 2001, at F7. In April 2002, however, an article in *Nature*, which published the original research on the presence of genetically modified genes found in native maize varieties in a region of Mexico (David Quist & Ignacio H. Chapela, *Transgenic DNA Integressed into Traditional Maize Races in Oaxaca, Mexico*, 414 NATURE 541 (2001)), concluded that the claim “that these transgenes have pervaded the entire native maize genome is unfounded.” Nick Kaplinsky et al., *Maize Transgene Results in Mexico are Artifacts*, 416 NATURE 601 (2002).

⁵³ The most famous case to date involves Percy Schmeiser, a Canadian farmer locked in patent infringement litigation with Monsanto over his use of saved seeds that had been cross-fertilized by neighbors' Roundup Ready crops. *Schmeiser v. Monsanto*, [2002] F.C.A. 448, available at <http://decisions.fct-cf.gc.ca/fct/2002/2002fca309.html> (last visited Apr. 5, 2003). See also *In re Trantham*, 286 B.R. 650 (Bankr. W.D. Tenn. 2002); *Monsanto v. Byrd*, 2000 WL 33952260 (E.D.N.C. Dec. 11, 2000); Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 587

significant and difficult to manage risks, which are unique to GM crops, are not part of USDA's plant pest calculus.⁵⁴

For most GM field trials—a necessary step in the approval process—USDA requires only advance notice,⁵⁵ and does not engage in a permitting process.⁵⁶ After receiving an advance notification, USDA has ten to thirty days to acknowledge that the field trial is appropriate or to deny permission.⁵⁷ To date, USDA has received advance notice of thousands of field trials.⁵⁸

Once a GM crop has been field tested, its developer can petition to obtain nonregulated status⁵⁹ and approval for commercial sales.⁶⁰ USDA will approve the petition if it concludes that granting nonregulated status will not

(2000).

⁵⁴ COMM. ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION (2000) (explaining that USDA does not consider insect resistance to be a plant pest risk). For a description of the resistance problem, see Bratspies, *supra* note 37, at 306-07.

⁵⁵ Notification for the Introduction of Certain Regulated Articles, 7 C.F.R. § 340.3(a) (2003). This position contrasts sharply with the European Union's regulatory approach. The EU requires regulatory approval at each and every step from laboratory testing to field testing and final marketing. See Council Directive 90/219/EEC, 1990 O.J. (L 117) 1, 1 (regulating situations in which release into the environment is not intended); Council Directive 90/220/EEC, 1990 O.J. (L 117) 15, 15 (regulating both the deliberate release into the environment and the marketing of genetically modified organisms). An indication of the European perspective can be found in the preamble to Regulation (EC) No. 258/97, which states in part that "to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the Community." Commission Regulation 258/97, 1997 O.J. (L 43) 1. Because of alleged uncertainties about the safety of these crops, in June 1999 the EU imposed a de facto moratorium on approvals of new GM crops. Chantal Nielson & Kym Anderson, *Global Market Effects of Alternative European Responses to GMO's*, at 3, available at <http://www.adelaide.edu.au/cies/0032.pdf> (July 2000); *Tables for Field Test Release*, *supra* note 47.

⁵⁶ 7 C.F.R. § 340.3(a).

⁵⁷ *Id.* § 340.3(e).

⁵⁸ *Tables for Field Test Releases*, *supra* note 47.

⁵⁹ Petition for Determination of Nonregulated Status, 7 C.F.R. § 340.6(a) (2003). After receiving a petition, USDA publishes a notice in the Federal Register and accepts comments for sixty days. 7 C.F.R. § 340.6(d)(2) (2003). USDA has one hundred and eighty days to deny or approve the petition. 7 C.F.R. § 340.6(d)(3) (2003).

⁶⁰ Restrictions on the Introduction of Regulated Articles, 7 C.F.R. § 340.0(a)(1) (2002).

create a plant pest risk.⁶¹ USDA has approved the vast majority of GM crop petitions for nonregulated status⁶² with more than fifty transgenic crops deregulated since 1992.⁶³

2. FDA Oversight

The FDA derives broad regulatory authority over foods from the Federal Food, Drug and Cosmetics Act ("FFDCA").⁶⁴ Under the FFDCA, the agency has the power: 1) to identify and remove "adulterated foods" from the human food supply;⁶⁵ 2) to regulate food labeling;⁶⁶ and 3) to approve all food additives before they are marketed.⁶⁷ FDA thus has the power to remove unsafe foods from the marketplace⁶⁸ and to hold producers legally responsible for the safety of the foods they market.⁶⁹ Had FDA embraced these powers and tightly regulated the introduction of GM foods to the marketplace, the StarLink crisis could never have happened. Instead, under the aegis of the Framework, FDA made a series of critical policy decisions that drastically limited the scope of its regulatory oversight of the new technology.⁷⁰

Two separate provisions of the FFDCA could have given FDA significant authority over GM crops.⁷¹ Section 402(a)(1) of the FFDCA

⁶¹ Because granting nonregulated status would be a major federal action that might have significant impacts on the environment under the National Environmental Policy Act ("NEPA"), USDA must conduct an environmental assessment before making a decision on the petition. 42 U.S.C. § 4332 (c) (2000); NEPA Rules, 40 C.F.R. §§ 1500-1508 (2003). *See also* USDA/APHIS Petition 96-317-01p for Determination of Nonregulated Status for Insect-Resistant/Glyphosate-Tolerant Corn Line MON 802 Environmental Assessment and Finding of No Significant Impact, May 1997 [hereinafter MON 802 FONSI], *available at* http://www.aphis.usda.gov/biotech/dec_docs/9631701p_ea.HTM (illustrating an instance of the need for an environmental assessment under NEPA requirements).

⁶² *Tables for Field Test Releases*, *supra* note 47.

⁶³ *See id.*

⁶⁴ Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301-399 (2000).

⁶⁵ FFDCA § 304(a), (b), 21 U.S.C. § 334(a), (b) (2000).

⁶⁶ FFDCA § 403, 21 U.S.C. § 343 (2000).

⁶⁷ FFDCA § 409(b)-(d), 21 U.S.C. § 348(b)-(d) (2000).

⁶⁸ FFDCA § 304, 21 U.S.C. § 334 (2000).

⁶⁹ FFDCA § 303(a), 21 U.S.C. § 333(a) (2000).

⁷⁰ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984-85 (May 29, 1992) [hereinafter 1992 FDA Policy].

⁷¹ The FFDCA also gives FDA the power to regulate and require food labeling. Under

defines a food as adulterated “[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health.”⁷² Because many GM crops have been modified to produce pesticides, this provision could have given FDA unique regulatory authority over the foods produced from these crops. Similarly, under section 402(b)(2), a food is adulterated “if any substance has been substituted wholly or in part therefor.”⁷³ This provision creates a category of adulterated food, defined in terms of a manufacturing process that includes use of an unapproved food additive. No food additive can be used in human food unless FDA has either determined that the additive is generally regarded as safe (“GRAS”), or has issued specific regulations addressing use of that particular food additive.⁷⁴ In other words, FDA must either require pre-market approval of food additives or must determine that the additive is GRAS. Because most GM crops involve the addition of genes that code for novel proteins (notably pesticide proteins

FFDCA §403(a)(1), 21 U.S.C. § 343(a)(1), a food is misbranded, and therefore subject to enforcement action, if its labeling is false or misleading in any particular. Under FFDCA section 201(n), 21 U.S.C. § 321(n), a label is also misleading if it fails to reveal any material facts about the food. While the legislative history of FFDCA section 201(n) contains little discussion of the word “material,” FDA has historically interpreted this materiality language to refer to information about the attributes of the food itself. See, FDA, *Guidance for Industry, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*, Draft Guidance (Jan. 2001), available at <http://vm.cfsan.fda.gov/~dms/bioabgu.html>. In determining which facts are material, and thus subject to a labeling requirement, FDA has rejected calls that the process of genetic engineering alone should trigger a labeling requirement. *Id.* FDA currently requires labeling of GM food products only when changes in the food composition (e.g., different nutritional property, addition of an allergen) “warrant labeling.” *Id.* This is an extremely restrictive reading of its statutory mandate. Most GM food products produced from genetically modified ingredients need not be labeled. This Draft Labeling Guidance was intended to assist manufacturers who wished to voluntarily indicate whether foods were made with bioengineered ingredients. *Id.* The guidance would have aided manufacturers in ensuring that their labeling is truthful and not misleading.

⁷² FFDCA § 402(a)(1), 21 U.S.C. § 342(a)(1) (2000).

⁷³ FFDCA § 402(b)(2), 21 U.S.C. § 342(b)(2).

⁷⁴ FFDCA § 301(a), 21 U.S.C. § 331(a) (2000) (prohibiting introduction of adulterated foods into interstate commerce). Adulterated foods include those containing a food additive determined as unsafe under FFDCA section 409, 21 U.S.C. § 348 (2000). FFDCA § 402(a)(1), 21 U.S.C. § 342(a)(1)(C)(I). FFDCA section 409(a), 21 U.S.C. § 348(a) excepts a food additive from a determination of unsafe if exempted under another provision under the section. Substances determined to be GRAS also fall outside regulation as food additives under FFDCA section 409, 21 U.S.C. § 348. 1992 FDA Policy, 57 Fed. Reg. at 22,985.

like Bt), this authority could also have been the basis for extensive FDA oversight of GM crops.

However, in 1992, FDA rejected an expansive view of its regulatory authority when the agency published its Statement of Policy: Foods Derived from New Plant Varieties.⁷⁵ Under this policy, FDA ceded its authority to regulate pesticides incorporated into foods to EPA.⁷⁶ FDA also elected not to promulgate regulations to deal specifically with GM foods as a class, but instead to apply existing food additive regulations.⁷⁷

FDA based this decision on a critical assumption—that GM foods were the substantial equivalent of conventional crops.⁷⁸ Under a substantial equivalent analysis, GM foods are considered mere variants of existing, well-accepted foods. This assumption of “substantial equivalence” has significant regulatory consequences.

As the “substantial equivalent” of conventional crops, GM foods are treated as though they present no different or greater safety concern than foods developed by traditional plant breeding.⁷⁹ FDA thus makes little or no distinction between the foods that are the product of conventional breeding and those that are the product of modern genetic engineering.⁸⁰ Because GM foods are considered the “substantial equivalent” of products already on the market, FDA treats GM foods as presumptively GRAS. Thus, FDA requires neither pre-market review nor labeling of these crops.⁸¹ As a necessary corollary to “substantial equivalence,” FDA concluded that genes added

⁷⁵ 1992 FDA Policy, 57 Fed. Reg. 22,984, 22,984-85 (May 29, 1992).

⁷⁶ 1992 FDA Policy, 57 Fed. Reg. at 23,005. See also Dr. Marc Lappe, *Biotechnology and Agriculture*, 10 MICH. ST. U. – DCL INT’L L. 39, 42 (2001) (describing FDA’s position on regulating pest protected plants (“PIP”s)).

⁷⁷ 1992 FDA Policy, 57 Fed. Reg. at 22,985.

⁷⁸ *Id.* at 22,984.

⁷⁹ See *id.* For an explanation of substantial equivalence, see generally, McGarity, *supra* note 37, at 426-32.

⁸⁰ 1992 FDA Policy, 57 Fed. Reg. at 22,984 n.3 (“‘Modification’ is used in a broad context to mean the alteration in the composition of food that results from adding, deleting, or changing hereditary traits, irrespective of the method Most, if not all, cultivated food crops have been genetically modified.”).

⁸¹ *Id.* at 22,990-91. FDA defines plant genetic modification as “the alteration of the genotype of a plant using any technique, new or traditional.” *Id.* at 22,984 n.3. This FDA definition makes no distinction between the manner that traditional techniques of selective breeding alter the genotype of a plant and the way modern biotechnology can alter the genotype of a plant.

through genetic engineering are not "food additives" for the purposes of the FFDCA's stringent pre-market review provisions.⁸²

These substantial equivalence decisions are in sharp contrast with European perspectives about biotechnology.⁸³ European consumers are staunchly opposed to GM crops and EU policies have reflected public opinion on that point. To understand the EU's position on GM crops, it must be viewed against the backdrop of a series of spectacular and recent European regulatory failures that put human health and environmental safety at risk: mad cow disease, dioxin-contaminated chickens, foot-and-mouth disease—the list goes on. These experiences have fostered an extreme precautionary sentiment among European consumers and have created a climate in which GM crops are greeted with profound skepticism and distrust.⁸⁴ Adding to this very real distrust of the new technology and of the government bureaucrats as guarantors of safety, a series of social, cultural and economic factors (including a desire to protect local agriculture) cut against ready European adoption of these crops. As a result, the EU has soundly rejected notions of substantial equivalence and requires GM manufacturers to demonstrate the safety of these crops before granting regulatory approval. The result has been a *de facto* moratorium on regulatory approvals.

The FDA's substantial equivalence determination may ultimately be vindicated. When made in 1992, however, it was, and indeed remains to this

⁸² *Id.* at 22,990. "A food additive shall . . . be deemed unsafe . . . unless it has been exempted or has otherwise been approved by the FDA." FFDCA § 409(a), 21 U.S.C. § 348(a) (2000).

⁸³ The EU requires that all foodstuffs, additives and flavors containing one percent or more genetically engineered material must be labeled. Nielson & Anderson, *supra* note 55, at 3; Commission Regulation 49/2000, 2000 O.J. (L 6) 13, available at <http://europa.eu.int/eur-lex/en/index.html>. In 2002, the EU further tightened these requirements by reducing the level of GM material allowed in products on the market to 0.5% and imposing stricter labeling requirements. Labeling requirements will also be extended to GM crops destined for animal feed. *Labeling GM Foods to Become European Law*, CHEMISTRY & INDUS., Dec. 16, 2002, at 4, available at 2002 WL 26742195. South Korea, Japan, Australia, Mexico, China and New Zealand have rejected FDA's vision of substantial equivalence and have instead decided to adopt the EU's position that GM crops should be labeled. See Nielson & Anderson, *supra* note 55, at 4.

