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Starlink™ -A Case Study of Agricultural Biotechnology Regulation

by

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STARLINK™ — A CASE STUDY OF AGRICULTURAL BIOTECHNOLOGY REGULATION

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I. INTRODUCTION AND SCOPE

The "*StarLink*™ saga," where traces of transgenic corn not approved for food use were discovered in human foods, provides a golden opportunity to review the U.S. regulatory system as applied to a specific genetically engineered product.[1] Such a review will provide insights into the operation of the regulatory system and help to identify both strengths and issues needing future resolution. *StarLink* is the trade name for corn hybrids genetically engineered to be (1) tolerant of glufosinate-ammonium herbicides such as Liberty™, and (2) resistant to specific insect pests.[2] To provide insect resistance, a gene from a common soil bacterium, a subspecies of *Bacillus thuringiensis ("Bt")*, was inserted into an approved corn variety genetically

1. The terms "transgenic," "genetically engineered," "genetically modified," "genetically enhanced," and "bioengineered" are used synonymously in this article. As used herein, these terms refer to applications of biotechnology where a gene from one organism is inserted into the genome of another organism. The ability to move genes among life forms that do not mate naturally, and to manipulate genes with greater precision, are the significant advancements resulting from genetic engineering. In other ways, these new biotechnology techniques are similar to older tools of biotechnology (e.g., plant breeding, animal breeding, tissue culture, cell culture, fermentation) used for centuries by plant and animal breeders, bakers, brewers, and vintners. All of the biotechnology tools, both old and new, allow humans to alter nature's handiwork. *See* STEVEN C. WITT, BIOTECHNOLOGY, MICROBES AND THE ENVIRONMENT 168 (1990).

2. *See* Aventis CropScience USA LP, Petition for Tolerance: *Bacillus thuringiensis* Subsp. *tolworthi* Cry9C Protein in or on the Raw Agricultural Commodity, *Corn*, Vol. 1, 8 (Apr. 19, 2001), *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last visited Apr. 23, 2002).

engineered to express herbicide tolerance.[3] This new gene causes *StarLink* corn plants to produce a pesticidal protein known as Cry9C, a substance toxic to European corn borers and other lepidopteran pests.[4] Thus, *StarLink* is a special variety of *Bt* corn, similar in many ways to other *Bt* corn hybrids that have been approved for both feed and food use in the United States.[5] However, as will be seen below, the Cry9C protein is somewhat more stable during food processing and takes longer to digest than its counterpart proteins found in other *Bt* corn varieties approved for both feed and food uses.

This article will (a) track the pre-*StarLink* evolution of U.S. biotechnology regulatory policy and the emergence of the Coordinated Framework for the Regulation of Biotechnology, (b) describe the specific actions taken by the Animal and Plant Health Inspection Service ("APHIS"), the Food and Drug Administration ("FDA"), and the Environmental Protection Agency ("EPA") in approving field trials and commercialization of *StarLink*, (c) highlight other new developments and subsequent *StarLink*-related regulatory actions, and (d) glean from the *StarLink* saga some lessons and insights regarding the U.S. system for biotechnology regulation. A synopsis of the *StarLink* saga appears in the following four paragraphs and will help the reader see the whole "forest" before focusing on the various *StarLink*-related regulatory actions.

The U.S. regulatory system (at the request of Plant Genetic Systems, and its corporate successor, AgrEvo) approved *StarLink* for sale as a commercial crop during the 1998 through 2000 growing seasons. Crops harvested from *StarLink* seed were, and continue to be, approved for use in animal feed and for non-food industrial purposes such as the production of ethanol. However, *StarLink* was not approved for direct human food use in the United States because its Cry9C protein might be an

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3. *See id.* at 25 *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last visited Apr. 23, 2002).

4. *See id available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last visited Apr. 23, 2002). Such a pesticidal protein, along with the genetic material necessary to produce it, is now known as a "plant-incorporated protectant;" it was previously known as a "plant-pesticide." *See* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772, 37,772 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174).

5. *Bt* toxins are proteins naturally produced by the bacterium *Bacillus thuringiensis*. *Bt* toxins can be very selective and have been used for many years by organic farmers as a "natural" pesticide. When, through genetic engineering, the toxin-expressing gene from the donor bacterium is successfully inserted into a recipient plant such as corn, the recipient plant produces the toxic protein within its plant tissue. Thus, genetically engineered plants such as "*Bt* corn" are toxic to selected insects like the European corn borer. The pesticide registrations for the plant-incorporated protectants in five *Bt* corn varieties (not *StarLink*) were recently extended another seven years. *See* Press Release, Environmental Protection Agency, Biotechnology Corn Approved for Continued Use (Oct. 16, 2001), *at* http://yosemite1.epa.gov/opa/admpress.nsf/ (last visited Apr. 19, 2002) (select 2001, then October, and Oct. 16, 2001).

allergen, and *StarLink* was not approved for consumption in the European Union and other countries that buy U.S. corn.[6]

Certain additional conditions were imposed on the owner of *StarLink* when the EPA approved *StarLink* corn for limited use (use as feed and for industrial uses, but not for direct human consumption). One was a required buffer of 660 feet around *StarLink* fields to capture pollen drift from the *StarLink* plants. Corn grown within the 660-foot buffer was also limited to non-food uses, just like the *StarLink*-planted fields.[7]

As a practical matter, some *StarLink* and "buffer corn" became co-mingled with large quantities of other corn in the harvesting, transportation, storage and marketing processes.[8] Some non-*StarLink* hybrids appear to have contained the *cry9C* DNA and may have been channeled into food uses.[9] Also some *StarLink* pollen may have moved beyond the 660-foot buffer and may have caused the harvest from these non-buffer fields to contain traces of Cry9C. Beginning in September 2000, traces of *cry9C* DNA were discovered in taco shells, other corn food products, and corn export shipments; [10] later, the Cry9C protein was also discovered in food products. Human foods containing the Cry9C protein or *cry9C* DNA were technically "adulterated" within the meaning of federal law, but there would be much debate about whether foods containing Cry9C could ever trigger an allergic reaction.[11]

Today, after the recall of various food products containing *StarLink*,[12] after the cancellation of *StarLink*'s registration,[13] after Aventis Crop Science USA (the successor corporate owner of *StarLink*) has expended millions of dollars in buying corn containing Cry9C protein and channeling it into non-food uses,[14] after months of continuing scientific review and debate, after further assessments of the U.S.

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6. *See* discussion *infra* Section III; *see generally* Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms,* 6 DRAKE J. AGRIC. L. 81, 95 (2001).

7. *See* U.S.E.P.A., *Biopesticide Fact Sheet - Bacillus thuringiensis subspecies tolworthi Cry9C Protein and the Genetic Material Necessary for Its Production in Corn* (006466), *at* http://www.epa.gov/pesticides/biopesticides/factsheets/fs006466t.htm (last visited Apr. 24, 2002).

8. *See* Des Keller & Dan Miller, *Biotech's Black Eye,* PROGRESSIVE FARMER, Dec. 2000, at 24, 25.

9. *See* Press Release, *Aventis CropScience Finds Bioengineered Protein in Non-StarLink Corn, at* http://www.fda.gov/oc/po/firmrecalls/aventis11_00.html.

10. *See* Keller & Miller, *supra* note 8, at 24, 26.

11. *See* FIFRA SCIENTIFIC ADVISORY PANEL, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE ENVIRONMENTAL PROTECTION AGENCY REGARDING: ASSESSMENT OF ADDITIONAL SCIENTIFIC INFORMATION CONCERNING STARLINK™ CORN, SAP REPORT No. 2001-09 (July 25, 2001) *available at* http://www.epa.gov/scipoly/sap/2001/july/julyfinal.pdf (last visited Apr. 6, 2002).

12. *See* discussion *infra* Section III.B.2.

13. Notice of Receipt of Request for Cancellation of Bacillus Thuringiensis (B.t.) subspecies tolworthi Cry9c Genetic Material Necessary for its Production in Corn, 66 Fed. Reg. 4825, 4825 (Jan. 18, 2001).

14. *See* discussion *infra* Section IV.A.

regulatory system for biotechnology,[15] and after the filing of numerous lawsuits alleging *StarLink*-related damages to corn producers and consumers,[16] the *StarLink* saga has become an important milestone in the evolution of U.S. regulatory policy toward biotechnology.

II. THE CONTEXT: PRE-*STARLINK* EVOLUTION OF U.S. BIOTECH REGULATORY POLICY, EMERGENCE OF THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY, AND LEGISLATIVE AUTHORITIES FOR KEY REGULATORY AGENCIES[17]

A. *The 1970s: Regulating Basic Biotechnology Research In the Laboratory*

1. *1974 Voluntary Ban on Plasmid Engineering Research and 1975 Recommendations of the Asilomar Conference*

In 1974, Professor Paul Berg and his colleagues with the National Academy of Sciences, wondering if they fully appreciated the possible impacts of recombinant DNA ("rDNA") should it inadvertently escape the laboratory, issued a letter calling for a voluntary moratorium by molecular scientists on two types of genetic engineering research until the potential biological hazards of rDNA molecules could be better evaluated or methods for preventing their spread could be better developed.[18] Thus, one of society's initial tools for regulating genetic engineering research was a voluntary, temporary ban on specific rDNA research imposed by scientists on themselves.[19] The letter also suggested that an international conference of scientists be convened in 1975 to further consider appropriate ways of dealing with the biohazards of rDNA molecules.[20]

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15. *See, e.g.*, National Research Council, Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation (2002), *available at* http://www.nap.edu/catalog/10258.html (last visited May 1, 2002).

16. *See, e.g., In re StarLink* Corn Products Liability Litigation, 152 F. Supp. 2d 1378, 1379-80 (J.P.M.L. 2001); *see generally,* Donald L. Uchtmann, *Biotechnology and Specialty Crops,* 2 ILL. L. & AGRIBUSINESS 11-1 (2001).

17. This section draws heavily from an article published in November 2000. *See* Donald L. Uchtmann & Gerald C. Nelson, *U.S. Regulatory Oversight of Agricultural and Food-Related Biotechnology*, 44 AM. BEHAV. SCIENTIST 350 (2000).

18. *See NAS Ban on Plasmid Engineering*, 250 NATURE 175, 175 (1974). *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902, 27,903 (July 7, 1976). Paul Berg received the 1980 Nobel Prize in chemistry for his work on recombinant DNA and is now Cahill Professor of Cancer Research and Biochemistry Emeritus at the Stanford University School of Medicine.

19. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902, 27,903 (July 7, 1976).

20. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,903.

The suggested international conference, to be known as the Asilomar conference, was held in 1975.[21] One hundred and fifty participants, including many scientists from around the world, debated what controls should be placed on transgenic research.[22] Participants believed that many rDNA experiments should proceed under appropriate physical and biological containment and made additional recommendations to be considered by the National Institutes of Health ("NIH").[23]

2. *Development of NIH's 1976 rDNA Research Guidelines*

The NIH Recombinant Advisory Committee ("RAC"), a group composed of eminent scientists, held public meetings and debated three different versions of rDNA research guidelines in formulating its recommendations to the Director of the National Institutes of Health.[24] In February of 1976, the Director convened a special meeting of the Advisory Committee to the NIH Director (a broader advisory group than the RAC).[25] At this special meeting, the Advisory Committee was asked for advice as to "whether, in their judgment, the guidelines balanced scientific responsibility to [protect] the public with scientific freedom to pursue new knowledge."[26] After additional opportunity for public and scientific comment on issues raised by the Advisory Committee, the NIH issued its first rules on biotech research, the 1976 NIH guidelines for research involving recombinant DNA molecules.[27]

The 1976 NIH guidelines were (a) applicable to research funded by NIH or conducted at NIH,[28] (b) generally prohibited six types of rDNA experiments until more could be learned,[29] (c) allowed other rDNA experiments to proceed under strict safety standards,[30] (d) required the physical or biological containment of rDNA recombinants in the laboratory,[31] (e) prohibited the deliberate release of rDNA organisms into the outside environment until more could be learned,[32] and (f) made

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21. The conference, held in February 1975 at the Asilomar Conference Center in Pacific Grove, California, was sponsored by the National Academy of Sciences and the National Science Foundation and supported by the National Institutes of Health. *See* Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 148 (D.C. Cir. 1985); Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,903.

22. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,903; WITT, *supra* note 1 at 46.

23. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,903.

24. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,903.

25. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,903.

26. Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,903.

27. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,912; *see also* WITT, *supra* note 1 at 112-13 (indicating that the NIH guidelines were key facts in the deliberate release debate during the 1970s).

28. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,902.

29. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,921.

30. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,908.

31. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,909.

32. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,907.

compliance with the guidelines a condition for continued NIH funding.[33] These initial guidelines represented a cautious approach to the regulation of rDNA research but they did allow such research to continue. Although the 1976 guidelines were not binding on non-NIH funded research, the Director expressed his hope that the guidelines would be voluntarily adopted for all research in the United States.[34]

3. *1978 Revisions to NIH Guidelines and Subsequent Developments*

Over time, the experience gained in rDNA laboratories mitigated many of the concerns associated with rDNA research, at least in the minds of many scientists,[35] and led to a modest relaxing of the initial guidelines and oversight mechanisms. For example, the temporary prohibitions on certain experiments and on the deliberate release of genetically modified organisms into the environment were removed in 1978 and replaced by provisions for special review and, if there were no significant risks to health and the environment, approval by NIH.[36] The 1978 revisions also widened the scope of the guidelines significantly. First, compliance was required of all institutions receiving support from NIH, whether or not the particular rDNA experiment was funded by NIH.[37] Second, the revised guidelines offered NIH's assistance to private industry whereby NIH would evaluate private rDNA research for voluntary compliance.[38] In so doing, the NIH guidelines also became "the yardstick for any common law liability."[39] The guidelines were also revised in 1982, 1983, 1986, and in subsequent years.[40] As the regulation of biotechnology in the laboratory continued to evolve, other agencies such as the U.S. Department of Agriculture ("USDA") adopted many of the approaches pioneered by NIH.[41]

In spite of the continuing special rules regarding transgenic research, especially containment rules, the general philosophy underlying the U.S. regulation of basic biotechnology research is to rely more on voluntary reporting and professional norms than on stringent governmental regulation.[42] This philosophy is based on the

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33. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,910.

34. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,906.

35. *See generally* Susan Wright, *The Status of Hazards and Controls*, 24 ENVIRONMENT 13 (July-Aug. 1982) (noting that the relaxation of the initial guidelines are not supported by all scientists, however).

36. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,906.

37. *See* Recombinant DNA Research Guidelines, 41 Fed. Reg. at 27,906.

38. *See* Guidelines for Research Involving Recombinant DNA Molecules, 43 Fed. Reg. 60,108, 60,123 (Dec. 22, 1978).

39. Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 151 n.5 (D.C. Cir. 1985).

40. The 1986 revision is published at 51 Fed. Reg. 16,958 (May 7, 1986).

41. *See* Final Policy Statement for Research and Regulation of Biotechnology Processes and Products , 51 Fed. Reg. 23,336, 23,338 (June 26, 1986); *see also* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,305 (June 26, 1986).

42. *See* MICHAEL J. MALINOWSKI, BIOTECHNOLOGY: LAW, BUSINESS, AND REGULATION at § 1.05[D] (1999).

recognition that relying on professional norms in basic research has a history of success, strict governmental regulation would be prohibitively expensive, the more promising biotechnology research will be subject to more stringent regulation during later-stage research preceding commercialization (for example, when field trials are conducted), and overly strict governmental regulation can chill creativity.[43]

B. *Field Testing Transgenic Organisms in the 1980s: Searching for the Best Regulatory Approach*

In many ways, the initial debates about regulating laboratory research set the stage for the later, intense debates about regulating genetically modified organism ("GMO") field trials. Since the Asilomar conference, genetic engineering was viewed as something with unique and hard to quantify risks.[44] Under the initial NIH research guidelines, society's main line of defense for these risks was GMO "containment" in the laboratory and an outright prohibition on "deliberate release."[45] Although NIH's blanket prohibition on deliberate release was later relaxed,[46] the public understood that letting GMOs out of the lab was a very significant step.[47] However, if basic genetic engineering research was to be developed into new crops or improved foods, the experiments would first have to move out of the labs and into the fields.

1. *The "Ice-minus" Field Trials*

In 1982 one of the initial requests to deliberately release a transgenic organism came from scientists at the University of California at Berkeley. The organism was an 'ice-minus' microbe intended to reduce frost damage to crops like tomatoes and potatoes. The events that unfolded provide insights into how the rules regarding GMO field trials evolved and how the state and federal courts, additional governmental agencies, Congress, environmental groups, prominent biotechnology activist Jeremy Rifkin, the press, vandals, and even local governments became involved.[48] An interesting, abbreviated case study appears in the accompanying footnote, but the overarching message is that in the early 1980s the United States did not have a coordinated regulatory apparatus for GMO field trials sufficient to meet the existing expectations of researchers, the public, or the

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43. *See* id.

44. *See Heckler*, 756 F.2d at 148.

45. *See* National Institutes of Health: Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902, 27,907 (July 7, 1976); *See also Heckler*, 756 F.2d at 148 (briefly explaining the initial NIH guidelines).

46. *See* National Institutes of Health: Recombinant DNA Research Revised Guidelines, 43 Fed. Reg. 60,080, 60,080 (Dec. 22, 1978). *See also Heckler*, 756 F.2d at 149.

47. *See* National Institutes of Health: Recombinant DNA Research Revised Guidelines, 43 Fed. Reg. at 60,080.

48. *See* Uchtmann & Nelson, *supra* note 17, at 354.

National Environmental Policy Act.[49]

2. *1984 Litigation: Foundation on Economic Trends v. Heckler Illustrates the Importance of NEPA to Biotech Regulatory Decisions*

Generally speaking, the National Environmental Policy Act ("NEPA") requires all federal agencies (e.g., NIH) to prepare an Environmental Impact Statement for major federal actions that significantly affect the quality of the human environment (e.g., NIH's science-based decision about approval of the "ice-minus" field trial).[50] When an agency believes its major federal action does not significantly affect the environment, the agency is required to document the evidence and analysis supporting that belief in a concise public document called an Environmental Assessment.[51] "Two fundamental principles underlie NEPA's requirements: (1) federal agencies have the responsibility to consider the environmental effects of major

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49. Using a genetic engineering technique, U.C. Berkeley plant pathologist Dr. Steven Lindow successfully removed the gene responsible for ice formation from a bacterium. It was hoped that the "ice-minus" bacteria would displace the naturally occurring "ice-plus" bacteria on the leaves of various crops and thus reduce frost formation and damage. In September, 1982 Drs. Lindow and Panopoulos submitted a request to NIH for approval of a deliberate release, a field test of the GMO. Approval pursuant to the revised NIH guidelines was required because the University of California was an institution which received funding from NIH. The NIH announced the request for approval in the Federal Register along with the date its Recombinant Advisory Committee ("RAC") would consider the request, thereby allowing the public an opportunity to comment (but no comments were submitted). After deliberations and a close vote by the RAC, the Director decided to postpone approval. The research scientists, responding to RAC concerns, resubmitted their request with some modifications (e.g., one experimental site, not six). In April 1983, the RAC voted unanimously to recommend approval, and the Director approved the experiment (decision published in June 1, 1983, Federal Register). In 1984, following initiation of a law suit by Jeremy Rifkin, the Washington D. C. Circuit Court of Appeals (opinion written by Judge Sirica) enjoined the release on the grounds that NIH had failed to properly review the potential environmental impacts of the release, as required by the National Environmental Policy Act. Later that year, EPA published its Interim Policy on Small Scale Field Testing of Microbial Pesticides. The interim policy required that EPA be given notice prior to small scale field tests (those on less than ten acres) involving certain genetically engineered microbs in order to determine if an experimental use permit would be required. Lindow and Panopoulos, and another scientist with NIH approval to field test a similar product (Frostban), notified EPA of their respective intents to conduct field trials. EPA approved the field trials in 1986 and 1987. The trials were finally conducted in 1987, but only after Congressional hearings, additional battles in both federal and California courts, a one year and a forty-five day testing ban imposed by county governments, protests by environmental groups, involvement of the press and local citizens, and the vandalizing of potato and strawberry test plots. By 1988, the field trials showed that treated potato and strawberry plants suffered significantly less frost damage than untreated plants, but the company interested in commercializing Frostban subsequently dropped plans for commercial development. *See* WITT, *supra* note 1, at 51-54; *See also Heckler*, 756 F.2d at 143.

50. *See* 42 U.S.C. § 4332(c) (1994).

51. *See* Counsel on Environmental Quality 40 C.F.R. §§ 1501.4(a)-(b), 1508.9 (1983).

actions significantly affecting environment, and (2) the public has the right to review that consideration."[52]

According to the U.S District Court, NIH did not comply with the decision-making and public notification requirements of NEPA when NIH approved the deliberate release of the genetically altered "ice-minus" microbe.[53] NEPA and its implementing regulations required federal agencies (1) "to take a hard look" at the environmental effects of major federal actions (such as approving releases of GMOs), and (2) to describe the evidence and analysis in a public document (either an Environmental Impact Statement or Environmental Assessment).[54] Thus, citizens would be empowered to scrutinize the public document and to understand the agency's analysis and decision. The D.C. Circuit Court of Appeals agreed with Justice Sirica's 1984 opinion that NIH, by approving the release without preparing either an environmental impact statement or environmental assessment, had not fulfilled its responsibility under NEPA.[55] In a separately written concurring opinion of special interest to scientists, Appellate Judge MacKinnon helped to explain how important NEPA's mandated Environmental Assessments and Environmental Impact Statements are to the lay public and the courts.[56]

The early 1980s were unsettling years for genetic engineering field trials. In 1983 NIH approved the first GMO field trial that would actually be conducted (but the approval had taken twenty months, and the experiment would be delayed another five

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52. *Heckler*, 756 F.2d at 147 (citing Baltimore Gas & Elec. v. Natural Res. Def. Council, Inc., 462 U.S. 87 (1983)).

53. *See id.* at 150-51.

54. *Id* at 151.

55. *See id.* at 146.

56. *See id.* at 160. An excerpt from J. MacKinnon's concurring opinion follows:

> I can understand how the RAC scientists who are knowledgeable in this field of genetic engineering would approve the experiment by a vote of 19-0 with no abstentions. It would seem an experiment that releases into the environment organisms substantially the same as some already living there, and subject to the same naturally occurring controls, would present no risk. However, the general public and those who have to pass on this action are not knowledgeable in this field and they are easily frightened by new scientific experiments and their possible consequences. It is such lay concerns that must here be satisfied by Environmental Assessments and Environmental Impact Statements. There is considerable merit, moreover, in having all the environmental considerations set forth and discussed in one document rather than compelling those who review such matters to look through the nooks and crannies of a very extensive record to see that all environmental considerations were satisfied. The present record does indicate that those who participated at all stages of this project were concerned with and did consider many, but not all environmental issues, but the proof thereof is scattered throughout the record. An Environmental Assessment or an Environmental Impact Statement would present the consideration of all relevant environmental issues in one document that would not only ease lay concerns, but facilitate [judicial] review as well. *Id.* at 161 (MacKinnon J., concurring).

years because of litigation and other circumstances).[57] In 1984, a congressional subcommittee issued a report sharply criticizing NIH's method of reviewing deliberate release experiments and recommending a temporary moratorium.[58] Also in 1984, Judge Sirica enjoined the GMO "ice-minus" experiment, and EPA published its interim policy on certain small scale field tests (apparently duplicating NIH's regulatory oversight of many GMO field trials).[59] In 1985 the U.S. Court of Appeals for the D.C. Circuit affirmed the "ice-minus" injunction and signaled that NIH and other regulatory agencies would need to do a better job of considering environmental impacts and documenting its considerations. In the meantime, a lot of basic research was ready for field trials, some companies were hoping to commercialize biotech products, and many people were confused about what agencies with what statutory authority would regulate the rapidly developing biotechnologies. Clearly there was a need for the United States to get its regulatory house in order, not only for field trials but also for commercial products of biotechnology.

C. *1986 Coordinated Framework for the Regulation of Biotechnology*

In the Spring of 1984, the Reagan Administration formed an interagency working group to consider the adequacy of the existing regulatory framework as the basis for regulating new products of biotechnology.[60] This working group "sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry."[61] The working group published Notice of its Proposal for a Coordinated Framework in December 1984, and announced its regulatory policy in June 1986.[62] Present in both the 1984 and 1986 notices is the working group's conclusion that existing laws as currently administered by existing agencies would adequately meet the regulatory needs for products of the newer biotechnologies, for the most part.[63] For example, all the agencies must take a hard look at the environmental impacts of their regulatory actions and develop Environmental Impact Statements or Environmental Assessments, as required by NEPA.[64]

The working group noted that relying on existing statutes and regulations (and their focus on the nature of the product), rather than adopting new laws specifically for the products of a biotech manufacturing process, had several advantages.[65] The

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57. Uchtmann & Nelson, *supra* note 17, at 355.
58. *See id.*
59. *See* WITT, *supra* note 1, at 52.
60. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302 (June 26, 1986).
61. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 303.
62. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 302.
63. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 303.
64. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 303.
65. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 302.

strategy provided immediate regulatory protection for consumers and avoided the need for the biotech industry to learn a new regulatory scheme. The group also noted that there did not appear to be an alternative: there was no well-developed proposal for a new, all encompassing biotechnology statute.[66]

Relying on existing federal laws, the Coordinated Framework assigned lead regulatory responsibility to one federal agency for each category of product use.[67] Where agency responsibilities or authorities adjoin or overlap under existing laws, the Coordinated Framework set out principles for coordinated and cooperative reviews.[68]

Selected categories of products potentially produced by biotechnology processes and the specific agencies given primary responsibility for approving their commercial use under existing laws are:

- *"[P]lants, seeds, plant pests, and certain genetically engineered organisms containing genetic material from plant pests"*: regulated by the Animal and Plant Health Inspection Service of the United States Department of Agriculture.[69]
- *Food additives and food (and animal feed):* regulated by the Food and Drug Administration of the U.S. Department of Health and Human Services ("HHS"). FDA actually regulates all food other than meat and poultry products. The Food Safety Inspection Service of USDA has jurisdiction for domestic livestock and poultry products, and EPA sets "tolerances" for pesticide residues in food.[70]
- *Pesticides (including microbial pesticides and genetically engineered plants that produce their own "plant-incorporated protectants," also known as "plant-pesticides") and other toxic substances*: regulated by the U.S. Environmental Protection Agency.[71] Interestingly, *StarLink* would fit into all three of these categories. Thus, *StarLink* was destined for regulation by three key federal agencies under a mosaic of legislative authority, much of which was originally enacted before the Coordinated Framework was published.

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66. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 303.
67. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 302.
68. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 302.
69. MALINOWSKI, *supra* note 42, at § 11.06[A], at 11-87.
70. *See id.; see also* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304.
71. *See* MALINOWSKI, *supra* note 42, at § 11.06[A], at 11-87; *see also* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304.

D. *Legislative Authority for APHIS, FDA, and EPA Regulation of StarLink*

1. *1957 Federal Plant Pest Act and 1912 Plant Quarantine Act (Relevant Content Now Contained in the 2000 Plant Protection Act)*

As *StarLink* was undergoing review by USDA, the authority for USDA's regulatory oversignt was the Federal Plant Pest Act and the Plant Quarantine Act.[72] These acts were later repealed by the Agricultural Risk Protection Act of 2000, but their relevant content has been included in new Title IV—Plant Protection—and codified as the Plant Protection Act, 7 U.S.C. §§7701-7772 (2000).[73]

The Plant Protection Act, like its predecessor Plant Pest Act and Plant Quarantine Act, gives USDA authority to regulate the movement, import, or release of plant pests or potential plant pests.[74] More specifically, the Plant Protection Act prohibits the unauthorized movement of plant pests[75] and gives the Secretary of Agriculture authority to restrict importation and interstate movement of plants, plant products, biological control organisms, noxious weeds, or other articles when necessary to prevent the dissemination of plant pests or noxious weeds,[76] including genetically engineered plants that can damage crops, public health or the environment.[77]

2. *1938 Federal Food, Drug, and Cosmetic Act (Including Amendments Enacted by the Food Quality Protection Act of 1996)*

Regarding the safety of all food, including food and feed developed from biotechnology, the key legislation is the 1938 Federal Food, Drug, and Cosmetic Act ("FFDCA").[78] The following provisions of the FFDCA, as amended, are especially significant when considering the safety of foods derived from bioengineered crops like *StarLink*:

FFDCA § 402 Adulterated Foods, Summary: The adulteration of food and the introduction into interstate commerce of adulterated food is prohibited by the Act.[79]

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72. *See* 7 U.S.C. §§ 150aa-jj (1994); *see also* 7 U.S.C. §§ 151-167 (1994).

73. *See* Agricultural Risk Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 358 (2000). Section 438(a) of the Act lists the laws that are repealed, including the Plant Quarantine Act, Plant Pest Act, and the Federal Noxious Weed Act.

74. *See* 7 U.S.C. § 7758(c) (2000). Section 438(c) of the Plant Protection Act states that regulations issued under authority of the superseded Plant Pest Act and Plant Quarantine Act remain in effect until new regulations are issued.

75. *See id.* § 7711(a).

76. *See id.* § 7711(a).

77. *See id.* § 7702(10).

78. *See* 21 U.S.C. § 301 (1994).

79. *See id.* § 331(a).

Foods are deemed adulterated, for example, if they contain any poisonous or deleterious substance in a quantity that ordinarily renders the food injurious to health.[80] Food is also adulterated if it contains an unsafe pesticide chemical residue, i.e., a residue exceeding a tolerance or exemption established by the Administrator of the EPA.[81] The Act provides criminal sanctions for violation of its prohibited acts[82] and, perhaps more significantly, by criminalizing conduct the Act provides a foundation for civil liability. Section 402 is also the statutory basis of the FDA's "*post-market*" authority to remove food from the market that has been found, through experience or otherwise, to be unsafe.[83]

FFDCA § 409 [Unsafe] Food Additives, Summary: The addition of an "unsafe" food additive to food, or the introduction into interstate commerce of food with an "unsafe" food additive, is prohibited.[84] Food additives are "unsafe" unless, for example, the additive and its use are in conformity with a federal regulation prescribing the conditions for safe use.[85] "Substances that are generally recognized as safe ("GRAS") by scientists are excluded from the definition of food additives and, therefore, cannot be a § 409 (Unsafe) Food Additive."[86] Food additives used prior to 1958 can also be GRAS because of the experience based on their common use in food. Importantly, Section 409 is the basis for FDA's only "*pre-market*" approval requirements.