⁸⁴ See David Vogel & Diahanna Lynch, Council on Foreign Relations, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, available at <http://www.cfr.org/publication.php?id=3937> (last visited Apr. 15, 2003).

day, wholly unsubstantiated by peer-reviewed scientific studies.⁸⁵ In developing this policy, FDA conducted no independent research on the effects of genetic engineering on foods, nor did the agency require manufacturers to engage in such research. Instead, the policy was the product of a political decision to smooth a path for this new technology.

Even more troubling, FDA allows manufacturers to make this GRAS determination unilaterally.⁸⁶ This approach transfers a tremendous amount of discretion from the regulatory authority to the regulated community. Manufacturers need not submit vetted scientific data to convince FDA that a GM crop is GRAS. Instead, FDA permits manufacturers to make this evaluation entirely on their own.⁸⁷ Not surprisingly, most manufacturers have concluded that their GM products are GRAS and thus exempt from expensive and rigorous pre-market review. Of course, even without regulation these manufacturers do have powerful incentives not to market products they know or suspect to be harmful. A GM food that causes an allergic reaction or otherwise threatens human health would be subject to FDA seizure, and the company, including its responsible officers, might face criminal prosecution.⁸⁸ And that is not to mention tort liabilities or the devastating effect such a product would have on the company's reputation.

⁸⁵ As such, the decision runs contrary to 21 U.S.C. § 321's definition of food additive and FDA's position that a lack of information cannot be the basis for a GRAS finding. *See United States v. 45/194 Kg. Drums of Pure Vegetable Oil*, 961 F.2d 808 (9th Cir. 1992) (demonstrating that a product is generally recognized as safe involves submitting evidence establishing that scientifically trained experts qualified to evaluate the product believe it to be generally recognized as safe); *United States v. An Article of Food*, 752 F.2d 11, 15 (1st Cir. 1985) (declaring that a substance may be excluded from classification as a "food additive" only if experience based on common use provides a basis for general recognition by scientists that the substance is safe under the conditions of its intended use); *Premo Pharm. Labs., Inc., v. United States*, 629 F.2d 795, 803-04 (2d Cir. 1980); *United States v. Articles of Food and Drug*, 518 F.2d 743, 747 (5th Cir. 1975); *Weinberger v. Bentelex Pharms., Inc.*, 412 U.S. 645 (1972) (general recognition of safe use established by controlled clinical studies published in recognized scientific literature).

⁸⁶ 1992 FDA Policy, 57 Fed. Reg. at 22,989 ("[C]ompanies developing new ingredients, new versions of established ingredients, or new processes for producing a food or food ingredient must make a judgment about whether the resulting food substance is a food additive requiring pre-market approval by FDA.").

⁸⁷ *Id.* For a stinging indictment of this laissez-faire regulatory approach, see McGarity, *supra* note 37.

⁸⁸ FFDCA §§ 302-304, 21 U.S.C. §§ 333(a)-304 (2000).

As far as the safety of GM crops goes, however, known risks are not the main concern. In addition to known risks, this new technology raises a host of questions about possible risks—questions that FDA's substantial equivalence policy creates no incentive to explore. In the absence of clear FDA requirements, GM manufacturers are left to make their own decisions about the standards of care necessary for evaluating the safety of these new products. There is no uniform, consistent protocol of analysis that would lend confidence to substantial equivalence determinations. Instead, these decisions are made on an *ad hoc* basis at the discretion of private, profit-motivated companies. There is a real possibility that these companies might make risk/reward assessments that the public would find unacceptable.

FDA does provide an avenue for voluntary pre-market consultations for GM foods.⁸⁹ This voluntary consultation process is said to help companies and the agency determine whether food made from GM organisms contained additives that would require pre-market approval.⁹⁰ FDA considers these pre-market notifications to be "prudent practices"⁹¹ on the part of producers regardless of any legal obligation to consult. Prudent or not, without a legally mandated approval process, FDA can only review whatever data a company chooses to share. To date, FDA "believes" that all developers of GM foods have consulted with the agency prior to marketing GM food in the United States,⁹² but because consultations are voluntary and GM products are not labeled in any way, FDA has no way of knowing for sure.

With no sound scientific underpinnings, FDA has come under intense criticism for this "substantial equivalence" policy.⁹³ In January 2001, the FDA proposed regulations that would have required submission of data and information about plant-derived bioengineered foods or animal feeds at least

⁸⁹ *Id.*

⁹⁰ 1992 FDA Policy, 57 Fed. Reg. at 22,984.

⁹¹ 1992 FDA Policy, 57 Fed. Reg. at 22,991.

⁹² See Pre-Market Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4706-38 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592) [hereinafter FDA Proposed Rule].

⁹³ THOMAS O. MCGARITY & PATRICIA I. HANSEN, CONSUMER FEDERATION OF AMERICA, BREEDING DISTRUST: AN ASSESSMENT AND RECOMMENDATIONS FOR IMPROVING THE REGULATION OF PLANT DERIVED GENETICALLY MODIFIED FOODS (2001), available at http://www.biotech-info.net/Breeding_Distrust.html; Erik Millstone et al., *Beyond 'Substantial Equivalence,'* 401 NATURE 525, 525 (1999) (arguing for a more structured and thorough examination of GM foods and food products).

120 days prior to commercial distribution.⁹⁴ Notification would have allowed FDA to ensure that industry decisions and plant-derived bioengineered foods complied with the FFDCA. The mandatory process would have replaced the voluntary consultation process.⁹⁵ After a lengthy investigation, FDA published these regulations during the last days of the Clinton administration.⁹⁶ The new regulations would have required companies to submit to the agency data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. Despite industry support for these regulations, one of the first acts of the incoming Bush administration was to suspend and withdraw these rules for further consideration.⁹⁷ To date the rules have not been enacted. In the fall of 2002, Senator Dick Durbin (D-IL) introduced legislation to replace the voluntary notification system with a mandatory pre-market approval system. This mandatory approval system would have required GM producers to submit much more detailed testing information and to obtain FDA approval before marketing their product. The bill was not enacted into law, but may be reintroduced in the 2003 legislative session.

3. EPA's Regulatory Authority

EPA has a comprehensive responsibility to examine the human health and environmental consequences of pesticides.⁹⁸ This responsibility derives

⁹⁴ FDA Proposed Rule, *supra* note 91, at 4706.

⁹⁵ Press Release, U.S. Department of Health & Human Services, FDA Announces Proposal and Draft Guidance for Food Developed Through Biotechnology (Jan. 17, 2001), available at <http://www.cfsan.fda.gov/~lrd/hhbioen3.html>.

⁹⁶ See Philip Brasher, *FDA Issues New Biotech Food Rules*, A.P., Jan. 17, 2001, available at http://www.biotech-info.net/FDA_rules.html. See generally FDA Proposed Rule, *supra* note 91. See also Raymond Formanek Jr., *Proposed Rules Issued for Bioengineered Foods*, FDA CONSUMER MAG. (Mar.-Apr. 2001), at http://www.fda.gov/fdac/features/2001/201_food.html.

⁹⁷ Memorandum from the Assistant to the President and Chief of Staff, White House Office, to the Heads and Acting Heads of Executive Departments and Agencies, 66 Fed. Reg. 7702 (Jan. 24, 2001) (directing that regulations sent to the Office of the Federal Register, but not yet published, be withdrawn, and that regulations already published but not yet in effect be postponed).

⁹⁸ See FIFRA and FFDCA, as clarified by the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996).

from FIFRA⁹⁹ and the FFDCA,¹⁰⁰ and includes the duty to determine acceptable tolerances for pesticide residues in food. Because most of the GM crops currently on the market have been genetically modified to produce endogenous pesticides,¹⁰¹ EPA plays a critical regulatory role.

With few exceptions,¹⁰² no person may sell or distribute any pesticide¹⁰³ that is not registered under FIFRA. To be registered, a pesticide must not cause "unreasonable adverse effects on the environment."¹⁰⁴ To determine whether an adverse effect is unreasonable, EPA must consider "the economic, social and environmental costs and benefits of the use of any pesticide."¹⁰⁵ A second set of criteria for FIFRA registration involve human dietary risk from pesticide residues.¹⁰⁶ Any substance that is a pesticide under

⁹⁹ 7 U.S.C. § 136a(a) (2000). EPA's pesticide regulations are set out in 40 C.F.R. pts. 150-189. Under FIFRA, EPA has no regulatory authority over plants that do not produce pesticides. This becomes important when the issue is regulation of biopharming. See *infra* Part III for an explanation of biopharming.

¹⁰⁰ 21 U.S.C. § 346a (2000).

¹⁰¹ Biopesticides are only exempt from FIFRA requirements if they are derived through the conventional breeding of sexually compatible plants. See *Plant-Incorporated Protectant from Sexually Compatible Plant*, 40 C.F.R. § 174.25 (2002). See also *General Qualifications for Exemptions*, 40 C.F.R. § 174.21 (2002).

¹⁰² EPA may, by regulation, exempt any pesticide from some or all of the requirements of FIFRA if the pesticide is "of a character which is unnecessary to be subject to" FIFRA in order to carry out the purposes of the Act. 7 U.S.C. § 136w(b)(2) (2000). EPA generally exempts pesticides that pose low probabilities of risk to the environment in the absence of regulatory oversight. See *Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant Incorporated Protectants (Formerly Plant-Pesticides)*, 66 Fed. Reg. 37,772, 37,772-73 (July 19, 2001) (codified at 40 C.F.R. pts. 152, 174) (Pesticides that do not qualify for exemption can still be approved for specific uses, but only if they do not "cause unreasonable adverse effects.").

¹⁰³ The term "pesticide" is defined broadly to include, *inter alia*, any substance intended to prevent, destroy or repel undesirable insects, weeds, rodents, bacteria or other living things EPA declares to be a pest. 7 U.S.C. § 136(t), (u) (2000).

¹⁰⁴ 7 U.S.C. § 136a(c)(5) (2000). In particular, this section of FIFRA provides that EPA shall register a pesticide if presented with a registration application that demonstrates: (1) the composition of the pesticide "warrant[s] the proposed claims for it;" (2) the "labeling and other material[s] required to be submitted comply with the requirements of [FIFRA];" (3) "it will perform its intended functions without unreasonable adverse effects to the environment;" and (4) "when used according with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." *Id.*

¹⁰⁵ 7 U.S.C. § 136(bb) (2000).

¹⁰⁶ A pesticide residue is not safe unless EPA has issued either a tolerance for the residue

FIFRA is automatically subject to regulation under FFDCA if used in the production of food or food crops.¹⁰⁷ If a pesticide's use is expected to cause residues to remain on or in food, EPA will not register that use under FIFRA unless it has also granted a tolerance under FFDCA, or has exempted the pesticide from the tolerance requirement. A food is adulterated, and subject to FDA enforcement authority, if it contains a pesticide residue that exceeds this EPA designated tolerance. The tolerance is thus the residue level that triggers an FDA enforcement action.¹⁰⁸ If pesticide residues exceed the tolerance level, the food will be subject to seizure.

EPA must set residue tolerances at a "safe" level.¹⁰⁹ In this context, safe is defined as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures"¹¹⁰ While this is not a zero tolerance standard—the agency need not conclusively conclude that the pesticide poses no harm—EPA's human dietary exposure analysis does not involve the balancing employed in the adverse environmental effect analysis. EPA may only exempt a pesticide from the tolerance requirement if the agency finds that the exemption is "safe" using the "reasonable certainty of no harm" standard. Under the FFDCA, a pesticide residue in or on food is not safe unless EPA has issued a tolerance for the residue (and the residue is within

(and the residue is within the tolerance limits) or an exemption. *See* FIFRA, 7 U.S.C. §136(bb); FFDCA, 21 U.S.C. §346a(a)(1).

¹⁰⁷ As for conventional pesticides, EPA must establish a tolerance level—a level of pesticide residue that is deemed safe—before permitting foods containing Bt residues to enter the human food chain. *See* FIFRA, 104 P.L. 170, § 103, 110 Stat. 1489, 1490 (1996) (codified as amended at 7 U.S.C. § 136a-1(g)(2)). *See also* 21 U.S.C. § 346a (2000). In this context, safe is defined as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures." 21 U.S.C. § 346a(b)(2) (2000). Again, the regulatory standard is one of reasonable, rather than absolute, safety.

¹⁰⁸ In the absence of a duly promulgated tolerance or exemption, or if the residue level detected in food exceeds the tolerance, the food is deemed adulterated under the FFDCA and is subject to enforcement by FDA. 21 U.S.C. § 346a(a)(3)-(4).

¹⁰⁹ FFDCA, 21 U.S.C. § 346a, 348.

¹¹⁰ FFDCA, 21 U.S.C. § 346a(b)(2)(A)(ii).

the tolerance limits)¹¹¹ or has issued an exemption from the requirements of a tolerance for the residue.¹¹²

Since 1994, EPA has interpreted FIFRA's pesticide registration provisions to encompass plant incorporated protectants ("PIPs") such as the Bt genes introduced into StarLink corn.¹¹³ Therefore, no PIP can be sold unless registered under FIFRA. Registration requires a demonstration that there will be no unsafe environmental or human dietary effects from the PIP. As part of this analysis, no PIP food crop can lawfully be sold for planting until EPA has either established a tolerance level for the PIP or has exempted the PIP from the tolerance requirement.¹¹⁴ To date, EPA has registered only a few PIPs, and with one exception, all have been crops with genes that encode Bt proteins.¹¹⁵ EPA has granted many of these Bt crops exemptions from the requirement for a tolerance level.¹¹⁶ Because the particular Bt gene used in StarLink corn raised human allergenicity concerns, EPA did not grant StarLink such an exception.¹¹⁷

¹¹¹ A pesticide in food qualifies under the first FIFRA exemption criteria of low probability of human dietary risk if it meets the FFDCA section 408 standard for an exemption from the requirement of a tolerance. 66 Fed. Reg. 37,773 (Jul. 19, 2001). However, under FIFRA, a pesticide cannot qualify for an exemption solely on the basis of consistency with FFDCA section 408. EPA must also evaluate occupational exposure, and risks to the environment from the pesticide. *Id.* at 37,774.