FFDCA § 343 Misbranded Food, Summary: The misbranding of food or introducing misbranded food into interstate commerce is prohibited.[87] Foods are misbranded if, for example, the label is false or misleading.[88]

FFDCA § 701 Regulations and Hearings: General authority to promulgate regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act is delegated to the Secretary of Health and Human Services (the "departmental home" for FDA).[89]

FFDCA § 408a *Pesticide Tolerances and the Standard of Reasonable Certainty of No Harm,* Summary: Foods containing "unsafe" levels of pesticide residues are brought within the meaning of § 402 Adulterated Foods, thus making their sale unlawful.[90] Unsafe levels of residues include those exceeding the "tolerances" established by EPA.[91] The Administrator of EPA is given the authority

80. *See id.* § 342(a)(i).
81. *See id.* § 346a.
82. *See id.* § 333.
83. *See id.* § 334(a)(1)(B).
84. *See id.* § 342(a)(C)(i).
85. *See id.* § 348(a)(2)(A).
86. *See id.* § 321(s).
87. *See id.* § 331(a)-(b).
88. *See id.* § 343(a).
89. *See id.* § 371(a).
90. *See id.* § 342(a)(1).
91. *See id.* § 346.

to issue regulations which establish, modify, or revoke tolerances for particular pesticide residues, or to exempt particular pesticide residues from the requirement of a tolerance.[92] Such tolerances must be "safe," meaning generally that "there is a reasonable certainty that no harm will result from aggregate exposure . . . ."[93]

3. *Federal Insecticide, Fungicide, and Rodenticide Act (Including Amendments Enacted by the Food Quality Protection Act of 1996)*

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") [94] delegates to the EPA regulatory authority over pesticides.[95] The following provisions of the Act, as amended, are especially significant when considering the regulation of plants, like *StarLink*, that have pesticidal characteristics:

Definition of Pesticide: FIFRA defines pesticide to include "any substance . . . intended for preventing, destroying, repelling or mitigating any pest"[96] such as an insect, rodent, fungus, or weed.[97]

General Requirement of Pesticide Registration: FIFRA generally prohibits the distribution and sale of pesticides in the United States unless the pesticide is registered for the particular use or exempt from regulation.[98]

Standard for Issuing Pesticide Registration; No Unreasonable Adverse Effects on the Environment: The registration process requires the submission of substantial data and a showing that the pesticide "will perform its intended function without unreasonable adverse effects on the environment" when used in accordance with common practice.[99] In this context, the term "environment" includes humans.[100] "Reasonableness determinations rest on a balance between the risks and benefits associated with the use of the pesticide."[101]

Experimental Use Permits: An exception to the pesticide registration requirement is where the EPA has issued an experimental use permit. The permit is to be issued only if the applicant needs the field tests to accumulate the data necessary to register the pesticide.[102]

Regulations and Coordination Between EPA and USDA: General authority to promulgate regulations for the enforcement of FIFRA is delegated to the

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92. *See id.* § 346a(b)(1); *see also* § 346a(b)(2)(D).
93. *Id.* § 346(b)(2)(a)(ii); *see also* 7 U.S.C. § 136w(a) (1994 & Supp. V 2000).
94. *See* Federal Insecticide, Fungicide, and Rodenticide Act §§ 2 to 34, 7 U.S.C. §§ 136-136y (2000).
95. *See id.* § 136w(a) (1994 & Supp. V 2000).
96. *Id.* § 136(u).
97. *See id.* § 136(t).
98. *See id.* § 136a(a).
99. *Id.* § 136a(c)(5).
100. *See id.* § 136(j).
101. MALINOWSKI, *supra* note 42, at § 11.06[A][1]; *see* 7 U.S.C. § 136(bb) and 136a(c) (2000).
102. *See* 7 U.S.C. §136c(a) (2000).

Administrator of the Environmental Protection Agency.[103] The Administrator is to work closely with the Secretary of Agriculture, for example, by providing the Secretary with an advance copy before publishing proposed or final regulations.[104]

III. *STARLINK* REGULATION BY USDA-APHIS, FDA, AND EPA

While *StarLink* was being developed in the laboratory and greenhouse (i.e., before it was released into the environment) it was subject to regulatory oversight in two ways. First, a biosafety committee typically oversees biotechnology research in the laboratory. Under NIH Biosafety Guidelines, these committees are only required for institutions receiving federal funding. However, to manage liability risks and for other reasons, private industry typically follows the NIH guidelines voluntarily.[105] Second, the greenhouses in which the research is continued are subject to USDA greenhouse standards and inspections.[106]

Before a genetically engineered plant or organism like *StarLink* is approved for field trials or commercial use, it is subject to more stringent regulation. Regulatory agencies conduct reviews required to assure conformity with standards set by federal or state statutes such as the Plant Protection Act; the Federal Food, Drug, and Cosmetic Act; and the Federal Insecticide, Fungicide, and Rodenticide Act. The following paragraphs chronicle the actions taken by each regulatory agency as *StarLink* moved from labs and greenhouses to field trials and full scale commercialization.

A. *USDA-APHIS: Regulating Movement, Field Trials, and Commercialization of StarLink*

StarLink was genetically engineered to contain two "stacked" genes, one conveying herbicide tolerance and one conveying insect resistance.[107] In an early step in StarLink's development, a gene from one common soil microorganism was inserted into corn to make it tolerant of Liberty™, a glufosinate-ammonium herbicide.[108] This

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103. *See id.* § 136(w)(a)(1).

104. *See id.* § 136(w)(a)(2).

105. One court has described the NIH Guidelines as "the yardstick of common law liability." Foundation of Econ. Trends v. Heckler, 756 F.2d 143, 151 n.5 (D.C. Cir. 1985).

106. *See* COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY, EVALUATION OF THE U.S. REGULATORY PROCESS FOR CROPS DEVELOPED THROUGH BIOTECHNOLOGY 9 (Issue Paper No. 19, Oct. 2001). Report available *at* http://www.cast-science.org/pubs/cropregulation.pdf (last visited Apr. 30, 2002).

107. *See* AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. 27041, 27042 (May 15, 1998).

108. See the Bio discussion of LibertyLink® Corn. Bio, *Agricultural Biotech Products on the Market, at* http://www.bio.org/er/agri_products.asp (last visited Apr. 30, 2002).

genetically engineered corn, to become know as *LibertyLink*, was subject to earlier regulation at various stages of its product development and commercialization.[109] In a later step in *StarLink*'s development, a gene from a second microorganism—a subspecies of *Bacillus thuringiensis*—was inserted into *corn, along with the gene conveying herbicide tolerance.* This created *StarLink* and gave it the additional characteristic of insect resistance.[110] This later step, which caused *StarLink* to express the Cry9C protein toxic to European corn borers, would also trigger regulation by the APHIS, the FDA, and the EPA. The following discussion focuses primarily on regulatory actions related to this second step in *StarLink*'s development.

1. *Permits or Notifications for Movement or Field Trials Under 7 C.F.R. § 340.4 and § 340.3*

The APHIS is responsible for protecting U.S. agriculture "from pests and diseases."[111] Under the authority of what is now the Plant Protection Act,[112] the APHIS regulations provide procedures for obtaining a permit or for providing notification, prior to introducing a "regulated article" into the United States.[113] "Regulated articles" are genetically engineered organisms and products (like *StarLink* corn) that are plant pests or that may be reasonably believed to be plant pests.[114] "Introduc[ing]" includes importation, movement through the United States, or release into the environment outside an area of physical confinement.[115] Thus, before a transgenic corn hybrid like *StarLink* could be moved or field tested, the company would need to (1) obtain a permit from APHIS or (2) provide notification to APHIS and receive an acknowledgment.[116]

- *1996-1999, APHIS Approves StarLink Field Trials:*

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109. *See, e.g.*, Notice, 60 Fed. Reg. 36,095, 36,095 (July 13, 1995) (APHIS advised the public of its determination that glufosinate tolerant corn, genetically engineered by AgrEvo, was no longer considered a regulated article).

110. *See* AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. 27041, 27042 (May 15, 1998).

111. Uchtmann & Nelson, *supra* note 17, at 361.

112. *See* The Plant Protection Act, 7 U.S.C. §§ 7701-7772 (2001).

113. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests, 7 C.F.R § 340 (2001). Notifications are addressed at § 340.3. Permits are addressed at § 340.4. For permits, APHIS reviews permit applications and prepares an Environmental Assessment in which the potential environmental impact of the release is evaluated. *See* Permits for the Introduction of a Regulated Article, 7 C.F.R. § 340.4 (2001); *see also* Information Systems for Biotechnology, *Background on the Environmental Releases Database, at* http://www.isb.vt.edu/biomon/explain.cfm (last visited Apr. 6, 2002); APHIS, *A General Introduction to Notification, at* http://www.aphis.usda.gov/bbep/bp/notgen.html (last visited Apr. 6, 2002).

114. *See.* 7 C.F.R. § 340.1.

115. *Id.* § 340.1.

116. *See id.* § 340.

An examination of the "Field Test Releases Database for the U.S." reveals that *StarLink* field tests were conducted in 1996 and 1997 at various locations in the United States.[117] All *StarLink* field tests appear to have been conducted under the Notification and Acknowledgment procedure by Plant Genetic Systems, a predecessor of Aventis.[118] Under the notification procedure Plant Genetic Systems had to satisfy six criteria.[119] For example, the genetic material must be known and "stably integrated," and its expression must "not result in plant disease" or the production of substances "toxic to nontarget organisms" or the "production of an infectious entity."[120] Because the field trials were conducted under the notification procedure, no environmental assessments were prepared by APHIS.[121]

Information concerning approval of the 1992 - 1995 field trials for *StarLink*'s genetically engineered, herbicide-tolerant ancestor is available in the accompanying footnote.[122]

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117. *See* Field Test Releases In the U.S., *at* http://www.isb.vt.edu/ (last visited Apr. 6, 2002). The author used the following search criteria: U.S. Field Test, Organism = corn, Institution = Plant Genetic Systems, Phenotype = Lepidopteran resistant. The thirty-three field trial records that emerged were all conducted pursuant to the notification procedure and all involved the donor gene "Bt tolworthi." The author assumes that all these field tests were for corn hybrids that were candidates for licensing as *StarLink*. Regarding movement of *StarLink* other than for field trials, the author could not locate any data regarding approvals by permit or notification. However, if *StarLink* was moved interstate other than for field trials, such movement would have been unlawful unless authorized by the same permit or notification process as applies to field trials. *See* 7 C.F.R. § 340.3 (Notification) and 7 C.F.R. § 340.4(c) (Permits).

118. *See* 7 C.F.R. § 340.3.

119. *See id.* § 340.3(b)(1-6).

120. *Id.* § 340.3(b)(2-4); *see* A General Introduction to Notification *at* http://www.aphis.usda.gov/bbep/bp/notgen.html (last visited Apr. 30, 2002) (discussing the six eligibility criteria for notification).

121. *See* 7 C.F.R. § 340.3(a) (stating that introduction in compliance with section 340.3 avoids permit requirements under section 340.4); *see also id.* § 340.4 (providing that APHIS grants permits for environmental release).

122. *See* Field Test Releases in the U.S. *at* http://www.isb.vt.edu/cfdocs/fieldtests1.cfm (last visited Apr. 6, 2002). The author searched for "Permits only" using the following search criteria: Organism = Corn, Institution = Hoechst-Roussel, Phenotype = Phosphinothricin tolerant, Gene = Phosphinothricin acetyl transferase, Date = since 6/1/91. The data suggests that four field tests of the herbicide-tolerant corn were initially conducted in 1992 and 1993 in the states of Iowa, Illinois, Indiana, Nebraska, and Minnesota. These initial field trials were authorized by Permits under 7 C.F.R. § 340.4 for which Environmental Assessments are generally prepared. *See* 7 C.F.R. § 340.4. In the Environmental Assessment for Permit No. 92-017-04, APHIS observed that the herbicide-tolerant corn plants were regulated articles because they contained genetic material from organisms that are plant pests. APHIS concluded that "no significant risk of introducing or disseminating a plant pest and that no significant impact to the quality of the human environment would result from issuing the permit." *See* Environmental Assessment and Finding of No Significant Impact, USDA, *available at* http://www.isb.vt.edu/biomon/relea/9201704r.eaa (last visited Jan. 30, 2002). Regarding field trials conducted pursuant to the Notification and Acknowledgment procedure of 60 C.F.R §340.3(b), the author searched for "Notifications only" using the following search criteria: Organism = Corn, Institution = AgrEvo, Phenotype = Phosphinothricin tolerant, Gene = Phosphinothricin acetyl transferase, Date = since 4/30/93 but prior to 6/1/95. An additional sixteen field tests were conducted throughout the United States

2. *Determinations of Nonregulated Status Under 7 C.F.R. §340.*

Under the authority of what is now the Plant Protection Act, the APHIS regulations also provide a petition process for the determination of nonregulated status.[123] "Once a determination of nonregulated status has been made, the product (and its offspring) no longer requires APHIS review for movement or release in the United States."[124] When genetically modified plants have been field tested and are candidates for commercialization, acquiring "nonregulated status" is *de facto* APHIS pre-market approval for commercial sales. When APHIS makes a decision that a genetically engineered plant like *StarLink* will no longer be regulated, APHIS prepares two formal documents. The first document addresses whether the genetically modified plant or microorganism poses a plant pest risk and the second document, the Environmental Assessment, addresses the potential environmental impact of no longer regulating the organism.[125]

- *February 23, 1998, APHIS Notice Concerning Receipt of Petition for Nonregulated Status for StarLink*:

On February 23, 1998, APHIS announced receipt of a petition from the AgrEvo USA Company (predecessor of Aventis).[126] The petition requested a determination that *StarLink* corn, now genetically engineered to be both herbicide-tolerant and insect resistant, did not pose a plant pest risk and should no longer be regulated by APHIS. APHIS invited written comments from the public to be submitted on or before April 24, 1998.[127]

- *May 15, 1998, APHIS Notice Concerning Determination of Nonregulated Status for* StarLink:

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in 1993 - 1995 pursuant to this procedure; no Environmental Assessments were prepared.

123. *See* 7 C.F.R. § 340.6.

124. United States Regulatory Oversight of Biotechnology, *at* http://www.aphis.usda.gov/biotech/OECD/usregs.htm (last visited Jan. 31, 2002); *see* Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms, 62 Fed. Reg. 23,945 (May 2, 1997) (codified at 7 C.F.R. pt. 340).

125. *See* National Environmental Policy Act Implementing Procedures, 7 C.F.R. § 372 (2001). Specifically, 7 C.F.R. § 372.5(b)(4) includes "[a]pprovals and the issuance of permits" involving genetically engineered species as an APHIS action normally requiring an Environmental Assessment. This rule was published as a final rule in 60 Fed. Reg. 6,000 (Feb. 1, 1995).

126. After receiving a petition for nonregulated status, APHIS publishes notice in the Federal Register and specifies that public comments on the petition will be accepted for 60 days. During the comment period, any interested person may submit written comments which become part of the petition file. APHIS has 180 days to deny or approve the petition for nonregulated status and notify the petitioner. *See* 7 C.F.R. § 340.6(d).

127. *See* AgrEvo USA Co.; Receipt of Petition for Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. 8,897, 8,897 (Feb. 23, 1998).

Based on a review of scientific data and literature, APHIS announced that *StarLink* did not present a plant pest risk and would no longer be a regulated article.[128] As a result, oversight by APHIS would no longer be required for field testing, importation, or interstate movement of *StarLink* or its progeny.[129] In effect, APHIS had given its approval for the commercialization of *StarLink*. An environmental assessment was completed in conjunction with this determination.[130]

APHIS made this determination based on an analysis that revealed that *StarLink* plants: (1) exhibit no plant pathogenic properties, (2) are no more likely to become a weed than insect resistant and herbicide-tolerant corn developed by traditional breeding, (3) are unlikely to increase the weediness potential of any other plant with which they can interbreed, (4) are not likely to cause damage to raw or processed agricultural commodities, (5) are unlikely to harm threatened or endangered species and organisms that are beneficial to agriculture, and (6) are unlikely to reduce the ability to control insect or weed pests in corn and other crops.[131] APHIS also concluded that there is no reason to believe that new corn varieties derived from *StarLink* progeny will exhibit new plant pest properties, i.e., properties substantially different from any observed for the *StarLink* already field tested, or those observed for corn in traditional breeding programs.[132] Of importance for this particular petition, APHIS had previously granted non-regulated status to numerous other genetically engineered Bt corn lines or glufosinate-tolerant herbicides.[133] This APHIS decision did not, however, release *StarLink* from the regulatory oversight of the Food and Drug Administration or the Environmental Protection Agency. Regarding EPA regulation, APHIS observed that a temporary exemption from the requirement of a tolerance for residues of *StarLink*'s insecticidal protein had been issued on April 10, 1998.

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128. *See* 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, 27,042 (May 15, 1998). The full text of the Determination of Nonregulated Status is available *at* http://www.aphis.usda.gov/biotech/dec_docs/9726501p_det.HTM.

129. *See* AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. at 27,042.

130. *See The Environmental Assessment, at* http://www.aphis.usda.gov/biotech/dec_docs/9726501p_ea.HTM (last visited Apr. 30, 2002).

131. *See* AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. at 27,042.

132. *See* AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. at 27,042.

133. *See* AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. at 27,042.

Information about the 1995 Determination of Nonregulated Status for genetically engineered corn, from which *StarLink* inherited herbicide tolerance, is available in the accompanying footnote.[134]

B. *FDA: Consulting Under the 1992 "Statement of Policy: Foods Derived from New Plant Varieties" and Exercising Post-Market Authority to Remove Foods Containing StarLink from the Marketplace*

The public relies heavily on the FDA for assurance that foods are safe and wholesome. The "FDA has authority under the Federal Food, Drug, and Cosmetic Act to ensure the safety of [most] domestic and imported foods in the United States market, except meat and poultry, . . . which are regulated by USDA."[135] Also, the FDA monitors foods to enforce pesticide residue tolerances set by the EPA.[136] The FDA regulates *StarLink* and other foods developed through genetic engineering in the same way it regulates other food products.[137] This means that a food or food ingredient developed by genetic engineering (e.g., *StarLink*) must meet the same rigorous safety standards as other food products, and the FDA has broad authority to take legal action against a genetically engineered product that poses a hazard to the public.[138]

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134. On February 27, 1995, APHIS published notice in the Federal Register that it had received a petition from AgrEvo (a predecessor of Aventis) seeking a determination of nonregulated status for corn designated as "Glufosinate Resistant Corn Transformation Events T14 and T25." Notice, 60 Fed. Reg. 10,537, 10,537 (Feb. 27, 1995). Corn designated as such would be an ancestor of *StarLink* and the source of *StarLink's* herbicide tolerance. APHIS solicited public comments during a 60-day comment period on whether this corn presented a plant pest risk. *See id.* In its notice published July 13, 1995, APHIS advised the public of its determination that glufosinate tolerant corn, genetically engineered by AgrEvo, was no longer considered a regulated article. *See* Notice, 60 Fed. Reg. 36,095, 36,095 (July 13, 1995). The determination was based on an evaluation of data submitted by AgrEvo, an analysis of other scientific data, and APHIS review of nine comments received from the public in response to the February 27th notice, all of which supported the AgrEvo petition. *See id.* In effect, APHIS had given its approval for the commercialization of genetically engineered, herbicide tolerant corn variety from which *StarLink* would inherit its herbicide tolerant characteristic. More specifically, APHIS determined that the genetically engineered corn: "(1) exhibit[ed] no plant pathogenic properties; (2) are no more likely to become weeds than other corn developed by traditional breeding techniques; (3) are unlikely to increase the weediness potential for any other cultivated or wild species with which it could interbreed; (4) will not harm other organisms . . . that are beneficial to agriculture; and (5) should not cause damage to processed agricultural commodities." *Id.* The Environmental Assessment and Finding of No Significant Impact is *available at* http://www.aphis.usda.gov/biotech/dec_docs/9435701p_ea.HTM (last visited Apr. 30, 2002).

135. Joseph A. Levitt, Statement Before the Health, Education, Labor, and Pensions Committee of the U.S. Senate (Sept. 26, 2000), *at* http://www.cfsan.fda.gov/~lrd/stbioeng.html (last visited Apr. 6, 2002); *see generally* 21 U.S.C. §§ 301, 341-350b, 371-379d (1999).

136. *See* 21 U.S.C. § 346a (1999).

137. *See* Joseph A. Levitt, Statement Before the Health, Education, Labor, and Pensions Committee of the U.S. Senate (Sept. 26, 2000), *at* http://www.cfsan.fda.gov/~lrd/stbioeng.html (last visited Apr. 6, 2002).

138. *See* Joseph A. Levitt, Statement Before the Health, Education, Labor, and Pensions

In 1992, the FDA published and invited public comment on a policy statement clarifying its oversight of food and animal feed derived from new plant varieties developed by both conventional and genetic engineering techniques.[139] The FDA's policy explained how whole foods, including animal feeds, derived from grains (e.g., *StarLink*) and other genetically engineered products are regulated under the Federal Food, Drug, and Cosmetic Act.[140] The 1992 policy was the FDA's working policy under which it would consider *StarLink*.[141] The centerpiece of the FDA's 1992 policy statement was a "comprehensive 'guidance to industry' section that discussed scientific issues . . . and regulatory questions for which firms should consult with the FDA."[142]

After a comprehensive scientific review of Calgene's data on the FlavrSavr™ tomato, FDA established a consultative process to help companies comply with the FFDCA's requirements for any new food, including a bioengineered food, that companies intend to market.[143] Since that time, companies have used the consultative

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Committee of the U.S. Senate (Sept. 26, 2000), *at* http://www.cfsan.fda.gov/~lrd/stbioeng.html (last visited Apr. 6, 2002).

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

140. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,984.

141. On September 29, 2000, the United States District Court for the District of Columbia dismissed the challenge to [FDA's] regulatory policies concerning genetically engineered foods like [*StarLink*]. The Alliance for Bio-Integrity and other public interest and religious groups had made allegations about the legality of FDA's 1992 Policy Statement, "Foods Derived from New Plant Varieties." The court agreed with FDA that the policy statement was not a rule requiring notice and comment rulemaking. The court also ruled that the Agency was not required to prepare an Environmental Assessment or Environmental Impact Statement because it was not a "major federal action" within the meaning of the National Environmental Policy Act. The court deferred to FDA's view that genetically engineered foods as a class do not require premarket review and approval of a food additive petition. The court also accepted FDA's view that special labeling for genetically engineered foods as a class is not required solely because of consumer demand or because of the process used to develop these foods. This lawsuit did not involve *StarLink* specifically, but the suit addressed the legality of the 1992 policy under which FDA had been regulating *StarLink*. *See* FDA Talk Paper, *U.S. District Court Dismisses Genetically Engineered Food Lawsuit Against FDA, at* http://www.fda.gov/bbs/topics/ANSWERS/ANS01043.html (last visited Apr. 23, 2002).

142. U.S. Food and Drug Administration, *FDA'S Policy for Foods Developed by Biotechnology, at* http://www.cfsan.fda.gov/~lrd/biopolcy.html (last visited Apr. 23, 2002) (a chapter in the proceedings of *American Chemical Society Symposium Series No. 605, 1995*, presented by J. H. Maryanski, Strategic Manager for Biotechnology, Center for Food Safety and Applied Nutrition, FDA); *see generally* U.S. Food and Drug Administration, *Guidance On Consultation Procedures—Foods Derived From New Plant Varieties, at* http://www.cfsan.fda.gov/~lrd/consulpr.html (last visited Apr. 23, 2002) (providing guidance to firms concerning the consultation process).

143. *See* Joseph A. Levitt, Statement Before the Health, Education, Labor, and Pensions Committee of the U.S. Senate (Sep. 26, 2000), *at* http://www.cfsan.fda.gov/~lrd/stbioeng.html (last visited Apr. 6, 2002).

> In 1994, for the first bioengineered product planned for introduction into the market, FDA moved deliberately, following the 1992 policy. [FDA] conducted a

process more than forty-five times, including consultations about *StarLink*, as they sought to introduce genetically altered plants representing ten different crops into the U.S. market. FDA is "not aware of any bioengineered food product on the market under FDA's jurisdiction that has not been evaluated by FDA through the consultation process."[144]

1. StarLink Consultations Under FDA's 1992 Policy Statement Regarding Foods Derived from New Plant Varieties.

• *May 29, 1998, AgrEvo Completes StarLink Consultations With The FDA:*

Pursuant to the 1992 Policy Statement, AgrEvo (predecessor of Aventis) completed *StarLink* consultations with the FDA on May 29, 1998.[145] In its May 29, 1998 note to file, the FDA noted AgrEvo's conclusion that Corn Line CBH-351 (now known as *StarLink*) is not materially different in terms of food safety and nutritional profiles from corn varieties currently on the market.[146] But the memo also noted that the safe use of the *StarLink*'s insecticidal protein, Cry9C, as a pesticide, is regulated by the EPA under FIFRA and FFDCA.[147] Therefore, the FDA had not addressed issues related to "the safe use of Cry9C as a pesticide or the safe use of the [*cry9C*] gene in the production of transgenic corn."[148] However, the FDA did consider the

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> comprehensive scientific review of Calgene's data on the *Flavr Savr* tomato and the use of the kanamycin resistance marker gene. FDA also held a public meeting of [its] Food Advisory Committee ... to examine applicability of the 1992 policy to products such as the *Flavr Savr* tomato. The Committee members agreed ... that the scientific approach presented in the 1992 policy was sound and that questions regarding the *Flavr Savr* had been addressed. The Committee members also suggested that [FDA] remove unnecessary reviews to provide an expedited decision process on the marketing of bioengineered foods that do not raise substantive scientific issues. *Id.* at www.cfsan.fda.gov/~lrd/stbioeng.html (last visited Apr. 6, 2002).

144. Joseph A. Levitt, Statement Before the Health, Education, Labor, and Pensions Committee of the U.S. Senate (Sep. 26, 2000), *at* http://www.cfsan.fda.gov/~lrd/stbioeng.html (last visited Apr. 23, 2002).

145. *See* Letter from Alan M. Rulis, Ph.D., Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, to Sally L. Van Wert, Ph.D., Manager, Regulatory Affairs—Biotechnology, AgrEvo USA Co. (May 29, 1998), *available at* http://www.cfsan.fda.gov/~acrobat2/bnfL041.pdf (last visited Apr. 6, 2002).

146. *See* Note to File, BNF0041, Dept. of Health and Human Servs. (May 29, 1998), *at* http://www.cfsan.fda.gov/~acrobat2/bnfM041.pdf (last visited Apr. 6, 2002).

147. *See* Note to File, BNF0041, Dept. of Health and Human Servs. (May 29, 1998), *at* http://www.cfsan.fda.gov/~acrobat2/bnfM041.pdf (last visited Apr. 6, 2002).

148. *See* Note to File, BNF0041, Dept. of Health and Human Servs. (May 29, 1998), *at* http://www.cfsan.fda.gov/~acrobat2/bnfM041.pdf (last visited Apr. 6, 2002).

safety of *StarLink*'s other genetically engineered protein that conferred herbicide resistence and the possible alterations in nutritional characteristics.[149]

In its May 29, 1998 letter to AgrEvo, the FDA noted that AgrEvo had submitted a summary of its safety and nutritional assessments of *StarLink*, and that this data would be retained in FDA's files regarding this consultation.[150] FDA also noted AgrEvo's conclusion that *StarLink* grain and forage are not materially different from that of other corn varieties currently on the market, and that *StarLink* does not raise issues that would require pre-market review or approval by FDA.[151] The letter concluded by saying that FDA had no further questions, but FDA reminded AgrEvo of its continuing responsibility to ensure that foods marketed by it "are safe, wholesome and in compliance with all applicable legal" requirements.[152]

Information about the earlier 1995 FDA consultations concerning the genetically engineered corn from which *StarLink* would inherit herbicide tolerance is available in the accompanying footnote.[153]

2. *The FDA: Actions to Remove Food Containing StarLink from the Marketplace*

- *September 22, 2000, The FDA Initiates Oversight of Class II Recall of Foods Containing* StarLink:

Recalls may be conducted on a firm's own initiative, by the FDA's request, or by the FDA's order under the authority of the Federal Food, Drug, and Cosmetic Act.[154] On September 18, 2000, the organization Genetically Engineered Food Alert reported that an independent laboratory under contract to Friends of the Earth, Genetic ID, found that certain brands of taco shells contained DNA associated with the *StarLink* corn variety.[155] Other tests soon confirmed this report. On September 22, Kraft Foods, Mission Foods, and others in the food industry initiated a voluntary recall of food products that appeared to contain *Bacillus thuringiensis* subspecies

149. *See* Note to File, BNF0041, Dept. of Health and Human Servs. (May 29, 1998), *at* http://www.cfsan.fda.gov/~acrobat2/bnfM041.pdf (last visited Apr. 6, 2002).

150. *See* Letter, *supra* note 145, *available at* http://www.cfsan.fda.gov/~acrobat2/bnfL041.pdf (last visited Apr. 6, 2002).

151. *See id. available at* http://www.cfsan.fda.gov/~acrobat2/bnfL041.pdf (last visited Apr. 6, 2002).

152. *See id., available at* http://www.cfsan.fda.gov/~acrobat2/bnfL041.pdf (last visited Apr. 6, 2002).

153. In August 1994 AgrEvo met with FDA officials to discuss their proposed safety and nutritional assessment of the genetically engineered, glufosinate tolerant corn. The FDA Letter and Memo to File are very similar to FDA's 1998 Letter and Memo concerning *StarLink*. *See* Letter, *supra* note 145, *available at* http://www.cfsan.fda.gov/~acrobat2/bnfL029.pdf (last visited Apr. 6, 2002); Note to the File from the Department of Health and Human Services (Dec. 12, 1995).

154. *See* Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 334 (1994).

155. *See* Bill Hord, *Food Industry Hungry for Biotech Tests: Companies Look for Ways to Quickly and Accurately Identify Genetically Altered Crops,* OMAHA WORLD-HERALD, Feb. 11, 2001, at 1M.

tolworthi Cry9C protein, the pesticidal ingredient in *StarLink*.[156] Tests had identified DNA from the *Cry9C* gene, which is not allergenic, but did not initially detect the potentially allergenic *Cry9C* protein.[157] Thus, FDA viewed the recall of *StarLink*-containing foods as a Class II Recall—a situation where use of a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.[158]

C. *EPA: Regulating StarLink Field Experiments and Commercialization Under FIFRA and FFDCA*

Genetically engineered pesticidal substances (like *StarLink*'s Cry9C protein) and the genetic material necessary to produce these substances (like *StarLink*'s *Cry9C* DNA) are now called "plant-incorporated protectants."[159] For regulatory purposes, EPA treats plant-incorporated protectants the same as chemical pesticides under FIFRA, if humans intend to use these substances for "preventing, destroying, repelling or mitigating any pest."[160] Thus, *StarLink*'s plant-incorporated protectant was subject to EPA regulation concerning experimental use permits and pesticide registration under FIFRA,[161] and EPA regulation concerning pesticide residues in feed and food under the FFDCA.[162]

1. *EPA and StarLink's Experimental Use Permit Under FIFRA*

An experimental use permit ("EUP") is generally required for testing of any unregistered pesticide or any registered pesticide being tested for an unregistered use on more than ten acres.[163] The EPA issues the EUP only if it determines that the

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156. *See* Carl Pope, Sierra Club, *False Friends*, SIERRA, Jan. 1, 2001.

157. *See* Steven Milloy, Editorial, *'Allergenic' Corn Another Failed Anti-Biotechnology Scare*, NATIONAL POST, June 15, 2001, at C19.

158. *See* FDA ENFORCEMENT REPORT FOR NOVEMBER 1, 2000, *at* http://www.fda.gov/bbs/topics/enforce/enf00666.html#Star (last visited Jan. 23, 2002) (listing of food products voluntarily recalled by Mission Foods of Irving, Texas); *see also* FDA Enforcement Report Index, *available at* http://www.fda.gov/opacom/Enforce.html (last visited Jan. 23, 2002) (complete FDA Enforcement Report Index).

159. *See* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772, 37,772 (July 19, 2001) (to be codified at 7 C.F.R. pt. 300).

160. *See* Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,817, 37,817 (July 19, 2001) (to be codified at 40 C.F.R. pt. 174).

161. *See* 7 U.S.C. §§ 136(a), 136(c) (2000).

162. *See* 21 U.S.C. § 346(a) (2000).