¹¹² 21 U.S.C. § 346a(a)(1) (2000).

¹¹³ 1992 FDA Policy, *supra* note 69, at 22,984-85.

¹¹⁴ 21 U.S.C. § 408(j)(3). In the absence of a duly promulgated tolerance or exemption or if the residue level detected in food exceeds the tolerance, the food is deemed adulterated under the FFDCA and is subject to enforcement by FDA.

¹¹⁵ See DONNA U. VOGT ET AL, CRS REPORT FOR CONGRESS, FOOD BIOTECHNOLOGY IN THE UNITED STATES: SCIENCE, REGULATION AND ISSUES, Jan. 19, 2001, tbl. 2, 15 (2001).

¹¹⁶ Many Bt genes, and their proteins, have not shown toxicity to humans. EPA has therefore typically granted the Bt crops exemptions from the requirement for a tolerance level. *See, e.g.*, 40 C.F.R. § 180.1155 (2002) (exempting CryIA(c)), 40 C.F.R. § 180.1173 (2002) (exempting CryIA(b)). For an explanation of these decisions to exempt certain Bt genes and proteins *see* 40 C.F.R. § 180.1173 (1996); 40 C.F.R. § 180.1155 (1995).

¹¹⁷ For StarLink corn, EPA concluded that there was a real question about the allergic potential of the proteins produced by the transposed Bt gene Cry9C. *See* Kathleen Hart, *Scientists Question Test for StarLink Corn Allergy*, FOOD CHEMICAL NEWS, July 23, 2001, available at 2001 WL 12773607. Therefore, EPA did not grant the corn an exemption for human consumption of the crop. *See* 40 C.F.R. § 180.1192 (2002) (limiting exemption to feed corn).

The StarLink fiasco revealed some gaping holes in this regulatory regime for GM crops. The holes are the direct result of forcing the new problems posed by biotechnology into the available answers provided by statutes and regulations not drafted with GM crops in mind. For example, EPA did not require Aventis to compile and provide information about when and how StarLink corn was planted.¹¹⁸ Instead, EPA viewed that information as the province of USDA, which patently did not consider the regulatory needs of its sister agencies before deciding to deregulate the crop entirely. As a result, neither EPA nor FDA developed a means of tracking whether StarLink corn entered the human food supply. EPA had the duty to regulate StarLink's Cry9C pesticidal proteins, but did not exert this duty over the plants that produced the toxins. Similarly, FDA was responsible for regulating food safety, but evaluated the safety of StarLink corn without considering the possible health effects, including allergenicity, of the incorporated pesticidal proteins. By relying on existing law in lieu of new statutes, the Framework thus prompted the agencies to maintain illogical regulatory divisions. Although the Framework is not law and cannot replace statutory mandates, the agencies used the Framework to interpret these statutory mandates narrowly and in ways that actually hindered the development of an effective oversight program.

II. THE STARLINK CRISIS

A. *StarLink's Registration Process*

More than thirty StarLink field trials were conducted in 1996 and 1997 under USDA's notification procedure.¹¹⁹ On February 23, 1998, USDA published notice that Aventis had petitioned for a determination that StarLink corn did not pose a plant pest risk and should be granted non-regulated

¹¹⁸ Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,496 (Nov. 23, 1994).

¹¹⁹ See Information System for Biotechnology, at <http://www.isb.vt.edu> (last visited April 14), for the underlying information. See also D.L. Uchtmann, *StarLink—A Case Study*, 7 DRAKE J. AGRIC. L. 159 (2002).

status.¹²⁰ On May 15, 1998, USDA announced that it would grant the StarLink petition for non-regulated status.¹²¹

At the same time Aventis began the USDA field trials, the company also initiated voluntary consultations with FDA. In March of 1998, Aventis submitted information to FDA to support its safety and nutritional assessment of StarLink corn.¹²² Even though the central food safety question was allergenicity—a food safety issue normally under jurisdiction of FDA—the Framework and FDA's 1992 Policy assigned EPA primary regulatory authority. Moreover, under the 1992 Policy, FDA relied on Aventis to evaluate food safety and substantial equivalence for StarLink corn. FDA conducted no independent analysis of these questions.

Aventis concluded that StarLink corn was not materially different in composition, safety or other relevant parameters from corn currently on the market.¹²³ With no further inquiry, FDA accepted Aventis' conclusion that StarLink corn did not raise issues requiring pre-market review or approval by FDA.¹²⁴ FDA carefully noted that it made no evaluation about the allergenicity of the pesticidal protein, but only of the food itself.¹²⁵ It was only with EPA's evaluation of a food tolerance for Cry9C that the significant allergenicity concerns surfaced.¹²⁶ Had FDA conducted an independent investigation, or had FDA's inquiry included the pesticidal protein, the question would surely have arisen sooner.

Corn containing a potentially allergenic protein is materially different in composition and safety from corn currently on the market.¹²⁷ If FDA had

¹²⁰ 63 Fed. Reg. 8,897 (February 23, 1998).

¹²¹ Determination of Nonregulated Status for Bt Cry9C Insect Resistant and Glufosinate Tolerant Corn Transformation Event CBH-351, 63 Fed. Reg. 27,041 (May 15, 1998), available at http://www.aphis.usda.gov/biotech/dec_docs/9726501p_det.HTM; see also generally StarLink Non-Regulated Determination, *supra* note 24.

¹²² Dep. of Health & Human Serv., Note to File BNF 041 (May 29, 1998), available at <http://www.cfsan.fda.gov/~acrobat2/bnfM041.pdf>.

¹²³ *Id.*

¹²⁴ Letter from Alan M. Rulis, Director, FDA Office of Pre-Market Approval, to Sally L. Van Wert, Manager of Regulatory Affairs (May 29, 1998), available at <http://www.cfsan.fda.gov/~acrobat2/bnfL041.pdf>.

¹²⁵ *Id.*

¹²⁶ Allergenicity Assessment of Cry9C Bt Corn Plant Pesticide, 64 Fed. Reg. 71,452 (Dec. 21, 1999).

¹²⁷ David L. Devernoe, Note, *Substantial Equivalence: A Valid International Sanitary and Phytosanitary Risk Assessment Objective for Genetically Modified Foods*, 51 CASE W. RES.

considered the entire organism—the corn with the pesticidal protein—it would never have been able to reach a “substantial equivalence” determination. FDA’s 1992 Policy Statement quite properly looks to the characteristics of the introduced protein to guide the regulatory process.¹²⁸ StarLink corn involved the addition of a protein that had no history of safe use in food.¹²⁹ Had the added protein not been pesticidal, and thus subject to the artificial regulatory divisions reified by the Framework, FDA might have been expected to ask a whole series of questions about the allergenicity and toxicity of the introduced protein.¹³⁰ However, under the Framework, FDA limited its inquiry to the corn excluding the pesticide.¹³¹ And, according to its laissez-faire regulatory stance, FDA relied solely upon Aventis’ interested representations about the safety of StarLink before considering the consultation complete.¹³²

Aventis thus obtained USDA “non-regulated” and FDA “substantial equivalence” status. The company needed only an EPA pesticide registration and food tolerance to begin full-scale marketing of the crop. Aventis initially requested that StarLink corn be exempted from a pesticide tolerance for all raw agricultural commodities, much the same way GM crops containing *cryIA* had been exempted.¹³³ Unlike *cryIA*, however, *cry9C* codes for a protein that shares several unusual molecular properties with known food allergens.¹³⁴

In evaluating the data supporting Aventis’ exemption request, EPA found that some of the submitted data was “compelling and supportive of the [registrant’s claim] of ‘no significant risk,’”¹³⁵ but that large portions of the

L. REV. 257, 277 (2000) (generally arguing in favor of substantial equivalence, but acknowledging that allergenicity concerns may be the unexpected effect of genetic modifications, and when those concerns surface, further safety assessments will be necessary).

¹²⁸ FDA, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1994).

¹²⁹ *Id.* at 22,984.

¹³⁰ *Id.* at 22,999-23,000.

¹³¹ *Id.* at 22,999-23,000.

¹³² *Id.* at 22,999-23,000.

¹³³ Notice of Filing of Pesticide Petitions, 62 Fed. Reg. 49,224 (Sept. 19, 1997).

¹³⁴ CDC Report, *supra* note 9, at 4.

¹³⁵ Allergenicity Assessment of Cry9C Bt Corn Plant Pesticide, 64 Fed. Reg. 71,452 (Dec. 21, 1999).

data were "either inconclusive or indicated that Cry9C proteins exhibit some characteristics of known allergins."¹³⁶ Specifically, EPA noted that the Cry9C proteins were resistant to protease breakdown, remained stable at high temperatures, and remained intact following four hours in simulated mammalian gastric juices.¹³⁷ EPA determined that these characteristics suggested a possibility that the protein might trigger allergic reactions in humans. Because of these unresolved allergenicity concerns, EPA concluded that Aventis failed to show that StarLink corn was "substantially equivalent in all essential respects to its unmodified parent."¹³⁸ This failure precluded the finding of "reasonable certainty of no harm" necessary for an exemption to the FFDCa tolerance requirement. Similarly, because the available data was insufficient to support the conclusion that Cry9C proteins were not potential allergens,¹³⁹ EPA concluded that it could not set a tolerance level for the proteins. Despite the fact that FDA had already signed off on Aventis' substantial equivalence claims for the crop, the lack of an EPA exemption or tolerance for Cry9C proteins meant that the presence of those proteins would render food adulterated and subject to FDA enforcement.

EPA specifically indicated what data was missing, and thus prevented a conclusion about allergenicity. There was no ambiguity. Aventis had the responsibility to provide that data before the corn variety could be approved for human consumption. Rather than provide the allergenicity information, however, Aventis amended its request for an exemption to cover only corn grown for animal feed and industrial uses.¹⁴⁰ As part of this amended request, Aventis provided EPA with a detailed plan for keeping StarLink out of the human food supply.¹⁴¹ Under this plan, farmers purchasing StarLink were: 1) told that corn grown from it could not be sold for human consumption; 2) required to sign a "Grower Agreement" to that effect; and 3) sent two letters

¹³⁶ *Id.*

¹³⁷ Notice of Filing of Pesticide Petitions, 62 Fed. Reg. at 49,225; *see also* OFFICE OF SCIENCE COORDINATION AND POLICY, EPA, CRY9C FOOD ALLERGENICITY ASSESSMENT BACKGROUND DOCUMENT, *available upon request from* <http://www.epa.gov/scipoly/oscpmail.html> (on file with author).

¹³⁸ EPA DATA EVALUATION RECORD — SAFETY ASSESSMENT, MRID No. 44714001 (1999), *available at* <http://www.epa.gov/opbtpd1/biopesticides/pips/old/cry9c/der-44714001a.htm>.

¹³⁹ CDC Report, *supra* note 9, at 6.

¹⁴⁰ Matt Crenson, *Rules for Genetically Modified Corn Broke Down Between Seed Plant, Farm*, ST. LOUIS POST-DISPATCH, Dec. 15, 2000, at A10.

¹⁴¹ *Id.*

of reminder about the restrictions, one at planting and one at harvest time.¹⁴² The “Grower Guide” explained the need for a buffer strip between StarLink and any other corn varieties, and that any corn grown within that buffer would also have to be limited to non-food uses.¹⁴³ Finally, the company promised to conduct a post-harvest survey to ensure that growers had followed the rules.¹⁴⁴

Based on these representations about crop segregation, EPA accepted Aventis’ modified petition and registered StarLink’s PIP for non-food use on May 12, 1998.¹⁴⁵ This split registration was explicitly predicated on Aventis’ plan to keep StarLink out of the human food supply, and out of international commerce.¹⁴⁶ As a result, EPA anticipated that there would be minimal human dietary exposure to the Cry9C protein, with the only course of exposure via ingestion of meat, poultry, eggs and milk from animals fed corn containing the Cry9C protein.¹⁴⁷

EPA’s split registration decision, combined with USDA’s grant of unregulated status, and FDA’s acceptance of Aventis’ substantial equivalence assessment, paved the way for commercial production of StarLink corn for the non-food uses that make up ninety percent of the corn market. Under the terms of the split registration, StarLink corn could be planted for one year on a maximum allowable acreage of 120,000 acres.¹⁴⁸ As express conditions of the split registration, StarLink corn, and any corn grown within 660 feet of it could be used only for animal feed or industrial use, and could not enter international commerce.¹⁴⁹ StarLink corn’s initial split registration was renewed for the 1999 and 2000 growing seasons.¹⁵⁰ For the 1999 growing

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ Approval of Pesticide Product Registrations, 63 Fed. Reg. 28,258-61 (May 22, 1998).

¹⁴⁶ Aventis did not submit StarLink corn for regulatory approval in the EU or Japan. Thus, when StarLink corn later turned up in shipments to these countries, its presence was a violation of the laws of those countries as well as a violation of United States law.

¹⁴⁷ *Id.* See also MIKE MENDELSON, EPA, PESTICIDE FACT SHEET: BT CRY9C IN CORN 5 (Apr. 1, 2000) [hereinafter BIOPESTICIDE FACT SHEET] available upon request at <http://www.epa.gov/opprd001/factsheets/pmcontacts.htm>.

¹⁴⁸ Approval of Pesticide Product Registrations, 63 Fed. Reg. 28,258, 28,258-61 (May 22, 1998).

¹⁴⁹ *Id.* at 28,258.