163. *See generally* 7 U.S.C. § 136c(a), (b),(c), (d) (1994) (providing general terms for issuance, permits tolerance levels, and experimental studies); *see also* MALINOSUSKI, *supra* note 42, at 1-76 (stating that EUP may be required when the testing area exceed ten acres).

applicant needs the permit to accumulate data needed to register the pesticide.[164] If the EPA finds that issuance of the EUP may be of regional or national significance, the EPA must publish notice that it has received an application and invite public comments. The EPA may hold a public hearing regarding the application if, based upon comments received, the EPA determines such a hearing is warranted. The EPA is to promptly publish notice of the issuance of the EUP in the Federal Register. If the EPA determines that issuing the permit would cause unreasonable adverse effects on the environment, the EPA may refuse to issue the permit or revoke a permit.[165]

- *March 14, 1997, EPA Issued an Experimental Use Peremit to Plant Genetic Systems, a Subsidiary of AgrEvo, to Test Corn Seeds Containing Cry9C Protein in 28 States:*

On March 14, 1997, the EPA published notice that it had issued experimental use permit 70218-EUP-1 which allowed the use of *StarLink*'s Cry9C protein in seeds shipped on 3,305 acres of corn to evaluate the control of the European corn borer and other lepidopteran corn pests.[166] The testing was authorized in Alabama, California, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Virginia, and Wisconsin.[167] The experimental use permit was effective from February 5, 1997, to November 30, 1997, and was issued with the limitation that all treated crops would be destroyed or used for research purposes only.[168]

2. *EPA and StarLink-related Pesticide Registration Under FIFRA*

Pesticide registration is the process through which the EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency, and timing of its use; and any storage and disposal practices.[169] The EPA evaluates the pesticide to ensure that it will not have any adverse effects on humans, the environment and non-target species.[170] Most pesticides cannot be legally sold or distributed in the United States if they have not been registered with the Office of Pesticide Programs.[171] Thus, *StarLink*'s plant-incorporated protectant (the Cry9C

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164. *See* 7 U.S.C. § 136c(a).

165. *See* 7 U.S.C. § 136(c); Procedures Governing the Rescission of State Primary Enforcement Responsibility For Pesticide Use Violations, 40 C.F.R. § 173 (2001) (providing procedures related to federally issued experimental use permits).

166. *See* Issuance of an Experimental Use Permit, 62 Fed. Reg. 12,185, 12,185 (Mar. 14, 1997).

167. *See* Issuance of an Experimental Use Permit, 62 Fed. Reg. at 12,185.

168. *See* Issuance of an Experimental Use Permit, 62 Fed. Reg. at 12,185.

169. *See* 7 U.S.C. § 136(a)(c).

170. *See id.* § 136(a).

171. *See* Pesticide Products Required to be Registered, 40 C.F.R. § 152.15 (2001).

protein and genetic material necessary for its production) had to be registered before *StarLink* could be sold commercially.

- *August 8, 1997, EPA Published Notice That Plant Genetics Systems Had Applied to Register StarLink's Cry9C As a Pesticide, Application Not Limited to Non-food Uses:*

"This notice announce[d] receipt on an application to register the pesticide product Bt Cry9C Corn" pursuant to FIFRA; "written comments [were to] be submitted by September 8, 1997."[172] The application did not propose that the registration would be conditioned on limiting the harvest from StarLink seeds to non-food uses.

- *May 12, 1998, EPA Approved Registration of StarLink's Cry9C Plant-pesticide (Now Known as a Plant-incorporated Protectant), Registration Limited to Non-food Use Only:*

On May 12, 1998, the EPA announced that *StarLink*'s plant-incorporated protectant registration was approved.[173] The registration required feed or non-food industrial uses of the corn only, not food use.[174] Also, *StarLink* could only be planted on 120,000 acres, neighboring non-Bt corn refuges would be required as a way of managing pesticide resistance, and the registration would expire May 30, 1999.[175] Ten days later EPA would announce its corresponding regulatory action to issue a tolerance or exemption for Cry9C pesticidal residues.

- *EPA Issues Amended Pesticide Registrations for 1999 and 2000 Crop Years, StarLink Still Limited to Non-food Uses:*

The pesticide registration for *StarLink* was subsequently amended several times.[176] For the year 2000 crop, EPA issued an updated Pesticide Registration subject to certain terms and conditions, e.g., *StarLink* (and corn grown within 660 feet) could only be used for animal feed/non-food industrial uses and grower agreements must specify the planting of twenty percent non-Bt corn refuges.[177] The 660 feet buffer

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172. Plant Genetics Systems Inc.; Application to Register a Pesticide Product, 62 Fed. Reg. 42,784, 42,784 (Aug. 8, 1997).

173. *See* Certain Companies; Approval of Pesticide Product Registrations, 63 Fed. Reg. 43,936, 43, 936 (Aug. 17, 1998).

174. *See* Certain Companies; Approval of Pesticide Product Registrations, 63 Fed. Reg. at 43,936.

175. *See* Certain Companies; Approval of Pesticide Product Registrations, 63 Fed. Reg. at 43,936.

176. *See* Certain Companies; Approval of Pesticide Product Registrations, 63 Fed. Reg. at 43,936.

177. U.S. EPA, *Biopesticide Fact Sheet: Bacillus thuringiensis subspecies tolworthi Cry9C Protein and the Genetic Material Necessary for Its Production in Corn* (April 2000), EPA Publication Number EPA 730-F_00-005 (copy available in authors files); *see* U.S. EPA, *Biopesticide Fact Sheet: Bacillus thuringiensis subspecies tolworthi Cry9C Protein and the Genetic Material Necessary for Its Production in Corn* (006466) (March 2001), *available at* http://www.epa.gov/pesticides/biopesticides/factsheets/fs006466t.htm (last visited May 3, 2002) (See the

reflects APHIS recommendations intended to minimize pollen spread from *StarLink* to other corn.[178] "The non-Bt corn refuges are part of EPA's on-going strategy to delay insect resistance to plant-expressed Bt pesticides."[179] The detailed terms and conditions applicable to the year 2000 crop follow:[180]

> A. This registration will automatically expire on midnight April 1, 2001. After this registration has expired, no field corn seed that contains the pesticide product may be sold or planted. However, harvesting of such corn planted prior to April 1, 2001 is permissible subject to the terms of this registration. Aventis Crop Science USA LP is liable for the actions of its customers in regard to meeting the terms and limitations of this registration.
>
> B. This registration is for field corn to be used only in animal feed, industrial non-food uses such as ethanol production, and seed increase. In addition, any corn grown within 660 feet of Cry9C corn must also be limited to use in animal feed and industrial non-food uses such as ethanol production. The acreage for corn planted may not exceed 2.5 million acres for the duration of this registration. Aventis Crop Science USA LP must implement their plan proposed in letter to EPA dated January 22, 1999 to direct the use of all grain not harvested for seed to animal feed or industrial non-food use.
>
> C. Grower agreements (Stewardship Agreements) will specify that growers must adhere to the refuge requirements as described in the Grower Guide/Product Use Guide and/or in supplements to the Grower Guide/Product Use Guide. Specifically, growers must plant a minimum structured refuge of at least twenty percent non-Bt corn. Insecticide treatments for control of European corn borer, corn earworm and/or Southwestern corn borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents). Crop insecticides must not be applied to non-Bt corn refuge[s]. Requirements for refuge deployment will be described in the Grower Guides/Product Use Guides. Growers must plant the refuge within one-half mile of their Bt corn acreage. In regions of the corn belt where conventional insecticides have historically been used to control [European corn borer] (ECB) and [Southwestern corn borer] (SWCB), growers wanting the option to treat these pests must plant the refuge within one-quarter mile of their Bt corn. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field. When planting the refuge in strips across the field, growers must be instructed to plant multiple non-Bt rows whenever possible.
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> D. Aventis Crop Science USA LP must provide and indicate how it will provide specific information through their technical bulletins, brochures, product labels, and educational presentations so that growers have the necessary tools to successfully implement an

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historical discussion of 1999 and 2000 year registrations at II.B).

178. *See id available at* http://www.epa.gov/pesticides/biopesticides/factsheets/fs006466t.htm (last visited May 3, 2002)

179. *Id available at* http://www.epa.gov/pesticides/biopesticides/factsheets/fs006466t.htm (last visited May 3, 2002)

180. *See id available at* http://www.epa.gov/pesticides/biopesticides/factsheets/fs006466t.htm (last visited May 3, 2002)

> integrated IRM plan. A World Wide Web site on the internet would be a practical way to provide specific resistance management information. Included in this IRM information should be instructions on the appropriate use of the Bt plant-pesticides in a resistance management program, compatibility with existing (IPM) programs, refuge deployment and management (including IPM options), monitoring, reporting of unusual pest damage, and any local and regional IRM considerations. The success of any IRM program will ultimately depend on growers who have the knowledge and tools to understand the problem of resistance and the steps that can be taken to combat it.
>
> E. Aventis Crop Science USA LP must maintain a (confidential) database to track sales by units and location of Cry9C corn on a state and county-by-county basis. This material should be submitted annually (by January 31 of the year following each growing season) to the Agency on a Confidential Business Information (CBI) basis. As part of this report, Aventis Crop Science USA LP must provide an estimate of the acreage for Cry9C corn within each state.[181]

- *January 18, 2001, EPA Publishes Receipt of Request for Cancellation of the Limited Use Registration of StarLink's Plant-incorporated Protectant:*

In September 2000, following discovery of *StarLink* in taco shells, Aventis announced that it would voluntarily end sales of *StarLink* seed. On October 12, 2000, EPA announced that Aventis had requested EPA to revoke the Pesticide Registration for *StarLink*'s plant-incorporated protectant.[182] Revocation would mean that future sales of *StarLink* seed, with its unregistered plant-incorporated protectant, would be unlawful (unless the Registration were reinstated at a later date).[183]

On January 18, 2001, EPA published notice of the Aventis request to cancel its "registration of *Bacillus thuringiensis* (B.t.) subspecies tolworthi Cry9C and the genetic material necessary for its production in corn."[184] The EPA noted that "unless the request[s] [were] withdrawn, the Agency [would] approve these use deletions . . . effective on February 20, 2001."[185]

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181. U.S. EPA, *Biopesticide Fact Sheet: Bacillus thuringiensis subspecies tolworthi Cry9C Protein and the Genetic Material Necessary for Its Production in Corn* (April 2000), EPA Publication Number EPA 730-F_00-005 (on file with authors).

182. *See* Press Release, EPA, Statement by Stephen Johnson, EPA Deputy Assistant Administrator for Pesticides, Regarding StarLink™ Corn (Oct. 12, 2000), *at* http://www.whybiotech.com/en/pressrel/con448.asp?MID=18&style=print (last visited Apr. 6, 2002).

183. *See* Press Release, EPA, Statement by Stephen Johnson, EPA Deputy Assistant Administrator for Pesticides, Regarding StarLink™ Corn (Oct. 12, 2000), *at* http://www.whybiotech.com/en/pressrel/con448.asp?MID=18&style=print (last visited Apr. 6, 2002).

184. Notice of Receipt of Request for Cancellation of Bacillus Thuringiensis (B.t.) subspecies tolworthi Cry9c Genetic Material Necessary for its Production in Corn, 66 Fed. Reg. 4825, 4825 (Jan. 18, 2001).

185. Notice of Receipt of Request for Cancellation of Bacillus Thuringiensis (B.t.) subspecies tolworthi Cry9c Genetic Material Necessary for its Production in Corn, 66 Fed. Reg. at 4825.

3. *EPA and StarLink-related Pesticide Residue Tolerances or Exemptions Under FFDCA*

Under Section 408 of the Federal Food, Drug, and Cosmetic Act, the EPA regulates chemical pesticide residues by establishing tolerances limiting the amounts of residues that may be present in or on food.[186] The tolerance establishes a maximum permissible level of the residue that is still considered safe.[187] Alternatively, the EPA can exempt pesticides from the requirement of a tolerance if the EPA determines that such an exemption is safe, i.e., there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide residue.[188]

EPA views residues of plant-incorporated protectants (including the Cry9C protein and *cry9C* DNA) as a "chemical pesticide residue" under FFDCA just as EPA views plant-incorporated protectants as a "chemical pesticide" under FIFRA.[189] Thus, the EPA sets tolerance limits for residues of plant-incorporated protectants on and in food and animal feed, or establishes an exemption from the requirement of a tolerance.[190] *StarLink* would need to have a tolerance established for residues of its plant-incorporated protectant, or be exempted from the requirement of a tolerance, before it could be sold commercially. A decision to establish a pesticide residue tolerance or exemption is conceptually linked to the decision to register a pesticide: if there is no safe level for the pesticide residue, then the pesticide will have an unreasonable adverse effect on the environment (including humans) and should not be registered.[191] Thus, the EPA decision whether to establish a tolerance or exemption for *StarLink*'s plant-incorporated protectant would be linked to the May 12, 1998 decision to register the plant-incorporated protectant.[192]

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186. *See* 21 U.S.C. § 346a (2000).

187. *See* Tolerances and Exemptions from Tolerance for Pesticide Chemicals in Food, 40 C.F.R. § 180 (2001).

188. *See id.* § 180.

189. *See* Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Part of Plant-Incorporated Protectants, 66 Fed. Reg. 37,817, 37,817 (July 19, 2001) (to be codified at 40 C.F.R. pt. 174).

190. *See* Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Part of Plant-Incorporated Protectants, 66 Fed. Reg. at 37,817. The EPA also establishes tolerances for residues of herbicides used on novel herbicide-tolerant crops like *StarLink*'s genetically engineered, herbicide tolerant ancestor. *See U.S. Regulatory Oversight in Biotechnology*, USDA, *at* http://www.aphis.usda.gov/biotech/OECD/usregs.htm (last visited Jan. 30, 2002). The APHIS and the EPA recently signed a Memorandum of Understanding regarding their process for sharing information on herbicide tolerant crops. *See* Memorandum of Understanding, USDA, *available at* http://www.aphis.usda.gov/biotech/mou1.html (last visited Jan. 31, 2002).

191. *See* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants, 66 Fed. Reg. 37,772, 37,773 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174).

192. *See generally* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants, 66 Fed. Reg. at 37,772 (providing protection for registered plant-incorporated protectants).

• *September 19, 1997, EPA Gave Notice That Plant Genetics Systems Had Requested an Exemption from the Tolerance Requirement for StarLink's Plant-incorporated Protectant, Request Not Limited to Non-food Uses:*

On September 19, 1997, EPA announced "the initial filing of a pesticide petition (PP 7F4826), submitted by Plant Genetic Systems (America) Inc., proposing the establishment of" an "exemption from the requirement of a tolerance for residues of" *StarLink*'s plant-incorporated protectant "in or on all raw agricultural commodities," not just on corn used as feed.[193] The published notice contained a summary of the petition as prepared by the petitioner and indicated written comments were to be received by October 20, 1997.[194] The petition summary included data that Cry9C, unlike other *Bt* proteins used in other plants, was stable and remained intact following four hours in simulated mammalian gastric juice.[195]

The greater stability of the genetically engineered Cry9C protein if *StarLink* corn were ingested into the human digestive system, with or without food processing, would raise concerns regarding the possible allergenicity of this protein if it was part of the human diet. On April 24, 1998, Plant Genetic Systems submitted an amendment to its petition for an exemption.[196] Instead of requesting an exemption for *StarLink*'s plant-incorporated protectant on all raw agricultural commodities, the amended petition requested an exemption only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.[197]

• *May 22, 1998, EPA Exempted* StarLink's *Cry9C Plant-Insecticide and Its Encoding Genetic Material (Now Known as a Plant-Incorporated Protectant) from the Requirement of a Tolerance for Pesticide Residues in Feed and the Meet, Milk or Eggs of Animals Fed the Feed:*

On May 22, 1998, ten days after EPA published notice that it had registered *StarLink*'s plant-incorporated protectant, EPA published its final rule regarding an exemption from the requirement of a tolerance for pesticide residues.[198] The final rule made permanent a temporary exemption (issued by EPA on April 10, 1998) "for residues of the insecticide, *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn for feed use only; as well as in meat, poultry, milk, or eggs resulting by animals fed such feed."[199] "This

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

194. *See* Notice of Filing of Pesticide Petitions, 62 Fed. Reg. at 49,224-225.

195. *See* Notice of Filing of Pesticide Petitions, 62 Fed. Reg. at 49,225.

196. *See* Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. 28,258, 28,258 (May 22, 1998) (to be codified at 40 C.F.R. pt. 180).

197. *See* Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,258.

198. *See* Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,258.

199. Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material

regulation eliminate[d] the need to establish a maximum permissible level"—a tolerance—for residues of this plant-incorporated protectant in these products.[200]

"Based on the toxicology data cited and the limited exposure [to humans] expected with animal feed use" only, EPA concluded there was "reasonable certainty that no harm [would] result from aggregate exposure to the U.S. population, including infants and children, to residues of" *StarLink*'s plant-incorporated protectant.[201] Importantly, the Agency "arrived at this conclusion because . . . the tolerance exemption [was] limited to feed use only."[202] "The conclusion of safety [was] supported by the lack of toxicity after administration of a high oral dose, the lack of [similarity] to known toxins or allergens, and the minimal to nonexistent exposure via dietary and non-dietary routes."[203] The exemption from the requirement of a tolerance would be revoked if subsequent data indicated that the tolerance is not safe.[204] Note that no exemption for a tolerance was established for corn consumed directly as food, for example, corn consumed as taco shells. A decision about whether a broader exemption should also be approved would require additional analysis regarding the allergenicity potential of *StarLink*'s Cry9C protein.

EPA's May 22, 1998 action to exempt *StarLink*'s plant-incorporated protectant from the requirement of a tolerance for pesticide residues (non-food use only) was a significant regulatory event.[205] This action by EPA, coupled with EPA's May 12 registration of *StarLink*'s plant-incorporated protectant (non-food use only), APHIS's May 15, 1998 determination of nonregulated status for *StarLink*, and FDA's May 29, 1998 consultations with AgrEvo regarding *StarLink*, paved the way for commercial production of *StarLink* for non-food uses only.[206] These regulatory

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Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,258.

200. Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,258.

201. Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,260.

202. Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,260.

203. Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,260.

204. *See* Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,260.

205. *See* Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for the Production of Corn: Exemption from the Requirement from the Tolerance, 63 Fed. Reg. at 28,258.

206. *See* AgroEvo USA Co.; Availability of Determination of Nonregulated Status for Corn

approvals came too late to have much effect on 1998 corn planting, but U.S. farmers would plant about 250,000 acres of *StarLink* in 1999 (0.3% of the total corn acreage that year) and about 350,000 acres in 2000 (0.4 % of total).[207] However, the goal of AgrEvo, and later Aventis, was to obtain approval of *StarLink* for both feed and food uses.[208] Subsequent to the May 1998 regulatory approvals, AgrEvo would gather additional data regarding *StarLink*'s potential as an allergen and request EPA to expand the tolerance exemption to include both feed and food uses.

- *April 7, 1999, EPA Announced Company Request To Expand Tolerance Exemption to Also Cover Direct Human Consumption of Food with Cry9C, in Addition to Feed:*

According to EPA's November 20, 1998 Safety Assessment, the *StarLink* data and other information provided did not provide a conclusive argument negating the allergenicity potential of the Cry9C protein. Most critical was the observation that the Cry9C protein is not immediately broken down in gastric digestion tests, a property that is also characteristic of most food allergens. Enhanced gastric stability does not necessarily make the Cry9C protein a food allergen, and in fact this protein lacked many of the other features associated with known allergenic proteins. However, because EPA could not reach a definitive decision regarding the allergenicity potential of the Cry9C protein, it requested AgrEvo to provide additional data. AgrEvo would supply additional data in conjunction with its new petition to approve *StarLink* for food use.

On April 7, 1999, the EPA announced the receipt of a pesticide petition from AgrEvo.[209] The petition proposed an amendment to 40 C.F.R. §180.1192 to expand the exemption from the requirement of a tolerance for *StarLink*'s plant-incorporated protectant.[210] At that time, and currently, the exemption covered these substances in corn, only when the corn was used for animal feed, and in meat, poultry, milk, or eggs resulting from animals fed such corn.[211] The petition sought to extend the exemption to all food commodities, i.e., to directly consumed foods containing Cry9C, in addition to feed and animal products used as food.[212]

Genetically Engineered for Insect Resistance and Glufosinate Herbicide Tolerance, 63 Fed. Reg. 27,041, 27,041 (May 15, 1998).

207. Aventis CropScience USA LP, *Petition for Tolerance: Bacillus thuringiensis subsp. tolworthi Cry9C Protein in or on the Raw Agricultural Commodity, Corn*, 35 *at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

208. *See generally* Note to the File, V. Kelly Banning, Ph.D., Department of Health and Human Services, Subject: Glufosinate Tolerant Corn (Dec. 12, 1995) *at* http://www.cfsan.fda.gov/~acrobat2/bnfm0219.pdf (last visited Apr. 6, 2002) (noting AgrEvo concluded that corn with T14 and T25 "are not materially different in composition, nutrition, and safety from corn currently grown, marketed, and consumed for animal feed or human food).

209. Notice of Filing of Petition, 64 Fed. Reg. 16,965, 16,965 (Apr. 7, 1999).

210. Notice of Filing of Petition, 64 Fed. Reg. at 16,966.

211. *See* Notice of Filing of Petition, 64 Fed. Reg. at 16,967.

212. *See* Notice of Filing of Petition, 64 Fed. Reg. at 16,966.

- *December 21, 1999, EPA Announced Completion of Review, Solicited Public Comment*:

EPA completed its initial review of the data submitted in support of AgrEvo's April 1999 petition and solicited public comment on the data evaluation records and on a list of questions regarding human allergenicity assessment for non-digestible proteins expressed as plant-incorporated protectants.[213]

- *February 29, 2000, EPA'S FIFRA Scientific Advisory Panel Met (Report Issued June 29, 2000: "no evidence to indicate that Cry9C is or is not a potential food allergen."):*

The evaluation of potential human allergenicity of non-digestible proteins expressed as plant-pesticides was the subject of a February 29, 2000 FIFRA Scientific Advisory Panel ("SAP") meeting.[214] According to the SAP report issued on June 29, 2000, the SAP "agreed that based on the available data, there is no evidence to indicate that Cry9C is or is not a potential food allergen."[215]

- *Summer 2000, EPA Took No Action on the Aventis Request To Expand the Tolerance Exemption to Also Cover Human Food:*

What if, after receiving the SAP report, EPA had determined that "there is a reasonable certainty that no harm will result from aggregate exposure to the . . . [Cry9C] . . . residue, including all anticipated dietary exposures . . ."[216] if foods directly consumed by humans, including children, contained Cry9C? Following such a determination of safety, the EPA Administrator may issue a regulation establishing the exemption.[217] If EPA had made such a determination of safety, and if it had issued a regulation establishing the exemption or established a tolerance for Cry9C in human food, the September 2000 discovery of *StarLink* in taco shells would have been a non-event. Instead, the approval by EPA of a bioengineered protein in human food, a protein more stable in the human digestive tract than other Bt proteins and not proven to be free of allergenic potential, might have become the news story.

In fact, the EPA did not make such a determination of safety and did not establish the exemption requested in AgrEvo's April 1999 petition, nor did it establish a tolerance for Cry9C in human food. Aventis did not keep *StarLink* in feed-only marketing channels. The subsequent discovery of *StarLink* in taco shells—dubbed "Taco-gate" by some—did become front page news (and the correctness of the EPA's non-action, and the broader question of how to address allergenicity issues when

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213. *See* Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-Pesticide, 65 Fed. Reg. 65,246, 65,247 (Oct. 31, 2000).

214. *See* FIFRA Scientific Advisory Panel; Open Meeting, 65 Fed. Reg. 5636, 5636 (Feb. 4, 2000).

215. Assessment of Scientific Information Concerning StarLink™ Corn Cry9C Bt Corn Plant-Pesticide, 65 Fed. Reg. at 65,247.

216. 21 U.S.C. § 346a(c)(2)(A)(ii) (1999) (this is the standard for an exemption as set forth in the FFDCA).

217. *See id.* § 346a(c)(2)(A)(i).

regulating foods containing novel proteins, continues to be debated today).[218] In the fall of 2000, Aventis voluntarily agreed to end sales of *StarLink* seed and voluntarily cancelled its pesticide registration for *StarLink*'s plant-incorporated protectant. Aventis would then work aggressively to manage the problem of *StarLink*'s unintended presence in human food, a problem stemming from the 1999 and 2000 crops.

IV. MANAGING THE *STARLINK* PROBLEM: CONTAINING CRY9C CORN IN APPROVED USES, MANAGING LIABILITY-RELATED CLASS ACTION LAWSUITS, AND SEEKING LIMITED APPROVALS FOR HUMAN FOOD USE

A. *Minimizing the Presence of Cry9C in Food and Managing StarLink-Related Liability*

1. *The StarLink Enhanced Stewardship Program: Moving Grain Containing the Cry9C Protein Into Approved Marketing Channels*

In the aftermath of the discovery of *StarLink* in human food, Aventis worked aggressively to locate and purchase corn containing Cry9C. In consultation with regulatory agencies and with Attorneys General in seventeen states, Aventis developed the *StarLink* Enhanced Stewardship ("SES") Program and adopted claims procedures for "*StarLink* Growers" and "Buffer Growers."[219]

The benefits of participating in the SES Program provided clear incentives for farmers to cooperate in the special effort to direct grain with Cry9C into approved marketing channels.[220] For example, growers would receive an additional $0.25 for

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218. *See id.* § 346(c)(2)(A)(ii).

219. *See* Aventis CropScience USA LP, Petition for Tolerance: *Bacillus thuringiensis* Subsp. *tolworthi* Cry9C Protein in or on the Raw Agricultural Commodity, *Corn*, Vol. 6 (Apr. 19, 2001), *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last visited Apr. 23, 2002); *see also Aventis Signs Formal Agreement to Mitigate Losses from StarLink Corn, at* http://www.state.ia.us/government/ag/StarLink_binding_agt_rel.htm (last visited Apr. 30, 2002); *Aventis Signs Supplemental Agreement to Mitigate Losses from StarLink Corn, at* http://www.state.ia.us/government/ag/StarLink_supplemental_agt_rel_Miller_Iowa.htm (last visited Apr. 30, 2002). Additional information about the StarLink Enhanced Stewardship Program and its claims procedures is available *at* http://204.148.37.140/starlinkcorn.htm (last visited May 1, 2002).

220. *See* Aventis CropScience USA LP, Petition for Tolerance: *Bacillus thuringiensis* Subsp. *tolworthi* Cry9C Protein in or on the Raw Agricultural Commodity, *Corn*, Vol. 6 (Apr. 19, 2001), *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last visited Apr. 23, 2002); *see also Aventis Signs Formal Agreement to Mitigate Losses from StarLink Corn, at* http://www.state.ia.us/government/ag/StarLink_binding_agt_rel.htm (last visited Apr. 30, 2002); *Aventis Signs Supplemental Agreement to Mitigate Losses from StarLink Corn, at* http://www.state.ia.us/government/ag/StarLink_supplemental_agt_rel_Miller_Iowa.htm (last visited Apr.

each bushel of *StarLink* Corn or buffer corn (corn grown within 660 feet of *StarLink* Corn) that would be handled through the SES Program. Participating growers would also receive a special additional payment of five or ten cents per bushel for qualifying non-*StarLink* Corn/non-buffer corn inadvertently commingled with their *StarLink* or buffer corn.

Elevators that received *StarLink*, buffer corn or co-mingled corn and suffered resulting economic loss could also submit claims for compensation.[221] For example, claims could be submitted for additional storage and transportation costs incurred as a result of handling Cry9C-containing corn, testing costs (Aventis provided test kits free of charge), and reasonable costs of cleaning grain storage and handling facilities. In addition, claims could be submitted for loss on sale, i.e., the amount by which the net sales price that an elevator would have received for the *StarLink* and commingled corn had it been sold as originally intended exceeded the net sales price actually received by the elevator.[222]

The SES Program was very successful in directing Cry9C-containing grain into approved uses. By April 2001, well over 99% of the year 2000 *StarLink* corn crop had been identified and was either being fed on farm or transported under controlled conditions to USDA approved non-food destinations.[223] The SES program testing procedures also detected large quantities of ordinary corn commingled with 1999 *StarLink* production.[224] Over 400 million bushels of commingled grain

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30, 2002). Additional information about the StarLink Enhanced Stewardship Program and its claims procedures is available *at* http://204.148.37.140/starlinkcorn.htm (last visited May 1, 2002).

221. *See* Aventis CropScience USA LP, Petition for Tolerance: *Bacillus thuringiensis* Subsp. *tolworthi* Cry9C Protein in or on the Raw Agricultural Commodity, *Corn*, Vol. 6 (Apr. 19, 2001), *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last visited Apr. 23, 2002); *see also Aventis Signs Formal Agreement to Mitigate Losses from StarLink Corn, at* http://www.state.ia.us/government/ag/StarLink_binding_agt_rel.htm (last visited Apr. 30, 2002); *Aventis Signs Supplemental Agreement to Mitigate Losses from StarLink Corn, at* http://www.state.ia.us/government/ag/StarLink_supplemental_agt_rel_Miller_Iowa.htm (last visited Apr. 30, 2002). Additional information about the StarLink Enhanced Stewardship Program and its claims procedures is available *at* http://204.148.37.140/starlinkcorn.htm (last visited May 1, 2002).

222. *See* Aventis CropScience USA LP, Petition for Tolerance: *Bacillus thuringiensis* Subsp. *tolworthi* Cry9C Protein in or on the Raw Agricultural Commodity, *Corn*, Vol. 6 (Apr. 19, 2001), *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last visited Apr. 23, 2002); *see also Aventis Signs Formal Agreement to Mitigate Losses from StarLink Corn, at* http://www.state.ia.us/government/ag/StarLink_binding_agt_rel.htm (last visited Apr. 30, 2002); *Aventis Signs Supplemental Agreement to Mitigate Losses from StarLink Corn, at* http://www.state.ia.us/government/ag/StarLink_supplemental_agt_rel_Miller_Iowa.htm (last visited Apr. 30, 2002). Additional information about the StarLink Enhanced Stewardship Program and its claims procedures is available *at* http://204.148.37.140/starlinkcorn.htm (last visited May 1, 2002).

223. *See* Aventis CropScience USA LP, *Petition for a Tolerance: Bacillus thuringiensis subsp. tolworthi Cry9C Protein in or on the Raw Agricultural Commodity, Corn*, Vol. 6, 17 *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

224. *See id. at 8 available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

containing Cry9C assumed to be from 1999 production had been identified and was being redirected to approved uses.[225] Nevertheless, the detection of Cry9C-containing grain was expected to continue into the foreseeable future.[226]

The costs to Aventis resulting from its diligent effort to remove *StarLink* and the Cry9C protein from the U.S. corn supply will undoubtedly be in the tens of millions of dollars. In Iowa alone, Aventis has paid Iowa farmers and elevators over $10.5 million as of October 1, 2001, about six million dollars to farmers and over $4.5 million to elevators.[227] According to Iowa Attorney General Tom Miller, these totals do not include amounts Aventis may have paid to food-producing companies in Iowa.[228]

2. *FDA Guidance for StarLink Testing at Food Processing Plants*

On January 22, 2001, the FDA announced recommendations for sampling and testing yellow corn and dry-milled yellow corn shipments intended for human food use to determine if the shipments contained Cry9C.[229] The guidance document was for dry milling and masa operations.[230] It recommended appropriate tests, representative sampling procedures, appropriate analytical procedures, and appropriate personnel training.[231] FDA believed these recommendations would help manufacturers identify corn containing *StarLink* and avoid the use of such corn in human food products.[232]

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225. *See id. at 5 available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

226. *See id. at 6 available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

227. *See* Press Release, Tom Miller, Iowa Attorney General, Miller: Aventis Has Paid $10 Million in Iowa—& Keeps Responsibility for StarLink™ Corn (Oct. 17, 2001) *at* http://www.state.ia.us/government/ag/latest_news/releases/Oct_2001/StarLink_Update_10_17_01_rel.htm (last visited Feb. 6, 2002).

228. *See* Press Release, Tom Miller, Iowa Attorney General, Miller: Aventis Has Paid $10 Million in Iowa—& Keeps Responsibility for StarLink™ Corn (Oct. 17, 2001) *at* http://www.state.ia.us/government/ag/latest_news/releases/Oct_2001/StarLink_Update_10_17_01_rel.htm (last visited Feb. 6, 2002).

229. *See* Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Availability, 66 Fed. Reg. 6627, 6627 (Jan. 22, 2001).

230. *See* Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Availability, 66 Fed. Reg. at 6628.

231. *See* Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Availability, 66 Fed. Reg. at 6627.

232. *See* Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Availability, 66 Fed. Reg. at 6627.