¹⁵⁰ *Id.*

season, StarLink corn could have been planted on up to 2.5 million acres, though only about 500,000 were actually planted. In 2000, about 315,000 acres were devoted to StarLink corn.¹⁵¹ Another 168,000 acres were supposed to be planted as a buffer area that would also be restricted to non-food use to prevent cross-pollination.¹⁵² Together these 483,000 acres represented about one half of the United States corn crop.¹⁵³

On April 7, 1999, EPA published Aventis' request that the split-registration be revised to expand the tolerance exemption for Starlink corn to include use in all food commodities, including the production of human food.¹⁵⁴ In considering this request, EPA called another meeting of the FIFRA Scientific Advisory Panel ("SAP").¹⁵⁵ EPA solicited advice by posing a series of questions to the SAP and the general public concerning the allergenicity risk posed by Cry9C in light of its unusual characteristics.¹⁵⁶ The SAP met to consider these questions, and concluded that the available data was insufficient to make a determination about allergenicity.¹⁵⁷ EPA therefore continued to deny StarLink corn full registration. Thus, for the 1998, 1999 and 2000 growing seasons, StarLink corn was not approved for human consumption.

As a condition of the continued split registration, Aventis agreed to ensure that all growers abided by the limitations and restrictions contained in the registration.¹⁵⁸ In a January 22, 1999 letter to EPA, Aventis proposed a

¹⁵¹ Illinois Dep't of Agriculture, StarLink Corn Information, *available at* <http://www.agr.state.il.us/news/Special/starlink.htm> (last visited Apr. 15, 2003).

¹⁵² *Id.*

¹⁵³ *StarLink Corn: How it Reached the Food Supply*, *supra* note 2.

¹⁵⁴ AgrEvo USA Company Cry9C Plant-Pesticides; Notice of Filing of Petition, 64 Fed. Reg. 16,965 (Apr. 7, 1999).

¹⁵⁵ The SAP is an advisory committee chartered under the Federal Advisory Committee Act, composed of independent non-agency experts, who assist the agency in assessing the risks of pesticides. EPA, ABOUT THE SCIENTIFIC ADVISORY PANEL (SAP), *available at* <http://www.epa.gov/oscpmont/sap/about.htm> (last visited Apr. 15, 2003).

¹⁵⁶ OFFICE OF SCI. COORDINATOR & POL'Y, EPA, *supra* note 136.

¹⁵⁷ FIFRA SAP, Open Meeting, 65 Fed. Reg. 5636 (Feb. 4, 2000); *See also* Assessment of Scientific Information Concerning StarLink TM Corn Cry9C Bt Corn Plant-Pesticide, 65 Fed. Reg. 65,247 (Oct. 31, 2000).

¹⁵⁸ BIOPESTICIDE FACT SHEET, *supra* note 146. Iowa was one of the primary markets for StarLink corn. One of StarLink corn's major Iowa retailers, Garst Seeds, maintains that it "warned farmers who bought StarLink seed that the corn produced could be used only for feeding livestock and should not be sold into commercial channels." *See* Ed Lotterman,

plan to direct the use of all StarLink corn to animal feed or industrial non-food uses. These terms were expressly incorporated into the 2000 registration.¹⁵⁹ Aventis then licensed StarLink corn to a number of corn seed companies who distributed the corn seed to farmers.

When sold, StarLink seed sacks were supposed to bear a tag indicating that StarLink seeds, plants, and plant materials were to be used domestically for animal feed or non-food industrial purposes and were not to be used for human food or to enter international commerce.¹⁶⁰ The actual language for at least one version of the tag stated: "Under this purchase agreement, customer or any user may: use this hybrid corn seed or any non-hybrid corn seeds found herein, for the purpose of producing grain for feeding or processing."¹⁶¹ Other than this single line on the back of the tag, there was no reference to registration restrictions. This line was wholly inadequate, because it did not explicitly identify or explain the registration restrictions. The word "processing," in this context, is highly ambiguous—it could readily have referred to the normal processing channels into which growers sell conventional corn for use as human food. Coupled with this ambiguous tag was supposedly a Grower Agreement which reiterated the registration restrictions. In the fall of 2000, however, Aventis was unable to produce Grower Agreements for a significant percentage of the corn that it sold.¹⁶² The Iowa Attorney General investigated allegations that after the crisis

Troubles that Grew with StarLink Corn Provide Lesson in Economics, Dec. 3, 2000, available at <http://www.edlotterman.com/FrameForLink.htm>. "According to news accounts after the crisis began reported that, according to many StarLink growers, 'warnings were accompanied by a wink and a nudge, together with advice to the effect that 'the government hasn't approved it for human use yet, but this is just red tape and it will be OK by harvest time.'" *Id.* See also, David Barboza, *Gene Altered Corn Changes Dynamics of Grain Industry*, N.Y. TIMES, Dec. 11, 2000, at A1. Many farmers and growers reported receiving no special warnings about keeping StarLink out of the human food supply and claimed that the seed bags bore nothing that could be considered to be a warning label. William Ryberg, *Growers of Biotech Corn Say They Weren't Warned*, DES MOINES REG., Oct. 25, 2000 at 1A.

¹⁵⁹ *Bacillus Thuringiensis Subspecies Tolworthi Cry9C Protein and the Genetic Material Necessary for its Production in Corn; Exemption From the Requirement of a Tolerance*, 40 C.F.R. § 180.1192 (2002).

¹⁶⁰ EPA, PETITION FOR TOLERANCE 9 (2001), available upon request at <http://www.epa.gov/epahome/question.html> [hereinafter PETITION FOR TOLERANCE].

¹⁶¹ *Bag Tag*, reprinted in NEIL E. HARL ET AL., *THE STARLINK SITUATION* (2000), available at <http://www.mindfully.org/GE/StarLink-Situation-15mar01.htm>.

¹⁶² Crenson, *supra* note 139.

unfolded, Aventis attempted to have Iowa growers sign agreements backdated to April 2000 (forty percent of the 2000 StarLink crop had been planted in Iowa.)¹⁶³ Aventis flatly denied these allegations, claiming that the retroactive letters did not originate from the company. Aventis did not dispute, however, that the company had failed to require many farmers to sign Grower Agreements—a direct violation of StarLink's registration.

Aventis thus failed to comply with the grower notification commitments that the company had made to obtain StarLink corn's split registration. But that was only the beginning. Aventis had also explicitly promised EPA that StarLink corn would not enter the human food supply and would not enter international commerce. Despite these legally-binding promises, Aventis set up neither tracking procedures, nor product testing protocols that could have served as an oversight mechanism. Nor did Aventis notify corn elevators of the restriction on use of StarLink corn. Other than the ambiguous seed tag, Aventis seems to have taken no steps to ensure that StarLink was grown in accordance with its registration requirements.

StarLink's registration restrictions also required that growers plant a 660 foot buffer of non-StarLink corn around their StarLink plantings.¹⁶⁴ This buffer was intended to capture any pollen drift, thereby preventing contamination of food corn.¹⁶⁵ Like the StarLink plantings themselves, this buffer corn was also restricted to animal or industrial uses.¹⁶⁶ This registration requirement was apparently either not communicated to the 2,070 growers who planted StarLink corn,¹⁶⁷ or the growers ignored the requirement. As a result, some non-StarLink growers wound up innocently selling StarLink-contaminated corn because their crops were cross-fertilized by StarLink from neighboring growers' fields.¹⁶⁸

¹⁶³ Lin et al., *supra* note 11, at 49.

¹⁶⁴ *StarLink Corn: How it Reached the Food Supply*, *supra* note 2.

¹⁶⁵ Biopesticide Fact Sheet, *supra* note 146. Corn is a wind pollinating, out-crossing species. Corn pollen can travel up to one-half a mile, farther than the distance required in the StarLink registration. *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ Kurt Eichenwald, *New Concerns Rise on Keeping Track of Modified Corn*, N.Y. TIMES, Oct. 14, 2000, at A1.

¹⁶⁸ Barboza, *supra* note 157.

B. *The Crisis and Its Aftermath*

When StarLink corn was discovered in various consumer food products in September 2000, it was in direct contravention of the product's registration restrictions. The food products that contained StarLink corn were adulterated under the FFDCA and indicated that Aventis had violated the terms of the split-registration. Aventis and government agencies scrambled to contain a growing crisis in food production and distribution. Further investigations revealed that millions of bushels of StarLink corn had been comingled with food corn in at least 350 grain elevators.¹⁶⁹ By November 2000, FDA had exercised its enforcement authority to recall more than 300 types of adulterated snack chips, corn flour, and other corn foods.¹⁷⁰ The expense of these recalls is estimated in the millions of dollars.¹⁷¹ Complaints began pouring into the Food and Drug Administration ("FDA") and the Center for Disease Control ("CDC") about allergic reactions to corn products attributable to StarLink contamination.¹⁷² On October 25, 2000, FDA requested that CDC conduct an epidemiological investigation of these reports of human illness potentially associated with the consumption of StarLink corn.¹⁷³

StarLink corn also began showing up in grain shipments to Japan, the largest foreign market for United States corn.¹⁷⁴ Exports to Japan, usually around 600 million bushels annually, dropped by more than fifty percent virtually overnight.¹⁷⁵ In South Korea, the second biggest importer of American corn, thousands of tortillas were recalled because of contamination fears.¹⁷⁶ Thailand began requiring importers to certify that their products were free of StarLink contamination.¹⁷⁷ The European Union redoubled its

¹⁶⁹ Eichenwald, *supra* note 166.

¹⁷⁰ FDA Enforcement Report for November 1, 2000, *supra* note 7.

¹⁷¹ Glover, *supra* note 8.

¹⁷² CDC REPORT, *supra* note 9.

¹⁷³ *Id.*

¹⁷⁴ *Japan Says Banned Corn Used in Products*, CHI. TRIB., Dec. 28, 2000; *see also Business of Buying*, FARM INDUSTRY NEWS, Dec. 30, 2000, 2000 WL 13070551; *StarLink Corn: How it Reached the Food Supply*, *supra* note 2.

¹⁷⁵ *Business of Buying*, *supra* note 173.

¹⁷⁶ Crenson, *supra* note 139.

¹⁷⁷ *Allergy Fears Trigger Action on GM Maize*, BANGKOK POST, Dec. 19, 2000, 2000 WL 29611501.

opposition to GM crops. United States corn exports plunged thirty-nine percent. Lost international sales because of StarLink presence in corn shipments are currently the subject of a multi-district litigation in the Northern District of Illinois.¹⁷⁸ What is not yet clear is whether StarLink produced a localized decrease in corn exports or whether the StarLink crisis will permanently alter these international commodities trading relationships. As of December 2002, Japanese imports of United States corn had only begun to return to pre-StarLink levels when a new discovery of StarLink contamination threatened to plunge the trade relationship back into crisis.¹⁷⁹ South Korean food processors continue to shun United States corn for food use, turning instead to Chinese and South American suppliers.¹⁸⁰ Despite the growing threat of famine in both countries, fears about GM corn prompted Zimbabwe and Zambia to refuse United States aid shipments that included biotech corn.¹⁸¹

Response to the StarLink crisis in the United States reflected how seriously the food industry took the crisis. Giant food processors like Kellogg, Archer Daniels Midland, and ConAgra shut down their plants to clear StarLink contamination.¹⁸² Upon reopening, the companies began testing incoming shipments for StarLink contamination, turning away whole rail cars of corn.¹⁸³ Things got even worse when Garst Seed, one of StarLink corn's distributors, announced that one of its other corn hybrids unexpectedly

¹⁷⁸ See *In re StarLink Corn Products Liability Litigation*, 211 F. Supp. 2d 1060 (N.D. Ill. 2002). Some of the consolidated cases allege nuisance, trespass and consumer fraud in addition to lost profits. Moreover, Aventis, the current patent holder for StarLink corn has spent between \$68 and \$100 million in an attempt to purchase the outstanding stocks of StarLink corn. Greg Frost, *Starlink Was Grown in Other Countries*, Oct. 31, 2000, at <http://www.thecampaign.org/newsupdates/oct00ii.htm>. Aventis paid farmers a twenty-five cents per bushel premium to buy back the StarLink corn.

¹⁷⁹ Randy Fabi, *Japan Got Trace of Biotech Corn, U.S. Exporters Say*, TORONTO STAR, Dec. 30, 2002, at D05.

¹⁸⁰ *Id.*

¹⁸¹ *Id.* These decisions to reject GM food aid were undoubtedly influenced by the prospect that such food aid might jeopardize agricultural trade with the European Union.

¹⁸² Victor Epstein, *ConAgra Foods Reopens Mill, Boosts Testing*, OMAHA WORLD-HERALD, Oct. 27, 2000, at 34; *Food Plants Running Again After StarLink Corn Scare*, TORONTO STAR, Oct. 31, 2000.

¹⁸³ Bill Hord, *Biotech Acceptability Worries: Farmers Carefully Weigh Options in Seed Varieties Biotech Planting in 2000*, OMAHA WORLD HERALD, Dec. 30, 2000, at Business 10; Crenson, *supra* note 139.

contained the StarLink gene and that the company had no idea how the contamination occurred.¹⁸⁴

Under heavy pressure from EPA, Aventis voluntarily withdrew StarLink's United States registration in mid-October 2000.¹⁸⁵ In conjunction with grain handlers and the milling industry, Aventis also instituted procedures to identify StarLink corn and to direct it into appropriate non-food uses.¹⁸⁶ Testing revealed that about ten percent of the United States corn crop had been contaminated with detectable amounts of the CRY9C proteins found in StarLink corn—an unsettlingly high percentage.¹⁸⁷ Most of the 2000 StarLink crop was ultimately repurchased by USDA and Aventis, and channeled to animal feed. But federal officials and Aventis were unable to locate about 1.5% of the 2000 crop, or about 1.2 million bushels.¹⁸⁸ And, of course, the earlier crops had already been sold to food producers.¹⁸⁹

In a move that outraged critics, Aventis sought to deal with the problem of StarLink contamination of the human food supply by requesting that EPA grant CRY9C a limited retroactive tolerance.¹⁹⁰ Claiming that removing StarLink completely from the human food supply was impossible, Aventis essentially asked EPA to ratify its failure to comply with the registration requirements by retroactively approving StarLink corn for human consumption.¹⁹¹ This request was for a four year temporary tolerance to cover any CRY9C protein and *cry9c* DNA that might be present in human food

¹⁸⁴ Troy Goodman, *Expert: StarLink Biotech Corn a Test Case for Regulatory Needs*, Nov. 30, 2000, at <http://www.cnn.com/2000/FOOD/news/11/30/starlink.epa/>.

¹⁸⁵ Press Release, EPA, *EPA Statement on Aventis Withdrawing StarLink Maize (2000)*, at <http://usinfo.state.gov/topical/global/biotech/00101304.htm>.

¹⁸⁶ Some of these steps are detailed in PETITION FOR TOLERANCE, *supra* note 159, at 20-30.

¹⁸⁷ Anthony Shadid, *Tests for Genetic Corn Spur Concerns, Amounts of Disputed Variety Found in 10% of US Grain Inspections*, BOSTON GLOBE, May 3, 2001, at C1.

¹⁸⁸ *Experts: Worries About Biotech Corn Are Overblown*, Nov. 14, 2000, at <http://www.cnn.com/2000/FOOD/news/11/14/biotech.corn.02>.

¹⁸⁹ Because crops are routinely co-mingled at grain elevators, tiny amounts of StarLink ultimately tainted billions of bushels of corn. Indeed, there were estimates that one half of Iowa's corn crop would end up mixed with StarLink. David Barboza, *Negligence Suit is Filed Over Altered Corn*, N.Y. TIMES, Dec. 4, 2000, at C2.

¹⁹⁰ Notice of Request for 20 Parts Per Billion Tolerance of Cry9C in Corn, 66 Fed. Reg. 31, 915 (June 13, 2001); Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical In or On Food, 66 Fed. Reg. 33,078 (June 20, 2001).

¹⁹¹ Updated Safety Assessment of StarLink Corn Containing Cry9C Protein, Oct. 25, 2000, available at http://www.biotech-info.net/Aventis_Final_StarLink.pdf.

made from StarLink corn planted in 1998, 1999, and 2000.¹⁹² In support of this application, Aventis submitted additional scientific information about allergenicity.¹⁹³

EPA convened another SAP meeting on November 28, 2000 to consider this new information and to revisit whether CRY9C was a potential human allergen.¹⁹⁴ EPA's charge to the SAP included a request that the SAP evaluate the likelihood that CRY9C is a food allergen, and whether the levels of CRY9C present in the United States diet would be sufficient to cause significant allergic reactions in exposed populations.¹⁹⁵ EPA provided the SAP its initial evaluation of the materials submitted by Aventis.¹⁹⁶ For each variable, EPA used more conservative estimates than had Aventis.¹⁹⁷ As a result, EPA's estimate of the concentration of CRY9C in StarLink corn, and the StarLink contamination in the United States' food supplies were significantly higher than those provided by Aventis.¹⁹⁸ The SAP considered Aventis' submissions and EPA's evaluation and issued a final report on in early December 2000.¹⁹⁹ The report expressed the panel's consensus that CRY9C had a "medium likelihood" to be an allergen but that the expression level of the protein and the amount of StarLink that had likely been co-mingled posed a "low probability" of allergic responses.²⁰⁰ Based on these SAP findings, EPA ultimately denied the requested tolerance.

¹⁹² Notice of Request for 20 Parts Per Billion Tolerance of Cry9C in Corn, 66 Fed. Reg. at 31,915 (June 13, 2001); Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical In or On Food, 66 Fed. Reg. at 33,078.

¹⁹³ Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food, 66 Fed. Reg. at 33,078.

¹⁹⁴ FIFRA Science Advisory Panel: Notice of Public Meeting, 65 Fed. Reg. 66,750 (Nov. 7, 2000).

¹⁹⁵ EPA, QUESTIONS FOR THE FIFRA SCIENTIFIC ADVISORY PANEL, ASSESSMENT OF SCIENTIFIC INFORMATION CONCERNING STARLINK CORN CRY9C, BT PLANT-PESTICIDE (Nov. 28, 2000), *available at* http://www.epa.gov/scipoly/sap/2000/november/cry9c_sap_qs.pdf.

¹⁹⁶ EPA, EPA PRELIMINARY EVALUATION OF INFORMATION CONTAINED IN THE OCTOBER 25, 2000 SUBMISSION FROM AVENTIS CROPSCIENCE (2000), *available at* http://www.epa.gov/scipoly/sap/2000/november/prelim_eval_sub102500.pdf.

¹⁹⁷ *Id.* at 14-21.

¹⁹⁸ *Id.*

¹⁹⁹ EPA, ASSESSMENT OF SCIENTIFIC INFORMATION CONCERNING STARLINK CORN 19-21 (2000), *available at* <http://www.epa.gov/scipoly/sap/2000/november/one.pdf>.

²⁰⁰ *Id.* at 9-14.

On January 19, 2001, five years after FDA had concluded its consultation with Aventis over StarLink corn, and months after StarLink contamination had been discovered, FDA issued Guidance on how to sample and test corn to identify StarLink contamination.²⁰¹ Also in January 2001, Aventis and the Attorneys General of seventeen states reached an agreement whereby Aventis agreed to pay growers a twenty-five cents per bushel premium over market corn prices to repurchase the StarLink crop.²⁰² In March of that year, Kraft Foods and other affected manufacturers entered into a multi-million dollar settlement with consumers allegedly affected by StarLink contamination.²⁰³ Aventis indemnified these manufacturers for their liability.²⁰⁴ In May 2001, the Missouri Attorney General sued Aventis, claiming that the company did not adequately educate farmers on how to keep StarLink out of the human food supply.²⁰⁵ The suit seeks damages on behalf of Missourians who could not sell their corn or get the price that they otherwise would have gotten if their corn had not been StarLink or mixed with StarLink.²⁰⁶ Similar individual suits were consolidated in a multi-district litigation in the Northern District of Illinois.²⁰⁷

²⁰¹ CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, GUIDANCE FOR INDUSTRY, FDA RECOMMENDATIONS FOR SAMPLING AND TESTING YELLOW CORN AND DRY-MILLED YELLOW CORN SHIPMENTS FOR CRY9C PROTEIN RESIDUES (2001) [hereinafter FDA CORN GUIDANCE], available at <http://vm.cfsan.fda.gov/~dms/starguid.html>.

²⁰² Aventis has also agreed to pay \$100 million to settle a whole series class action and putative class action suits brought on behalf of farmers who grew non-StarLink corn and claimed to have been injured because of Cry9C's presence in the United States corn supply. See *In re StarLink Corn Products Liability Litigation, Settlement Class Certification, Proposed Settlement and Fairness Hearing*, MDL #1403, Feb. 14, 2003, available at <http://www.non-starlinkfarmerssettlement.com>.

²⁰³ *In re StarLink Corn Products Liability Litigation*, N.D. Ill., MDL #1403, Mar. 7, 2002, available at http://www.jpml.uscourts.gov/Pending_MDLs/Products_Liability/MDL-1403/mdl-1403.html. See also *Judge Approves \$9 Million Settlement in Class Action Over StarLink Corn*, PRODUCTS LIABILITY DAILY, Mar. 21, 2002.

²⁰⁴ *Judge Approves \$9 Million Settlement in Class Action Over StarLink Corn*, *supra* note 203.

²⁰⁵ See Eric Palmer, *Missouri Attorney General Files Suit Over Bioengineered Corn*, KAN. CITY STAR, May 5, 2001, at C8.

²⁰⁶ *Id.*

²⁰⁷ *In re StarLink Corn Products Liability Litigation*, N.D. Ill., MDL #1403, Mar. 7, 2002, available at http://www.jpml.uscourts.gov/Pending_MDLs/Products_Liability/MDL-1403/mdl-1403.html.

III. REGULATORY FLAWS

Fears about potential allergic reactions to StarLink corn are abating in the scientific community.²⁰⁸ The SAP ultimately concluded that although there was a “medium likelihood” that StarLink corn was allergenic, so little of the corn made its way into the food supply that there was only a “low probability” that consumers would actually develop allergies to it.²⁰⁹ The incident nonetheless raises serious questions about the adequacy of the Framework, and of the GM regulatory scheme in general. The presence of StarLink corn in human food was unambiguously unlawful, rendering the foods in question adulterated under the Food, Drug and Cosmetic Act,²¹⁰ and violating the corn’s Plant Incorporated Pesticide Registration.²¹¹ Simply put, this corn should never, under any circumstances, have found its way into the human food supply. The fact that not enough StarLink corn entered the food supply to be particularly harmful is the result of the vigilance of anti-GM activists, *not* the effectiveness of the Framework or the regulatory scheme it created.²¹² But for the hypervigilance of staunch GM opponents, it is unlikely

²⁰⁸ See CDC REPORT, *supra* note 9. Blood tests failed to find signs of antibodies to the protein in the genetically engineered corn. Thus, the federal Center for Disease Control and Prevention concluded that although the study participants may have experienced allergic reactions, based upon the results of their study alone, CDC “could not conclude that a reported illness was a [StarLink] allergic reaction.” CDC also cautioned that they could not rule out the possibility because food allergies may occur without detectible serum antibodies to the antigen.

²⁰⁹ FIFRA SAP, ASSESSMENT OF SCIENTIFIC INFORMATION CONCERNING STARLINK™ CORN, SAP Report No. 2000-06 (2000), available at <http://www.epa.gov/scipoly/sap/2000/index.htm>.

²¹⁰ Under 21 U.S.C. § 346a(a)(1) (2000) and 21 U.S.C. § 342(a)(2)(B) (2000), the presence of StarLink corn or Cry9C in human food products rendered those products adulterated under the federal Food, Drug and Cosmetic Act. Pursuant to 21 U.S.C. § 331(a), the introduction of an adulterated food into interstate commerce is illegal.

²¹¹ See *Bacillus Thuringiensis* subspecies *tolworthi* Cry9C Protein and the Genetic Material Necessary for its Production in Corn: Exemption From the Requirement of a Tolerance, 63 Fed. Reg. 28,258 (May 22, 1998). This exemption regulation eliminated the need to establish a maximum permissible level for residues of this plant pesticide in, or on, corn used for feed, as well as in meat, poultry, milk or eggs resulting from animals fed such feed. The exemption specifically did not permit human consumption of the StarLink corn itself.

²¹² Senator Durbin (D-Ill.) alleged that EPA knew as early as 1998 that conventional corn was contaminated with StarLink proteins but took no action to remedy the problems. See *Durbin Says EPA Knew of Possible StarLink Problems in 1998*, FOOD & DRINK WKLY., Dec. 11,

that the registration violations at the heart of the crisis would *ever* have come to light absent a public health catastrophe.

The government had no mechanism to oversee the registration restrictions and no means of verifying compliance. Safety depended solely upon voluntary, unmonitored compliance from a regulated community that fell woefully short of the mark. It is not at all clear that critical registration requirements were even communicated to the growers actually planting, harvesting and selling StarLink corn. For example, in contravention of a clear registration requirement, Aventis did not ensure that its growers contractually committed to following any procedures designed to keep StarLink corn from the human food supply.²¹³ Some growers contended that they were never told of StarLink corn's use restrictions and others said that they were told not to worry about segregation because EPA approval was expected shortly.²¹⁴ Others claimed that the tag affixed to StarLink corn misleadingly suggested that the corn could be used for human food.

Were StarLink an isolated incident, it would be troubling, but at least it would be nearly over. But there are other Bt hybrids subject to the same lax regulatory scheme. Like StarLink corn, these other Bt crop registrations include numerous detailed provisions intended to protect human health and the environment, most notably by inhibiting the development of insect resistance to Bt as a pesticide.²¹⁵ Resistance to Bt would be a serious problem for organic and conventional farmers who rely on Bt as a component of their crop protection arsenal. Everyone, both GM advocates and their opponents, agree that pest resistance to Bt is a real problem and that measures must be taken to impede or prevent the evolution of such resistance. The StarLink fiasco raises a real concern that, as to these other GM crops, environmental protections are implemented in exactly the same way as StarLink corn's use

2000, *available at* 2000 WL 30905574. If true, EPA apparently registered and re-registered StarLink corn in the face of evidence that the registration restrictions were patently inadequate. These allegations suggest that agency failures are even more significant than described in this Article.

²¹³ Eichenwald, *supra* note 166.

²¹⁴ Barnaby J. Feder, *Farmers Cite Scarce Data in Corn Mixing*, N.Y. TIMES, Oct. 17, 2000, at C1.

²¹⁵ See Agricultural Biotechnology Stewardship Technical Committee, Bt Corn Insect Resistance Management Survey: 2000 Growing Season, Jan. 31, 2001, *available at* <http://www.ncga.com/biotechnology/insectMgmtPlan/pdf/finalIRMsummarysurvey.pdf>.

restrictions (i.e., not at all).²¹⁶ Realistically speaking, these environmental safety restrictions are just as unenforceable as was StarLink's "no human food use" restriction, and for exactly the same reason. Without knowing where GM crops are planted, independent oversight is simply not possible.