3. *Class Action Suits By Growers of Corn Without Cry9C*

Farmers who grew *StarLink* and those whose corn otherwise tests positive for the Cry9C protein may be fully compensated for their *StarLink*-related economic losses through the *StarLink* Enhanced Stewardship program described above. But what about other corn growers? Did the *StarLink* saga have a depressing effect on the price of U.S. corn generally, and if so, how much? Numerous *StarLink*-related class action complaints against Aventis, including *Kramer v. Aventis Crop Science USA Holding, Inc.*, have been consolidated as multi-district litigation in the Northern District of Illinois.[233] Other class action suits are pending in state courts. One allegation in these lawsuits is that the *StarLink* saga also depressed the price of U.S. corn that was free of Cry9C and that all U.S. growers of this corn suffered economic losses as a result.[234]

B. *EPA and Aventis's Request To Exempt StarLink from the Requirement of a Tolerance in Food for Four Years, the Estimated Time Needed to Clear Foods Containing StarLink from the Market*

- *October 31, 2000, EPA Announced Receipt of New Information, Request To Include All Food Commodities in the Cry9C Exemption for Four Years Only:*

"On October 25, 2000, Aventis submitted new information in support of its petition (PP 9F5050) for an exemption from the requirement of a tolerance for the genetically engineered 'plant-pesticide' materials in *StarLink* corn."[235] "While the original petition requested an exemption covering both the Cry9C DNA and Cry9C protein in all food commodities, this [new] submission limit[ed] the request only to foods made from StarLink."[236] Because the requested exemption would apply only to food products made from the 1998, 1999, and 2000 *StarLink* corn crops (Aventis has stopped selling *StarLink* for later years), Aventis proposed that the exemption would only be for four years—the time needed for the food items from these crop years to clear the channels of trade. The submission specifically addressed the potential allergenicity of the Cry9C protein that may be present in human food made from

233. *See In re StarLink* Corn Products Liability Litigation, 152 F. Supp. 2d 1378, 1379-80 (J.P.M.L. 2001). A consumer class action lawsuit naming Aventis and numerous food companies as defendants was reportedly settled for $9 million, although defendants reportedly denied any liability to the proposed class. Jill Carroll, *Judge Will Approve Settlement on Use of StarLink Corn*, WALL ST. J., Mar. 7, 2002, at A4.

234. *See* Sutter v. Aventis Crop Science USA Holding, Inc., 145 F. Supp. 2d 1052, 1053 (S.D. Iowa 2001).

235. Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-Pesticide, 65 Fed. Reg. 65,246, 65,246 (Oct. 31, 2000).

236. Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-Pesticide, 65 Fed. Reg. at 65,246.

StarLink. Aventis contended the information included in its submission shows that: 1) the Cry9C protein and DNA are neither toxic nor human food allergens; 2) exposure to the Cry9C protein is so low that it is unlikely to have caused sensitization; and 3) exposure to the Cry9C protein is so low that it is not likely to cause allergic responses in humans.[237]

The EPA's "notice provide[d] information on Aventis' submission and outline[d] the U.S. Environmental Protection Agency's process for seeking public comment on and external scientific review of the new information."[238] Further, the EPA announced its intention to hold a public meeting of an independent, external scientific peer review group during the week of November 27 through December 1, 2000, to consider the potential allergenicity of the Cry9C protein.[239]

- *November 13, 2000, EPA Announced Preliminary Evaluation of Aventis' October 25 Submission, Announced SAP Meeting to be November 28:*

EPA prepared a "Preliminary Evaluation" for the FIFRA Scientific Advisory Panel ("SAP"), an advisory committee of independent, external, expert scientists who provide advice to EPA on scientific issues arising in the context of pesticide regulation.[240] The issue before the SAP is whether or not the presence of the *StarLink*™ corn in the human food supply, in finite quantities and for a limited time duration, poses an unacceptable risk of allergenicity.[241] Since EPA did not have sufficient expertise on the range of issues raised by the Aventis petition, particularly with respect to allergenicity, EPA's Preliminary Evaluation focused solely on framing the science issues to be considered by its SAP, and did not present any final, overall conclusions about the Aventis submission.[242] EPA and other federal agencies would consider the SAP report in making decisions about future regulatory actions.[243]

EPA divided its evaluation of the Aventis submission into three specific topic areas: (1) the toxicity and potential allergenicity of Cry9C; (2) sensitization to the

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237. *See* Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-Pesticide, 65 Fed. Reg. at 65,248.

238. Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-Pesticide, 65 Fed. Reg. at 65,246.

239. *See* Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-Pesticide, 65 Fed. Reg. at 65,250.

240. *See* EPA, *Preliminary Evaluation of Information Contained in the October 25, 2000 Submission from Aventis Crop Science, at* http://www.epa.gov/scipoly/sap/2000/november/prelim_eval_sub102500.pdf (last visited May 1, 2002).

241. *See* EPA, *Preliminary Evaluation of Information Contained in the October 25, 2000 Submission from Aventis Crop Science, at* http://www.epa.gov/scipoly/sap/2000/november/prelim_eval_sub102500.pdf (last visited May 1, 2002).

242. *See* EPA, *Preliminary Evaluation of Information Contained in the October 25, 2000 Submission from Aventis Crop Science, at* http://www.epa.gov/scipoly/sap/2000/november/prelim_eval_sub102500.pdf (last visited May 1, 2002).

243. *See* EPA, *Preliminary Evaluation of Information Contained in the October 25, 2000 Submission from Aventis Crop Science, at* http://www.epa.gov/scipoly/sap/2000/november/prelim_eval_sub102500.pdf (last visited May 1, 2002).

Cry9C protein; and (3) simulated exposure to the Cry9C protein through food consumption.[244] Some highlights of EPA's preliminary evaluation follow.

- *Toxicity and potential allergenicity:* EPA's only remaining concern was whether the Cry9C protein may pose a risk of allergenicity if directly present in the human food supply. EPA still questioned whether Cry9C was or was not an allergen.
- *Sensitization to the Cry9C protein:* EPA still had questions on the subject of potential sensitization.
- *Simulated exposure to the Cry9C protein through food consumption*: EPA thought that the available information supported an overall conclusion that the potential dietary exposure to the Cry9C protein is extremely low—in the range of parts per billion or parts per trillion of food consumption by the most highly exposed individuals in the population. The Agency sought the Scientific Advisory Panel's views on whether Aventis has demonstrated scientifically a level of exposure below which Cry9C would not elicit an allergic response in sensitized individuals, if Cry9C behaves as an allergen.

The text of EPA's Scientific Advisory Panel "Final Report" for the November 28, 2000 meeting was released December 5 and is available on the Internet.[245] In summary, the SAP found, based on available information:

- *Allergenicity:* There is a "medium likelihood" that *StarLink* protein is a potential allergen.[246]
- *Sensitization:* The Panel declined to speculate on the issue of sensitization to *StarLink*. But, the Panel noted that children may be more sensitive than adults and that the study of infant diets should be given high priority.[247]
- *Exposure:* There is a "low probability" of allergenicity in the population exposed to the corn, given the low levels of *StarLink* in the U.S. diet.[248]
- *Priority for further study:* The Panel recommended as its highest priority that individuals who claim to have experienced adverse effects from *StarLink*

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244. *See* EPA, *Preliminary Evaluation of Information Contained in the October 25, 2000 Submission from Aventis Crop Science, at* http://www.epa.gov/scipoly/sap/2000/november/prelim_eval_sub102500.pdf (last visited May 1, 2002).

245. A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE ENVIRONMENTAL PROTECTION AGENCY REGARDING: ASSESSMENT OF SCIENTIFIC INFORMATION CONCERNING STARLINK™ CORN, FIFRA SCIENTIFIC ADVISORY PANEL, SAP REPORT NO. 2000-06 (Dec. 1, 2000) *available at* http://www.epa.gov/scipoly/sap/2000/november/one.pdf (last visited Feb. 2, 2002).

246. *See id. available at* http://www.epa.gov/scipoly/sap/2000/november/one.pdf (last visited Feb. 2, 2002).

247. *See id. available at* http://www.epa.gov/scipoly/sap/2000/november/one.pdf (last visited Feb. 2, 2002).

248. *See id. available at* http://www.epa.gov/scipoly/sap/2000/november/one.pdf (last visited Feb. 2, 2002).

corn consumption be studied as soon as possible to determine whether *StarLink* was the source of the reactions.[249]

EPA took no action on the Aventis petition following publication of the SAP report. In a press release, EPA said it would "continue its evaluation of the scientific information, and develop the appropriate regulatory approach . . . to ensure protection of public health and continued consumer confidence in the . . . food supply."[250]

C. *Aventis's Petition for a Tolerance of Twenty Parts Per Billion for StarLink in Foods*

• *April 23, 2001, EPA Announces Aventis' Petition for a Tolerance of twenty Parts Per Billion That Would Allow StarLink Corn in Processed Food:*

The Aventis petition proposed a tolerance for the Cry9C protein and genetic material necessary for its production of twenty parts per billion ("ppb") for corn used to make human food.[251] The proposed tolerance was conditioned on the testing of corn delivered to "dry mills" using a lateral flow strip test that has been approved by the Grain Inspection, Packers, and Stockyards Administration and Aventis with a level of detection of 20 ppb.[252] Note that the petition was for a tolerance, not an exemption as had been requested in earlier submissions.

Aventis believed the data it submitted indicated that screening and processing would minimize the potential for consumers to be exposed to any significant amounts of Cry9C protein. Earlier tests had indicated that *StarLink* corn which undergoes the wet-milling process contains essentially no residues of *StarLink*'s Cry9C protein in finished human food.[253] The testing of corn delivered to "dry mills" and the rejection

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249. On June 13, 2001, FDA reported on *StarLink*-related consumer complaints of allergic reactions. Though not necessarily conclusive, the analysis of consumer complaints by FDA did not indicate *StarLink* was present in the corn products consumed by those who had complained of adverse reactions after eating corn products. *See* A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE ENVIRONMENTAL PROTECTION AGENCY REGARDING: ASSESSMENT OF SCIENTIFIC INFORMATION CONCERNING STARLINK™ CORN, FIFRA SCIENTIFIC ADVISORY PANEL, SAP REPORT NO. 2000-06 (Dec. 1, 2000) *available at* http://www.epa.gov/scipoly/sap/2000/november/one.pdf (last visited Feb. 2, 2002); *see also* CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FDA, FDA EVALUATION OF CONSUMER COMPLAINTS LINKED TO FOODS ALLEGEDLY CONTAINING STARLINK™ CORN (June 13, 2001), *at* http://www.epa.gov/scipoly/sap/2001/july/fda.pdf (last visited Apr. 6, 2002).

250. Press Release, EPA, Advisory Panel Report Assesses Scientific Information Concerning StarLink™ Corn (Dec. 5, 2000) *at* http://www.epa.gov/scipoly/sap/2000/november/starlinkpress.pdf (last visited Apr. 6, 2002).

251. *See id. available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

252. *See id. available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

253. *See* U.S. Environmental Protection Agency Office of Pesticide Programs, White Paper on the Possible Presence of Cry9C Protein in Processed Human Foods Made from Food Fractions Produced through the Wet Milling of Corn (Draft), *at* http://www.epa.gov/pesticides/biopesticides/otherdocs/wetmill18.PDF (last visited May 1, 2002) (On

of shipments containing more than twenty ppb Cry9C would further limit the amount of Cry9C contained in human foods.[254] According to Aventis, even if all corn used for foods contained twenty ppb Cry9C and even if Cry9C were an allergen, the highest consumer of corn products would not encounter enough Cry9C to experience either sensitization or allergic reaction.[255] Aventis indicated that small amounts of Cry9C remain widely dispersed at very low levels throughout the corn supply.[256] Although likely to diminish over time, traces of Cry9C are likely to persist in the human food supply for an indefinite period.[257]

Aventis argued that the additional data supported a determination that the proposed twenty ppb tolerance satisfies the "reasonable certainty of no harm" standard required by the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act.[258]

- *June 13, 2001, EPA Announces SAP Meeting to Be Held July 17 and 18.*[259]

The SAP meeting was to assess additional scientific information concerning *StarLink* corn.[260] The SAP would review the scientific data in the Aventis petition for a tolerance for Cry9C protein of twenty ppb in corn grain, EPA's paper on the possible presence of Cry9C protein in processed human foods from wet milling of corn, the work the United States Department of Agriculture and Aventis Crop Sciences have done to reduce the amount of *StarLink* corn going into the food supply, validation of new detection methods for Cry9C protein in finished foods, and the Food and Drug Administration and Centers for Disease Control and Prevention's efforts to develop a

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March 7, 2001, EPA released for public and scientific peer review a draft paper examining how food processing affects levels of the *StarLink* protein in finished food. The draft document explained that *StarLink* corn which undergoes the wet-milling process contains essentially no residues of *StarLink*'s Cry9C protein in finished human food. In contrast, food products from the dry milling process do contain the protein).

254. *See* Aventis Crop Science USA LP, *Petition for Tolerance: Bacillus thuringiensis susp. tolworthi Cry9C Protein in or on the Raw Agricultural Commodity, Corn*, Vol. 1, 20, *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

255. *See* Aventis Crop Science USA LP, *Petition for Tolerance: Bacillus thuringiensis susp. tolworthi Cry9C Protein in or on the Raw Agricultural Commodity, Corn*, Vol. 1, 22, *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

256. *See id.* at 20 *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

257. *See id.* at 30 *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

258. *See id.* at 23, *available at* http://www.epa.gov/oppbppd1/biopesticides/otherdocs/stlink/stlinkdata.htm (last updated Apr. 23, 2001).

259. *See* FIFRA Scientific Advisory Panel; Notice of Public Meeting, 66 Fed. Reg. 31,915, 31,915 (June 13, 2001).

260. FIFRA Scientific Advisory Panel; Notice of Public Meeting, 66 Fed. Reg. at 31,915.

test method for blood serum from individuals who reported having allergic type responses after eating foods containing corn.[261]

- *July 2, 2000, EPA Announces Its Assessment of Additional Scientific Information Related to Aventis's Petition for a Tolerance:*

In its assessment, EPA provided a brief summary of its review of the Aventis submission and other relevant information. EPA believed that the Aventis submission, taken with other information received from USDA, FDA, and the Centers for Disease Control and Prevention, supported the conclusion that exposure to Cry9C is significantly less than EPA estimated in its paper in November 2000. EPA also believed that the ongoing efforts of Aventis and others were greatly reducing and would essentially eliminate, by 2004 or 2005, the amount of inadvertent Cry9C in U.S. corn supplies.[262]

- *July 25, 2001, EPA's SAP Report Issued, SAP Did Not Agree on a Safe Threshold Below Which There Is Reasonable Scientific Certainty That No Allergic Reaction Could Occur:*

The Scientific Advisory Panel could not determine a threshold level of Cry9C where there would be a reasonable scientific certainty that exposure would not be harmful to public health. The panel noted that no reliable data is available on threshold levels of isolated food proteins for inducing allergic response in highly sensitive individuals. Thus, the Panel concluded, based on a reasonable scientific certainty, there is no identifiable maximum level of Cry9C that can be suggested that would not provoke an allergic response and thus would not be harmful to the public.[263]

Since receiving the SAP report, EPA has not established a tolerance for *StarLink*'s plant-incorporated protectant. Thus, there remains a zero tolerance for the presence of Cry9C protein in human food. Regarding *cry9C* DNA, it would be exempted from the requirement of a tolerance, along with the DNA of other plant-incorporated protectants.

What about the fate of other genetically engineered *Bt* corn varieties that were originally approved by EPA for both feed and food uses? Coincidentally, the plant-incorporated protectants produced in *Bt* corn varieties like YieldGard™ and Hurculex™ were undergoing the pesticide re-registration process while the *StarLink* saga was unfolding. Although *StarLink*, with non-food use approval, was planted on less that one-half percent of the total U.S. corn acreage in 1999 and 2000,[264] other *Bt*

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261. FIFRA Scientific Advisory Panel; Notice of Public Meeting, 66 Fed. Reg. at 31,916.