Even more troubling, Bt crops are merely the tip of the iceberg. In particular, the prospect of corn biopharming in the corn belt poses serious contamination and food safety issues. Biopharming involves inserting genes into plants to make them manufacture drugs, vaccines, enzymes, antibodies, hormones or industrial chemicals such as plastics, detergents, and adhesives. Right now, biopharming is the cutting edge of biotechnology. Although biopharming uses corn as its production vehicle, biopharm crops are not food and are not intended for human consumption. According to some predictions, at least ten percent of United States agricultural lands will be devoted to biopharming by the end of the decade.²¹⁷

Nothing prevents these biopharm crops from being planted near corn intended for human consumption. As such, biopharming challenges the Framework in new and more fundamental ways. The likelihood of commingling is real. For example, in December 2002, USDA announced that ProdiGene, Inc. had failed to comply with strict guidelines for completely removing a biopharming crop in two separate locations, one in Nebraska and the other in Iowa.²¹⁸ At both sites, a grower under contract to ProdiGene had failed to remove volunteer corn before planting soybeans on the same land.²¹⁹ Unlike StarLink corn, which had received full USDA regulatory clearance,

²¹⁶ In December 2002, the Philippines approved a Bt crop, Monsanto's YieldGuard corn borer, for use in the next growing season. Leilani M. Gallardo, *FOCUS Bt Corn—More Harm Than Good, or Vice Versa?*, BUS. WORLD (Philippines), Jan. 9, 2003, at 1. The Philippines did not, however, adopt the resistance management plans deemed essential to safe use of the crop. Rather the Ministry of Agriculture announced that farmers would be instructed to either plant Bt crops every other year, or to use non-corn crops as refuges to prevent resistance. In a region where farmers routinely save seeds for planting, the former option is completely unenforceable, and United States scientists have soundly rejected the adequacy of the second option to preserve insect susceptibility.

²¹⁷ Aaron Zitner, *Fields of Gene Factories*, L.A. TIMES, June 4, 2001, at A1; Scott Kilman, *Food, Biotech Industries Feud Over Plans for Bio-Pharming*, WALL ST. J., Nov. 5, 2002, at B7.

²¹⁸ *USDA Investigates Biotech Company for Possible Permit Violations*, Nov. 13, 2002, at <http://aphisweb.aphis.usda.gov/lpa/news/2002/11/prodigene.html>.

²¹⁹ *Feds Probe Biotech Firm for Crop Mixing*, Nov. 12, 2002, at <http://www.cnn.com/2002/US/11/14/biotech.contamination/>.

biopharming is still experimental. Therefore, the ProdiGene sites were still subject to federal inspection. Inspectors discovered corn that had been engineered to produce a swine vaccine growing amidst soybeans in a field that had been planted with the biopharming corn a year earlier.²²⁰

Volunteer plants of this sort are not uncommon. For biopharming to work safely, the public must be able to trust that growers will take all necessary steps to eradicate such volunteers. In the ProdiGene incidents, the grower was told to destroy the corn plants to prevent the possibility of contamination.²²¹ Instead of complying, the grower simply harvested the fields and sent the soybeans to an elevator, where they were mixed with the soybeans already present in the elevator.²²² Stalks and leaves from the bioengineered corn were discovered mixed with the soybeans.²²³ Because of contamination fears, regulators ordered the destruction, not only of all the soybeans in the elevator, but also of ordinary corn fields that had surrounded the biopharm corn.²²⁴ USDA levied a significant fine against the company, but the underlying problem remains.²²⁵ The grower had not been careful—had not taken to heart the need to prevent cross-contamination and to keep its swine vaccine corn out of the human food supply. Nor had ProdiGene taken any steps to ensure grower compliance with the clear and legally binding

²²⁰ *Agriculture Department Fines ProdiGene for Biotech Mishaps* (Dec. 7, 2002), at <http://earthboundfarm.com/news-world/GMOfine.html>.

²²¹ Philip Brasher, *Biotech Corn May Have Tainted Soybeans*, DES MOINES REG., Nov. 13, 2002, at 1A.

²²² *Id.*

²²³ *Corn Near Gene-Altered Site to be Destroyed*, N.Y. TIMES, Nov. 14, 2002, at C10.

²²⁴ *Id.* See also Philip, *supra* note 220.

²²⁵ Press Release, Matt Lloyd & Jerry Redding, 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>. ProdiGene was assessed a \$250,000 fine, and required to pay more than \$3 million to repurchase the soybeans and to clean the silo. See Christopher Doering, *ProdiGene to Spend Millions on Bio-Corn Tainting*, Sept. 12, 2002, at <http://www.planetark.org/avantgo/dailynewsstory.cfm?newsid=18935>.

Prodigene also agreed to a \$1 million bond and higher compliance standards, including additional approvals before field testing and harvesting genetically modified material. The company will develop a written compliance program with USDA to ensure that its employees, agents, cooperators and managers are aware of, and comply with, the Plant Protection Act, federal regulations and permit conditions.

Lloyd & Redding, *supra*.

requirements about how this biopharm crop must be handled.²²⁶ In this case, none of the biopharmed corn made it into the food supply, but it was a close call.

ProdiGene is not alone. As 2002 drew to a close, EPA announced it had levied fines against two more biopharming firms, this time in Hawaii, for failure to properly manage biopharming crops.²²⁷ Dow Agrosciences and Pioneer Hi-Bred were both fined for failure to take proper measures to prevent commercial crops intended for human consumption from being contaminated with experimental biopharmed corn.²²⁸

Because they are viewed as an economic boon, Biopharm crops are being rushed into production with little or no attention to control mechanisms—and with even less attention to the grower education that must be the centerpiece of any safety program. Meanwhile, the StarLink corn fiasco suggests what the outcome will be. The next violation may not be caught in time, and the next crisis might not be so benign. The integrity of the United States food supply could be placed in jeopardy.

Even though EPA has vowed never to issue another registration for a genetically modified food crop unapproved for human consumption, biopharming provides a fertile ground for the particulars of the StarLink crisis to recur.²²⁹ Biopharming corn and other crops are emphatically not for human consumption as food. To date, however, they are indistinguishable from those intended for human consumption, and they are being grown in Iowa and other parts of the cornbelt. The Grocery Manufacturers of America have urged biotech companies to stop using food crops as vehicles for growing biotech products that humans and animals are not supposed to eat.²³⁰ Such calls face

²²⁶ Brasher, *supra* note 220.

²²⁷ Justin Gillis, *EPA Fines Biotechs for Corn Violations*, WASH. POST, Dec. 13, 2002, at E3.

²²⁸ *Id.* On a related note, FDA is investigating whether genetically modified pigs were improperly sold into the human food supply. Aaron Zitner, *Pigs in Genetic Study May Have Ended Up as Food*, L.A. TIMES, Feb. 6, 2003, at 17. This incident underscores the very real possibilities that any GM products might wind up in the human food supply. The likely effects of a failure to segregate must be considered at the approval stage.

²²⁹ Of course EPA has no regulatory authority over biopharming because the crops do not incorporate pesticides. So EPA's vow does nothing to protect the public from a StarLink-like fiasco involving a biopharmed crop.

²³⁰ Press Release, Grocery Manufacturers of America, GMA Urges the Use of Non-Food Crops for Biotech Drugs (Nov. 14, 2002), at <http://www.gma-brands.com/news/docs/NewsRelease.cfm?DocID=1029&>.

stiff political opposition from cornbelt officials. Indeed, in the wake of the ProdiGene incident, a biotech industry trade group, BIO, issued and then revoked a commitment not to grow biopharm corn in the cornbelt.²³¹

If there is one clear lesson from this StarLink corn incident, it is that under the current system co-mingling of these crops, either by design or inadvertence, is inevitable. A crisis is waiting to happen. In the meantime, public fear and distrust of the new technology continues to grow. The failures are real and so is the public concern. The only way to assuage the public's concern is for the regulatory agencies involved to take a hard look at their laissez-faire policies and to develop more stringent oversight procedures. Only new, more stringent procedures can rebuild public trust and create confidence in the safety of GM products.

IV. LESSONS LEARNED

It is important to understand what went wrong with StarLink, Prodigene and the other recent biotech incidents. The central culprit is a laissez-faire regulatory philosophy. The 1990's echoed with repeated calls for regulators to adopt a more cooperative stance with the regulated community.²³² These so-called "Next Generation" reforms relied heavily on voluntary compliance by corporations that had internalized a stewardship ethic.²³³ This idea, that EPA could work in partnership with these corporate stewards to achieve environmental goals without all the acrimony and conflict generated by heavy-handed regulatory oversight and enforcement,²³⁴

²³¹ See Philip Brasher, *Iowa Denied New 'Drug' Corn*, DES MOINES REG., Oct. 23, 2002, at 1A; Philip Brasher, *Biotech Group Lifts Corn Ban*, DES MOINES REG., Dec. 4, 2002, at 1A.

²³² See, e.g., ASPEN INST., *THE ALTERNATE PATH: A CLEANER, CHEAPER WAY TO PROTECT AND ENHANCE THE ENVIRONMENT* (1996); YALE CTR. FOR ENVTL. LAW AND POLICY, *THINKING ECOLOGICALLY: THE NEXT GENERATION OF ENVIRONMENTAL POLICY* (Marian R. Chertow & Daniel C. Esty eds., Yale Univ. Press 1997); NATL ACAD. OF PUB. ADMIN., *TRANSFORMING ENVIRONMENTAL PROTECTION FOR THE 21ST CENTURY* (2000).

²³³ Project XL was EPA's most visible experiment with stewardship and cooperative regulation. Regulatory Reinvention (XL) Pilot Projects, 60 Fed. Reg. 27,282 (May 23, 1995).

²³⁴ See, e.g., David Case, *The EPA's Environmental Stewardship Initiative: Attempting to Revitalize a Floundering Regulatory Reform Agenda*, 50 EMORY L. J. 1 (2001); Dennis A. Rondinelli, *A New Generation of Environmental Policy: Government-Business Collaboration in Environmental Management*, 31 Env'tl. L. Rep. (Env'tl. L. Inst.) 10,891 (2001).

has become a central tenet of the second Bush Administration. Such an approach to regulation is based on a fundamental belief that corporate stewards will rise to the occasion and will voluntarily assume the burdens of protecting the environment and society.

StarLink provides a chilling example of how badly an oversight system built solely upon voluntary compliance can fail. All three agencies relied on manufacturer self-policing as the primary means to enforce regulatory requirements. Aventis initially expressed confidence that StarLink corn could not wind up in the human food supply, claiming that its stewardship program "had the full participation of the corn industry" and that the company had "every indication it [was] working well."²³⁵ These initial claims proved to be false—there was no stewardship program, other than inadequate warning labels, and grain elevator operators were entirely unaware of the split registration and the need to keep StarLink corn segregated. Many farmers had never even been informed of the obligation to keep StarLink corn from the human food supply.²³⁶ Others reported that seed companies played down the significance of these restrictions.²³⁷ News accounts similarly reported that "warnings were accompanied by a wink and a nudge," together with advice to the effect that the government had not approved StarLink for human use yet, but that was just "red tape" that would be resolved by harvest time.²³⁸

These failures undermine the basic assumption underlying compliance schemes based on cooperation and self-policing—a belief that public and private interests converge in environmental stewardship. This assumption is problematic under the best of circumstances. Corporations are private entities, with private goals. These private goals occasionally coincide with public goals, but more often in the abstract than the concrete. On a very basic level, we do all agree—cleaner air and water, and safer food are certainly desirable public goods. When it comes to allocating who should bear the cost

²³⁵ *Unapproved Corn*, *supra* note 2, at A-2.

²³⁶ Matt Crenson, *How Starlink Corn Got Loose*, PITTSBURGH POST GAZETTE, Dec. 4, 2000, at A8.

²³⁷ According to a representative of the Iowa Attorney General's office, for example, "farmers who grew StarLink were told by seed dealers not to worry about the restrictions, that EPA was on the verge of approving StarLink for human consumption. By the time they harvested their crop there would be no reason to separate StarLink." *Id.*

²³⁸ Lotterman, *supra* note 158.

of providing and preserving these public goods and, more critically, to determining what costs are appropriate, private and public interests rapidly diverge. It is in the public's interest, and is therefore the regulator's task, to persuade, coerce or force companies to internalize the costs of maintaining these public goods. It is no condemnation of private business entities to say that their interests differ on this point—the duty to maximize profits drives corporations to resist internalizing these previously externalized costs.

No amount of warm and fuzzy language can obscure this basic conflict of interests. Certainly there are times when creative and far-sighted regulators can help align public and private interests. Market-based incentives can be a powerful tool to achieve that end. In certain contexts, there are private companies willing or even eager to adopt stewardship measures. We should certainly strive for a regulatory system flexible enough to recognize those actors and those situations. But an effective regulatory system cannot start from the assumption that private actors will achieve public ends in the absence of direction and oversight from the public sector. Otherwise, fiascos like StarLink will be the inevitable result.

A. *The Framework Cannot Meet the Challenges of Regulating GM Crops*

The test of any regulatory system must be its ability to resolve the problems it is charged with regulating. Viewed through that lens, the Framework has been an abysmal failure. StarLink corn proved that the existing regulatory regime, with its divided regulatory authority, and its reliance on voluntary compliance, cannot meet the challenges posed by biotechnology. The failures are numerous, but the critical flaw in the Framework is the lack of any structural means of oversight and a concomitant lack of accountability on the part of GM manufacturers. The peculiar creature that was “split registration” ensured the StarLink crisis only because it existed in an inadequate regulatory environment. As one food company executive commented: “This whole system has been self-policing by the seed industry and obviously it hasn't worked.”²³⁹

Neither EPA nor FDA had an oversight program to back up their laissez-faire regulatory approach towards this biotech crop. The agencies had

²³⁹ Eichenwald, *supra* note 38.

no systematic monitoring program to ensure that StarLink—a crop that was not approved for human consumption—was not, in fact, entering the human food supply. Despite a complete regulatory inability to trace genetically modified food crops such as StarLink corn through the growing—processing—consuming cycle, EPA issued a registration that assumed, and required, careful tracking of the crop. The faith such a regulatory action demonstrates in a company's good intentions may be touching, but, absent some enforcement and oversight mechanism, it can hardly be called reasonable agency action. The growing presence of biopharming lends urgency to this concern. Without immediate change, there will be more StarLinks, and future outcomes may not be so benign.

If we had set out to create a regulatory system specifically designed for GM crops, the existing regulatory system would not have been the end product. But lawmakers almost never write on a *tabula rasa*. Rather, laws are adopted for specific purposes and are then adapted to newly presented challenges. It was not unreasonable for the Framework to propose using existing regulation as a starting point for approaching GM crops. To the extent that existing legal structures could be adapted to address the challenges posed by biotechnology, it was only logical to rely on them. At some point, however, adaptation can no longer serve—new circumstances pose a challenge beyond the capability of existing law to bend and twist. At that point, either new legal and regulatory structures must be crafted, or the challenge goes unanswered. We are at such a point.

In the seventeen years since introduction of the Framework, GM technology has posed issues unforeseen and unaddressed in 1986. The central problem is that the Framework's division of regulatory authority was created for a world that no longer exists. The Framework assumes that plant and pesticide are separate things, each of which can be independently regulated under a separate regulatory regime. In the old, pre-GM crops days (circa 1986), this division of regulatory authority may not have been a handicap to effective regulation. The mere planting of a crop did not necessarily imply the use of pesticides; and, when pesticides were used, they were sprayed on the outside of the plant and were not incorporated into the plant itself. Only traces of this sprayed-on pesticide would linger in the ultimate food product.

Biotechnology changed all that. Plant, pesticide, and food are now inextricably linked: plant and pesticide are the same biological entity; food and pesticide are the same thing as well. But, this new, integrated plant-

pesticide-food is still being regulated by three separate agencies, with three separate regulatory missions and three separate regulatory structures. A company developing a Bt crop theoretically demonstrates to USDA that the crop would not pose a danger to agriculture; satisfies EPA that the crop is safe for the environment and does not contain dangerous levels of pesticides; and shows FDA that the resulting product will be as safe as other foods.²⁴⁰

Theory does not match reality. To approve StarLink corn for market, USDA and EPA repeatedly disregarded significant but unresolved logistical problems.²⁴¹ These sorts of decisions might be expected from USDA—an agency charged with promoting agriculture. Given that mission, it may well have been reasonable for the agency to construe uncertainties in the best possible light. Indeed, it was this very tendency that prompted Congress to remove pesticide regulation from USDA's purview in the 1920s.²⁴² The same cannot be said for EPA or FDA. The primary charge to these agencies is to protect human and environmental health and safety. Their defaults should therefore have been protective, not promotional. Had EPA erred on the side of caution the agency could never have justified creating a system that hinged entirely on voluntary compliance with inconvenient registration restrictions—restrictions moreover that were likely to reduce profits for both growers and the manufacturer but offer them little in the way of concrete rewards.

Regulations assume that plant and pesticide are separate things, each of which can be independently regulated under a separate regulatory regime.

²⁴⁰ See ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, UNITED STATES REGULATORY OVERSIGHT IN BIOTECHNOLOGY, at <http://www.aphis.usda.gov/biotech/OECD/usregs.htm> (last visited Apr. 5, 2003).

²⁴¹ Unlike "pure science," where the proper response to uncertainty is to reserve judgment, regulators make decisions based on incomplete information. It is common for regulators to make decisions with significant social and economic costs against a background of substantial uncertainty about the scope of a hazard, and the possible benefits of risk reduction. A regulatory decision to reserve judgment is a decision not to regulate that has real-world consequences. As a result, scientists in regulatory proceedings frequently feel pressure to produce "answers" even if highly speculative. For an excellent discussion of how science is used and misused in the regulatory process, see Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

²⁴² DONNA U. VOGT, CONG. RESEARCH SERV., FOOD SAFETY: RECOMMENDATIONS FOR CHANGES IN THE ORGANIZATION OF FEDERAL FOOD SAFETY RESPONSIBILITIES 1949-1997 (1998).

In the old, pre-GM crops days (circa 1986), this division of regulatory authority may not have been a handicap to effective regulation. By combining plant and pesticide in a single organism, PIPs invalidate the Framework's underlying regulatory premises. Moreover, because plant and pesticide are now united as one, neither USDA nor EPA has the requisite expertise to regulate effectively. The combination of plant and pesticide represented by PIPs thus challenges the fundamental assumption of the administrative state—agency expertise. EPA did not know how corn was co-mingled after harvest. USDA did, but USDA ceded all consideration of environmental and human health protection to EPA. FDA, the agency with the ability to inspect the ultimate food product, also viewed the safety question as one for EPA. USDA's plant-pest inquiry is far too narrow when the plant involved raises questions of insect resistance and gene flows. FDA makes "substantial equivalence" determinations without considering the whole food. Similarly EPA's ignorance of farming practices renders its PIP regimes vulnerable to the sort of blunders that produced a regulatory regime entirely ill-suited to actual farming behaviors.

The Framework encourages these agencies to maintain the fiction that plants, pesticides, and foods can be considered separately. As a result, the agencies do not bring the full weight of their delegated authority to bear on any analysis of the safety of these new crops. These problems are artifacts caused by an undue reliance on existing law to address brand new problems. Meeting these challenges involves amending existing laws, and may have to include some new laws. The Framework itself repeatedly cautioned that it must evolve in accord with actual experience and that existing law might have to be modified in light of that experience. It is time to take those cautions seriously. The regulatory system must adapt, that is change, to match the new challenges embodied in these new technological capabilities.

B. *Resorts to Science Cannot Fill this Regulatory Hole*

Proponents of GM technology typically argue that evaluating the safety of these new technologies is largely a scientific matter. Under such reasoning, the risks of using the technology are simply balanced against the benefits, and the appropriate degree and kind of regulation will become apparent. Unfortunately, regulation is almost never an arithmetic process. Vital scientific information about risks and benefits is often not available, and

the absence of necessary information does not vitiate the need to make regulatory decisions.²⁴³

GM crops have been granted exemptions from the rigorous testing and risk management requirements that are the regulatory norm for food additives and pesticides. Given that backdrop, industry claims that regulation must be science-based strike an odd note. Appeals to science usually suggest a reliance on data—and the regulatory exemptions have largely freed industry from the obligation to develop and provide that data. USDA does not require site specific or crop specific information before the agency will grant non-regulated status. FDA leaves the determination of “substantial equivalence,” and therefore the need for pre-market testing to the manufacturer. These regulatory decisions have promoted the rapid growth of the agricultural biotech industry. However, those same decisions now mean that the ag-biotech industry has no body of solid scientific evidence to back up safety claims for GM crops. The fact that industry cannot point to such a body of evidence does not mean that the products are harmful, but the failure to develop data does engender public scepticism about purportedly “science-based” safety pronouncements. This scepticism is only further entrenched when those companies point to the lack of data about harms as a sound scientific basis for a conclusion that these crops are safe.

Moreover, StarLink corn’s elaborate split registration is a clear example of how accommodation of a regulated entity’s reluctance to develop product safety data can create chaos. The split registration scheme grew out of Aventis’ unwillingness to develop scientific information that EPA deemed necessary to the registration process. This was not a situation in which the agency *had* to act in the absence of necessary scientific information. EPA’s SAP found more study to be necessary before any conclusion about human allergenicity could be drawn. Aventis proposed a split-registration to avoid performing the otherwise necessary research on human allergenicity. Profitability concerns, not technical impossibility or unfeasibility, were the root of Aventis’ objection to performing this research. On a more cynical note, doing the research might also have created an inconvenient factual record that the company would have been hard pressed to disavow. The CDC

²⁴³ P. Anand, *Decision-Making When Science is Ambiguous*, 295 SCIENCE 1839 (2002). For an excellent discussion of the competing pressures on an agency making decisions with less than perfect information, see Howard Latin, *Regulatory Failure, Administrative Incentives, and the New Clean Air Act*, 21 ENVTL. L. 1647 (1991).

emphasized the difficulty of a retrospective evaluation of the public health implications of the introduction of StarLink corn to the human food supply, and emphasized the importance of evaluating the allergic potential of genetically modified foods before they become available for human consumption.²⁴⁴

It is true that no other Bt crop registrant had to account for research expenses incurred to allay allergenicity fears. It is certainly possible that doing the necessary research might have raised costs too much, thereby pricing StarLink corn out of the market. But, no other Bt crop incorporated *cry9c*. Aventis clearly saw a strategic advantage in the use of this gene, a benefit that would be of advantage in the marketplace. While Aventis is free to make that business decision, it must also be bound by the consequences of that choice—even when the consequences ultimately threaten Aventis' initial risk-reward calculus for the product as a whole.

EPA had two options. It could have concluded that StarLink corn could not be marketed unless and until the proper scientific showing of non-allergenicity had been made—thus telling industry that these costs were internal ones, to be accounted in the commercial decision to proceed with development of a crop. Or the agency could have helped the company look for ways to profit from its product without first answering the unresolved allergenicity question. The regulatory/statutory scheme directed EPA to ensure that the new technology did not pose “unreasonable risks to public health or environmental safety.” The choice should have been clear. Instead, the agency seems to have felt itself bound by the Framework's charge of promoting the new technology, or by pressures not to impose significant costs on a regulated entity. Rather than requiring the manufacturer to perform further studies, EPA accepted the Aventis' proposal for a split registration, thereby permitting Aventis to sell StarLink corn without demonstrating its safety. This decision was based on an assumption that the StarLink corn could, and would, be segregated from other corn and kept out of the human food supply. In light of current industry representations about the impracticability of segregating GM crops from non-GM crops in the context of GM labeling discussions, this assumption was simply incredible.

²⁴⁴ CDC REPORT, *supra* note 9, at 10. The great irony, of course is that had Aventis done the necessary research, StarLink might well have been approved for human consumption at the outset.

C. *The Laissez-Faire Approach to Regulating These Crops has Failed*

Promoters of GM crops have successfully invoked the traditional criticisms of command-and-control regulation to prevent, or at least to delay, effective regulatory oversight of GM crops. Relying on the familiar critique that command-and-control's "top-down" regulatory approach is insensitive to variations and too often produces an ossified regulatory system that stifles innovation,²⁴⁵ GM promoters argue that such regulation would retard the growth of a vitally important industry. Instead, they argue for a continuation of the public/private partnership to enforce Bt registration restrictions that has been held up as an example of so-called "Next Generation" regulation.²⁴⁶

StarLink, ProdiGene, and other recent biotech industry failures to meet the minimum standard of care necessary to ensure public safety underscore just how precarious a reliance on voluntary compliance can be. While it certainly makes sense to harness market forces to achieve public goods when possible, StarLink and ProdiGene are exactly what we can expect from an overreliance on self-policing.²⁴⁷ Without a clearly defined and coherent regulatory strategy that includes oversight as a vital component, registration restrictions are reduced to a farce. Market-based incentives can only work if the regulatory scheme aligns the financial incentives of companies with environmental objections.²⁴⁸ GM regulations have failed utterly on this front and have revealed the strategy of relying on voluntary compliance alone to be incomplete.

²⁴⁵ See, e.g., Bruce A. Ackerman & Richard B. Stewart, *Reforming Environmental Law: The Democratic Case for Market Incentives*, 13 COLUM. J. ENVTL. L. 171 (1988); Bruce A. Ackerman & Richard B. Stewart, *Reforming Environmental Law*, 37 STAN. L. REV. 1333 (1985). But see Wendy E. Wagner, *The Triumph of Technology-Based Standards*, 2000 U. ILL. L. REV. 83 (2000) (rejecting this critique); Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729 (1991).

²⁴⁶ Stanley H. Abramson & J. Thomas Carranto, *Genetically Engineered Agriculture: Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L.J. 241, 259 (2001).

²⁴⁷ For a defense of command and control regulation, see generally Wagner, *supra* note 245; Shapiro & McGarity, *supra* note 245.

²⁴⁸ For a discussion of the relationship between deterrence and compliance incentives, see Clifford Rechtschaffen, *Deterrence vs. Cooperation and the Evolving Theory of Environmental Enforcement*, 71 S. CAL. L. REV. 1181, 1215 (1998).

Despite an initial reaction to the crisis that “we have difficulty imagining how our corn could end up in the human food supply,”²⁴⁹ Aventis later asserted that such an outcome was inevitable²⁵⁰ and blamed the problem on EPA’s grant of a split, rather than full, registration.²⁵¹ Although it was Aventis’ failure to implement the registration restrictions that surely made the ultimate “disaster” inevitable from the beginning, the regulatory agencies must shoulder a large portion of the blame as well. It was EPA that granted the misguided split-registration in the first place, and USDA and FDA that failed to conduct thorough, independent analyses before permitting the crops to be planted and sold. These agencies created a system under which they were totally unaware of compliance failures. Indeed, one of the most striking points about the StarLink corn crisis is that, in retrospect, everyone agrees that it was inevitable that the stuff would end up in the food supply, but nobody—not Aventis, and not any of the three agencies with partial regulatory jurisdiction over StarLink corn—took any steps to prevent this occurrence. With such lax regulatory oversight, the StarLink fiasco may well have been “inevitable” from the beginning. Rather than the fulfillment of the self-policing, corporate steward ideal, the registration restrictions were a complete failure.

There is certainly much to criticize in the United States’ approach to environmental regulation. It can be overly complex, with difficult and sometimes conflicting mandates. “Next Generation” critics are right to challenge regulators to reform—to make the regulatory scheme better, fairer and easier to understand. That said, even the most vigorous advocates of “Next Generation” regulatory reform would acknowledge that industry can only be a partner in environmental stewardship if it actually lives up to commitments made in the collaborative process. Non-adversarial, cooperative strategies—important as they are to regulatory reform initiatives—cannot, by

²⁴⁹ See *Unapproved Corn*, *supra* note 2.

²⁵⁰ PETITION FOR TOLERANCE, *supra* note 159.

²⁵¹ See *id.* at 18. “[S]plit registration was based on the assumption that crops produced for [animal feed and non-food industrial] uses could be completely segregated from the human food supply. It is now clear that assumption was incorrect. Indeed, EPA recently announced it would no longer grant split registrations for products of biotechnology.” *Id.* But it was only that this split registration was granted in a regulatory framework that specifically prevented tracking of GM crops that made contamination of the food supply inevitable once StarLink corn was introduced commercially for feed use.

themselves, ensure that the public interest is protected. To be successful, "Next Generation" policies must build on, rather than abandon the strengths of traditional regulation. The focus should be on overcoming the limits of traditional command and control regulation rather than merely abandoning regulation altogether.

StarLink's registration entirely abandoned oversight and monitoring, the primary strengths of traditional regulation, and replaced them with a vague hope of good behavior. Neither EPA nor FDA had any way to verify compliance or to discover non-compliance. Despite determining that the registration conditions were necessary to protect public safety, EPA made no attempt to create any oversight structure. This regulatory impotence was no secret to either the agencies or the registrant. StarLink provides a good indication of what can happen when there is no likelihood that regulatory violations will be discovered, let alone pursued. The lesson is clear—regulation cannot be effective without oversight and the possibility of enforcement.

Market forces can undoubtedly be harnessed to achieve environmental ends. The Clean Air Act's sulphur emissions trading scheme is perhaps the clearest example of how well market mechanisms can achieve environmental ends if properly structured. SOx trading was a success because it was situated within a developed regulatory system—it did not attempt to take the place of such a system. Within a regulatory system, complete with an oversight system to monitor compliance and with consequences for non-compliance, it, indeed, makes sense to enlist market forces to encourage the most efficient means of compliance.

Unfortunately, Aventis had neither market nor regulatory incentives to enforce the "no human food use" and "no international commerce" registration restrictions that were imposed as a condition of registration. With no promise of a carrot and no threat of a stick, Aventis was left to self-police its own adherence to conditions that may have ensured a public good, but were against its own short-term economic interests. StarLink corn demonstrated that under such circumstances, industry self-policing will likely be a disastrous failure. Such a situation undermines confidence in regulatory agencies, and feeds into public fears about government's inability to protect against the dangers inherent in new technologies. Time and again, new technologies initially hailed as miraculous have had unanticipated side effects that range from the harmful to the disastrous: Thalidimide, DDT, radiation,

Fenphen, . . . the list goes on. Each failure adds to a growing public distrust of technology and to suspicion about governmental assurances of safety.

That the StarLink fiasco could happen here in the United States with our fully developed regulatory scheme, begs the question of what will happen in developing countries without advanced regulatory systems. Europe and Japan repeatedly raise this question. To some extent the StarLink crisis confirmed their worst fears—inadequate regulation in one country can create a problem that could spread rapidly throughout the world. This concern is real. For example, the Philippines approved Bt corn hybrid YieldGuard in December 2002.²⁵² To the dismay of critics, the Philippines announced it will not seek to implement the refuge strategy required in the United States.²⁵³ Instead, the Agriculture Ministry will tell farmers to plant Bt corn every other year, or to rely on non-corn crops as refuge.²⁵⁴ The alternate year strategy is totally unenforceable in a country like the Philippines where farmers routinely save seeds for planting, and the alternative refuge strategy was flatly rejected in the United States as wholly inadequate to preserve insect susceptibility.²⁵⁵

It is clear that improperly managed GM field trials or ill-considered approvals of GM crops in one country pose dangers for all nations. The rapidly globalizing world agriculture trade ensures that every importing and exporting country would be affected by lax controls in one country. The StarLink crisis gives real world contours to this concern. Despite clear requirements that the corn be restricted to domestic, non-food uses, StarLink corn found its way into foods sold throughout the world. In one year, one firm, with one genetically modified product, managed to contaminate food for millions of households and affect the price of a commodity grown by some 300,000 farmers with a value of tens of billions of dollars. If this can happen in the United States, what will happen in nations with more limited capacities to assess and manage the risks of GM crops?

²⁵² Gallardo, *supra* note 215.

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ For a detailed discussion of the refuge requirement, and an explanation of why measures like those proposed in the Phillipines are inadequate, see UNION OF CONCERNED SCIENTISTS, NOW OR NEVER: SERIOUS NEW PLANS TO SAVE A NATURAL PEST CONTROL (Margaret Mellon & Jane Rissler eds., 1998).

V. A NEW REGULATORY FRAMEWORK

The Framework permitted, and even encouraged, the agencies to rely on self-policing and industry cooperation as the sole means of ensuring compliance. Aventis, the patent-holder and registrant of StarLink Corn, committed to a whole series of measures intended to keep StarLink corn out of the human food supply. But because of the structure of agricultural commerce in the United States, the burden of implementing those measures fell not on the registrant, but on independent growers who, as third parties to the registration, were not directly subject to regulatory jurisdiction. Moreover, at the time the registration was approved, there was no regulatory framework to monitor and enforce these registration restrictions. Rather than a regulatory scheme of clear standards of care, the existing scheme was tantamount to a regulatory vacuum. That has to change.

An exclusive focus on voluntary self-policing transfers far too much power to the regulated entities. Rather than fulfilling their statutory role as watchdog and guardian of public safety, the agencies are reduced to the role of cheerleaders, urging good behavior from the sidelines but powerless to require it. The public interest has been left unprotected. It is time for Congress to take the matter in hand and to give the agencies clear regulatory authority to address the unique challenges posed by this new technology. The agencies need statutory guidance and authorization to consider environmental and human health concerns in a unified, organized, and transparent fashion.

The StarLink crisis' relatively happy ending should not be viewed as evidence that the existing regime is adequate. The CDC may have concluded that there is too little StarLink contamination to pose a human health risk, but the dangers the crisis revealed about an inadequate regulatory climate remain significant and unaddressed. StarLink corn was present in the food supply in such small quantities only because of the vigilance of anti-GM activists. Had they been less vigilant, much more of the food supply would have been contaminated with StarLink corn—possibly leading to untold tragedy. A serious human health crisis was averted despite the Framework, rather than because of it. The safety of the food supply in this context owes no debt to successful government regulation.²⁵⁶

²⁵⁶ It would be clearly inappropriate for a regulatory agency to build a regime that relied on the possibility of a hypervigilant public as the primary means of enforcing health and safety

After StarLink, it is clear that reliance on self-policing alone cannot guarantee safe implementation of this new technology. On the other hand, even the combined resources of USDA, EPA, and FDA would be inadequate to inspect every field or to interview every grower. Self-policing must be a major part of the answer. But rather than wholly abdicating enforcement responsibility to registrants and "the market," the agencies must leverage their limited resources by building an enforcement regime that creates private incentives for stewardship and self-policing. An integral element of any such scheme must be regulatory oversight and clear sanctions for noncompliance.

Because GM crops are patented intellectual property, a rudimentary self-policing infrastructure already exists. While it would be a mistake to rely entirely on self-policing, government regulators can certainly build on this pre-existing structure. Though StarLink corn showed that Growers Agreements cannot be the sole means of enforcing registration restrictions, they can be a powerful tool for leveraging private conduct to achieve public ends. Before these Agreements can serve that function, however, they must be placed in the proper regulatory context.

In the United States, Monsanto requires farmers to sign a contract upon the purchase of GM seeds.²⁵⁷ This "Technology Use Agreement" states Monsanto is not selling the seeds but is instead granting the grower a limited licence to use the seeds. As a condition of the license, growers are forbidden to save seeds for replanting, and are prohibited from exchanging or giving seeds to other farmers.²⁵⁸ Monsanto retains the right to monitor the field of farmers at anytime within three years from the time of purchase.²⁵⁹ Monsanto hires full-time investigators to assist in the enforcement of the licenses.²⁶⁰ Other GM producers require similar contractual agreements as a condition of purchasing GM seeds.

Like Aventis' Growers Agreements, these Technology Use Agreements require that growers implement governmentally-imposed

requirements. Any such scheme is likely to be overwhelmed by a collective action problem and by transaction costs. Moreover, such a scheme would call into question the underlying rationale for having administrative agencies.

²⁵⁷ 2003 Monsanto Technology/Stewardship Agreement, *available at* http://www.monsanto.com/monsanto/us_ag/content/tools_dir/mta2003.pdf (last visited April 15, 2003).

²⁵⁸ *Id.*

²⁵⁹ Gallardo, *supra* note 251.

²⁶⁰ *Monsanto v. Byrd*, No. 7:99-CV-154-F1, 2000 WL 33952260 (E.D.N.C. Dec. 11, 2000).

registration restrictions, namely, an insect resistance management plan, and also require that growers channel the crop to appropriate uses (largely keeping the crops out of international shipments to the European Union which has not approved many of these crops).²⁶¹ These requirements are all good ones. But these Agreements alone will not avoid future StarLink fiascos. There must also be a strong regulatory "floor" underpinning these otherwise self-policed requirements.

Monsanto has been vigorous in enforcing its intellectual property rights, inspecting growers' fields, and bringing lawsuits challenging unapproved uses of its proprietary seeds.²⁶² The lawsuits not only vindicate Monsanto's rights in particular instances, but also send a powerful message to the grower community: Someone is watching, and there are consequences for failing to follow the rules. Were that same message spread about observing resistance management programs and appropriately channeling crops, it might go a long way towards solving the problems identified in this Article. The problem is one of incentives. Monsanto has a clear incentive to be vigilant in protecting its intellectual property. To date, it has had no similar incentive to bring that same attention and energy to enforcing the registration restrictions that are the precondition for commercial use of these plants. GM registrants are unlikely to face either costs or sanctions if growers fail to comply with those restrictions. Growers have even less stake in compliance. Instead, the costs of such non-compliance is externalized onto society as a whole. Such a scheme will never produce significant, let alone full compliance.

GM registrants should be required, as a condition of registration, to contribute funds that can be used to establish an independent auditing program. The independent auditors will be charged with monitoring grower compliance with the registration restrictions. Although the auditing program would be funded by the biotechnology industry, the auditors would not be employees of the biotech companies, either individually or collectively. The

²⁶¹ Monsanto, *supra* note 256.

²⁶² See, e.g., Richard Thompson, *Tennessee Grower Awaits Fine in Monsanto Case*, CROPCHOICE NEWS, Jan. 8, 2003, available at <http://www.cropchoice.com/leadstry.asp?/recid=1279>. Since 1996, Monsanto has settled more than 100 cases over alleged appropriation of its intellectual property. In sixty cases, a lawsuit was filed and Monsanto has not lost any of the handful that actually went to trial. *Id.* See also *Schmeiser v. Monsanto*, [2002] F.C.A. 309, available at <http://decisions.fct-cf.gc.ca/fct/2002/2002fca309.html>.

auditing program would exist as an independent entity, with the mandate of monitoring grower behavior and reporting non-compliance to EPA and the relevant biotechnology company.

To facilitate the independent auditing process, all GM producers should be required to provide the auditing program, and EPA, with the records of GM crops sold, and the names of growers who have signed the Agreements at the start of the growing season. The auditors will then verify that the registrants or their licensees are selling only to growers who contractually agree to the registration restrictions, and will report and discrepancies to EPA. As incentive to comply with this requirement, any GM registrant that can demonstrate that it sold its product only to growers who executed appropriate Grower Agreements could be offered the same sort of safe harbor available to those who discover and self-report environmental violations discovered through an environmental audit. The second part of the auditor's task would be to follow up with the growers via a field inspection program, preferably at planting time, designed to determine whether the GM crops were planted in accordance with the refuge requirement and any other registration restrictions.

Imposing an annual, pre-growing season reporting requirement, and creating an independent auditing program would enable regulators to capture the benefits of both traditional regulation and "New Generation" initiatives. Empowered by information, regulators could create a system of "voluntary compliance plus"—with the plus being the auditing program that would enable regulators to verify compliance, and to sanction non-compliance. Such a system would give the agencies valuable information about where and by whom the GM crops are grown. Once agencies have information about where GM crops are grown, on-the-ground physical inspections become possible. Auditor reports of irregularities could trigger physical on-site agency follow up inspections, and any appropriate sanctions to both the grower and the GM registrant.

In addition to these follow-up inspections, agencies would also need a small-scale random direct inspection program. The prospect that a grower might be subject to an unannounced agency compliance inspection, and sanctioned for any non-compliance, would give growers an additional clear incentive for complying with the registration restrictions. Holding the GM registrant responsible for violations of the registration restrictions would provide a similar incentive to industry. An appropriately designed random

direct inspection program would have the added advantage of statistically validating the auditing process, thereby giving an additional level of confidence that growers were, in fact, complying with registration restrictions.

Of course, regulators could not possibly conduct rigorous inspections of every single grower's fields. Such a project would be both prohibitively expensive and unduly burdensome. The mere possibility of agency inspections, coupled with the auditing program, will go a long way towards insuring compliance as long as there are significant penalties for non-compliance. For such a scheme to work, however, there must be serious consequences to both the registrant and the growers for failure to comply. The consequences must be significant enough to force the GM registrants to bring the same vigor and intensity to promoting compliance with the environmental registration restrictions that they currently bring to protecting their intellectual property. Such a regime might well have a chance to succeed if coupled with an independent audit of grower planting behaviors.

VI. CONCLUSION

If there is one thing that the StarLink crisis made clear, it is that the time has come to scrap the Framework in favor of a new normative approach to managing the risks and promises of GM technology. Regulation must be specially tailored to address the unique challenges posed by these crops. New regulation and legislation are unavoidable if we are to successfully capture the benefits of these crops without exposing the food supply to an unacceptable level of risk. StarLink corn highlighted some spectacular inadequacies of the Framework and existing regulations. Congress must take an affirmative role and give the agencies guidance on how to implement their mandates with regard to these new crops. In particular, Congress should create a new regulatory Framework to coordinate EPA, USDA, and FDA activity to carefully monitor registration conditions in the field, and as grains are brought to market. The successful regulatory regime will recognize the challenges posed by the new technology and will address them head on. The public will have confidence in GM crops only if the government formally approves them as safe after a thorough and transparent review. The biotech industry itself should be clamoring for that kind of a process.