262. *See* EPA, *Assessment of Additional Scientific Information Concerning StarLink Corn (July 2,2002), available at* http://www.epa.gov/scipoly/sap/2001/july/agencypositionpaper.pdf (last visited May 1, 2002).

263. *See* FIFRA SCIENTIFIC ADVISORY PANEL, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE ENVIRONMENTAL PROTECTION AGENCY REGARDING: ASSESSMENT OF ADDITIONAL SCIENTIFIC INFORMATION CONCERNING STARLINK™ CORN, SAP REPORT No. 2001-09 (July 25, 2001) *available at* http://www.epa.gov/scipoly/sap/2001/july/julyfinal.pdf (last visited Apr. 6, 2002).

264. *See* EPA, BIOPESTICIDES REGISTRATION ACTION DOCUMENT: BACILLUS THURIGIENSIS (Bt) PLANT-INCORPORATED PROTECTANTS I22 (Oct. 15, 2001), *available at*

corn varieties approved for both feed and food use were being planted on about 25% of U.S. corn acreage.[265] The reassessment of plant-incorporated protectants in these *Bt* corn varieties was completed on October 15, 2001, and the "registrations are now set to expire automatically on October 15, 2008."[266] EPA conditioned the registrations on the submission of certain confirmative data regarding, for example, field impacts of the *Bt* pesticidal proteins on non-target species and sampling to determine whether the non-Bt refuge requirements were actually being followed by farmers.[267]

V. ASSESSING STRENGTHS AND WEAKNESSES AND MAKING ADJUSTMENTS IN THE U.S. BIOTECHNOLOGY REGULATORY SYSTEM

As the *StarLink* saga unfolded, several important assessments of the strengths and shortcomings of the regulatory system for biotechnology were reported or initiated. These assessments coupled with the experience gained from *StarLink* have led to some recommendations and adjustments in the U.S. system of biotechnology regulation. That process is likely to continue.

A. *Assessing Strengths and Weaknesses*

1. *FDA and Biotechnology in the Year 2000 and Beyond*

- *October 25, 1999, FDA Announced Public Meetings to Consider Biotechnology in the Year 2000 and Beyond:*

On October 25, 1999, FDA published its plans to conduct three public meetings to consider specific issues related to biotechnology. The issues focused on scientific and safety evaluation, labeling, and public information concerns related to foods derived from plants developed using bioengineering techniques, e.g., *StarLink*.[268] The meetings were held in Chicago, Washington, D.C., and Oakland

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http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_brad2/1%20overview.pdf (last visited May 1, 2002).

265. *See id. available at* http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_brad2/1%20overview.pdf (last visited May 1, 2002).

266. *Id. available at* http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_brad2/1%20overview.pdf (last visited May 1, 2002).

267. *See id. available at* http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_brad2/1%20overview.pdf (last visited May 1, 2002).

268. *See* Meeting Notice, 64 Fed. Reg. 57,470, 57,470 (Oct. 25, 1999).

during November and December. Transcripts of these meetings are available on the FDA website.[269]

2. *National Research Council Assesses Strengths and Weaknesses of U.S. Regulatory System for Genetically Modified Pest-Protected Plants*

During the year 2000, the National Academy of Sciences' National Research Council ("NRC") issued a report titled *Genetically Modified Pest-Protected Plants: Science and Regulation.* In its executive summary, the NRC observed that the United States biotech regulatory system had been operating effectively for over a decade but that improvements could be made. [270] In Chapter four: *Strengths and Weaknesses of the Current Regulatory Framework,* the NRC made seventeen recommendations, including the following:

> EPA's rule and preamble should clearly restate the agency's position that genetically modified pest-protected plants (that is, plants modified by either transgenic or conventional techniques) are not subject to regulation as pesticides. EPA must remain sensitive to the erroneous perception that plants are being regulated as pesticides.[271]
>
> EPA and FDA [should] develop a memorandum of understanding (MOU) that establishes a process to ensure a timely exchange of information on plant-expressed pesticidal substances that are potential food allergens. The MOU should articulate a process under which the agencies can regulate potential food allergens in a consistent fashion– by EPA through tolerance setting and by FDA through food labeling.[272]
>
> FDA should put a high priority on finalizing and releasing preliminary guidance on the assessment of potential food allergens, while cautioning that further research is needed in this area.[273]

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269. *See* U.S. FOOD AND DRUG ADMINISTRATION, BIOENGINEERED FOODS, *at* http://www.fda.gov/oc/biotech/default.htm (last modified Jan. 22, 2001).

270. *See* NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 15 (2000), *at* http://books.nap.edu/catalog/9795.html (last visited Apr. 6, 2002).

271. NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 152 (2000), *available at* http://books.nap.edu/catalog/9795.html (last visited Apr. 6, 2002).

272. NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 163 (2000), *available at* http://books.nap.edu/catalog/9795.html (last visited Apr. 6, 2002).

273. NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 169 (2000), *available at* http://books.nap.edu/catalog/9795.html (last visited Apr. 6, 2002); *see also* COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY, ISSUE PAPER NO. 19, EVALUATION OF THE U.S. REGULATORY PROCESS FOR CROPS DEVELOPED THROUGH BIOTECHNOLOGY (2001), *available at* http://www.cast-science.org/pubs/cropregulation.pdf (visited May 1, 2002). This report describes the regulatory system for agricultural biotechnology and offers recommendations for

3. *Initiating the National Academy of Sciences Examination of USDA Oversight of Transgenic plants*

In January 2000, USDA asked the National Academy of Sciences (NAS) to examine the scientific basis underlying USDA regulation of transgenic plants. The Committee on Agricultural Biotechnology, Health, and the Environment of the National Research Council (the operating arm of NAS) created a special committee to review the scientific basis and operation of APHIS's oversight of environmental issues related to current and future transgenic plants and their products. The report from this study was published early in 2002 and contains a number of important findings and recommendations.[274]

4. *The Pew Initiative on Food and Biotechnology*

The Pew Initiative on Food and Biotechnology intends to produce reports and sponsor workshops and conferences to showcase the diverse, expert points of view on topics relevant to the agricultural biotechnology debate.[275] The goal is to encourage debate and dialogue about the scientific, economic, marketing, and regulatory issues relevant to agricultural biotechnology.[276]

An early report of the Pew Initiative on Food and Biotechnology is titled "The *StarLink* Case: Issues for the Future."[277] Noting that the *StarLink* saga is helpful in identifying important issues facing the regulatory system for agricultural

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improved regulation:

1. Retain the current case-by-case safety assessment approach and continue to emphasize regulatory conditions carefully tailored to address risks identified for individual biotechnology-derived plant products.
2. Finalize the FDA's current proposal for a mandatory, premarket notification in lieu of the present policy of voluntary consultation for all food products of agricultural biotechnology.
3. Provide the public with rapid, comprehensive accessibility to applications and supporting health and safety data submitted to regulatory agencies for biotechnology-derived products.
4. Issue approvals for both food and feed use for crops that are intended to enter commodity streams.
5. Provide the additional resources sorely needed for key regulatory review functions. *See id.*

274. *See* NATIONAL RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION (2002), *available at* http://www.nap.edu/catalog/10258.html (last visited May 1, 2002).

275. *See* Pew Initiative on Food and Biotechnology, *About the Pew Initiative on Food and Biotechnology: Mission Statement, at* http://pewagbiotech.org/about (last visited Feb. 2, 2002).

276. *See* Pew Initiative on Food and Biotechnology, *About the Pew Initiative on Food and Biotechnology: Mission Statement, at* http://pewagbiotech.org/about (last visited Feb. 2, 2002).

277. *See* MICHAEL R. TAYLOR & JODY S. TICK, THE STARLINK™ CASE: ISSUES FOR THE FUTURE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY (Oct. 2001), *available at* http://www.rff.org/disc_papers/PDF_files/0149StarLink_Final.pdf (last visited Apr. 6, 2002).

biotechnology, this report identifies thirteen such issues.[278] Among these are what evidence should be required to resolve allergenicity questions in genetically engineered proteins, whether various regulatory agencies have the necessary legal authority to enforce use restrictions (such as refuge requirements to combat pesticide resistance in insects or buffer requirements to manage pollen drift), and whether the U.S. system for biotechnology is properly organized.[279]

B. *Post-StarLink Adjustments in the Regulatory System for Agricultural Biotechnology—The Early Steps*

1. *EPA and Split Approvals (Registering a Plant-Incorporated Protectant for Feed Use Only)*

On March 7, 2001, the U.S. Environmental Protection Agency assured the public that the type of split pesticide registration, which approved *StarLink* to be used for animal feed but not for human food, would no longer be considered a regulatory option for products of biotechnology.[280]

2. *EPA and the Issue of Whether the DNA of All Plant-incorporated Protectants, StarLink's Cry9C DNA Included, Should Have An Exemption From the Requirement of a Tolerance*

- *July 19, 2001, EPA Publishes Final Rule Exempting the DNA Of All Plant Incorporated Protectants:*

In this final rule published July 19, 2001, EPA exempts residues of nucleic acids that are part of a plant-incorporated protectant (e.g., DNA from *StarLink* corn) from the FFDCA requirement of a tolerance.[281] EPA observed that nucleic acids are present throughout all forms of life, "have always been present in human and domestic animal food and are not known to cause any adverse health effects when consumed as part of food."[282] Thus, there is a reasonable certainty that "no harm will

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278. *See id.*

279. *See id.*

280. *See* Press Release, Dave Deegan & Martha Casey, EPA, EPA Releases Draft Report on StarLink Corn (Mar. 7, 2001), *available at* http://yosemite.epa.gov/opa/admpress.nsf/b1ab9f485b098972852562e7004dc686/cd90138019732598852 56a0800710574?OpenDocument (last visited May 3, 2002).

281. *See* Exemption from the Requirement of A Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Part of Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,817, 37,817 (July 19, 2001) (to be codified at 40 C.F.R. pt. 174).

282. *See* Exemption from the Requirement of A Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Part of Plant-Incorporated Protectants (Formerly

result from aggregate exposure to residues of nucleic acids that are part of a plant-incorporated protectant."[283]

3. EPA and Increased Monitoring of Conditions Imposed in a Pesticide Registration

StarLink's pesticide registration included two very important conditions: (1) that *StarLink* and buffer corn grown within 660 feet would remain in feed and non-food industrial uses only, and (2) that fields of *StarLink* would have non-Bt refuges of at least 20% to help manage the potential development of insect resistance to *StarLink's* pesticidal protein.[284] In the aftermath of the *StarLink* saga, it was apparent that additional post-approval monitoring might be needed to assure that such requirements would actually be communicated to growers and carried out at the farm level. Monitoring for the planting of non-Bt insect refuges was especially important as the EPA considered whether to reissue pesticide registrations for other Bt crop varieties.

On October 15, 2001, when the EPA extended the registrations of five Bt corn products (not *StarLink*) an additonal seven years, EPA included new requirements for companies marketing Bt corn. Such companies are now required to (1) actually secure the grower's signature on grower agreements prior to receipt of any seed, (2) make the grower agreements available to EPA, and (3) hire an independent third party to actually survey growers and identify the extent to which the refuge requirements are being implemented at the farm level.[285]

4. *FDA and Foods Derived from Genetically Engineered Crops*

• *January 17, 2001, FDA Proposes Mandatory Rules that Would Tighten Oversight of Bioengineered Foods:*

In a May 3, 2000 press release, "FDA announced plans to refine its regulatory approach regarding foods derived through the use of modern biotechnology," such as

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Plant-Pesticides), 66 Fed. Reg. at 37,817.

283. *See* Exemption from the Requirement of A Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Part of Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. at 37,817.

284. *See* discussion *supra*, at III.C.2 (*EPA Issues Amended Pesticide Registrations for 1999 and 2000 Crop Years, StarLink Still Limited to Non-food Uses).*

285. *See* U.S. EPA, *Biopesticides Registration Action Document: Bacillus thuringiensis Plant-Incorporated Protectants*, Part V (Bt Corn Confirmatory Data and Terms and conditions of the Amendment) (October 15, 2001), *available at* http://www.epa.gov/pesticides/biopesticides/reds/brad_bt_pip2.htm (last visited May 3, 2002); *see also* U.S. EPA, *Press Release: Biotechnology Corn Approved for Continued Use* (October 16, 2002), *available at* http://www.epa.gov/pesticides/biopesticides/ (last visited May 3, 2002).

foods like *StarLink*.[286] These initiatives stemmed "in part from input received during FDA's public outreach meetings held" in 1999.[287] FDA announced it would "publish a proposed rule mandating that developers of bioengineered foods and animal feeds notify the agency when they intend to market such products."[288] FDA also announced it would "require that specific information be submitted to help determine whether the foods or animal feeds pose any potential safety, labeling or adulteration issues."[289]

Proposed mandatory rules for tightening FDA oversight of bioengineered foods were published January 17, 2001. The rules would require that manufacturers of plant-derived, bioengineered foods and animal feeds notify the FDA at least 120 days before the products are marketed. As part of the notification, the manufacturer would provide information showing that the foods or feeds are as safe as their conventional counterparts. In effect, the proposal addresses public concerns about the "voluntary" nature of consultations under FDA's 1992 policy statement, such as AgrEvo's 1998 voluntary consultations with FDA regarding the safety of *StarLink*. If the proposed rules were implemented, such consultations would be mandatory, and manufacturers would be required to submit safety and nutritional information to FDA. Also, under the proposed rules, the evaluation process would become more "transparent." Information submitted by manufacturers, as well as FDA responses, would be posted on the Internet or otherwise made more accessible.[290]

5. *FDA and Labeling Genetically Engineered Foods*

• *January 17, 2001, FDA Issues Draft Guidance on Voluntary Labeling, "Bioengineered" is OK but "GMO Free" is Not:*

In January 2001 FDA issued draft guidance on labeling intended to assist manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients.[291] The guidance will aid manufacturers in ensuring that their labeling is truthful and not misleading.[292] "The FDA views the terms 'derived through biotechnology' and 'bioengineered' as acceptable."[293] Examples of terms that are not acceptable are "GM free", "GMO", and "modified."[294]

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286. Press Release, U.S. Dept. of Health and Human Services, FDA to Strengthen Pre-market Review of Bioengineered Foods (May 3, 2000) *available at* http://vm.cfsan.fda.gov/~lrd/hhbioen2.html (last visited May 6, 2002).

287. *Id. available at* http://vm.cfsan.fda.gov/~lrd/hhbioen2.html (last visited May 6, 2002).

288. *Id. available at* http://vm.cfsan.fda.gov/~lrd/hhbioen2.html (last visited May 6, 2002).

289. *Id. available at* http://vm.cfsan.fda.gov/~lrd/hhbioen2.html (last visited May 6, 2002).

290. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4723 (Jan. 18, 2001). *See also* Press Release, *supra* note 286, *available at* http://vm.cfsan.fda.gov/~lrd/hhbioen3.html (last visited Feb. 2, 2002).

291. *See* Press Release, *supra* note 286, *available at* http://vm.cfsan.fda.gov/~lrd/hhbioen3.html (last visited Feb. 2, 2002).

292. *See id. available at* http://vm.cfsan.fda.gov/~lrd/hhbioen3.html (last visited Feb. 2, 2002).

293. *Id. available at* http://vm.cfsan.fda.gov/~lrd/hhbioen3.html (last visited Feb. 2, 2002).

294. *See id. at* http://vm.cfsan.fda.gov/~lrd/hhbioen3.html (last visited Feb. 2, 2002).

"This draft guidance represents FDA's current thinking on voluntary labeling of foods indicating whether foods have or have not been developed using bioengineering."[295] "It does not create or confer any rights for or on any person and does not operate to bind FDA or the public."[296]

VI. SUMMARY AND PRELIMINARY LESSONS FROM THE *STARLINK* SAGA

This case study has provided an extensive review of the pre-*StarLink* evolution of the U.S. regulatory system for biotechnology and how that system, particularly the regulatory oversight of APHIS, FDA, and EPA, was applied to *StarLink*. It has also described the significant efforts of the regulatory system, Aventis, other government agencies, and the grain industry to address the problems associated with the September 2000 discovery of *StarLink* in taco shells and other foods. This case study represents an effort to mold information available from three regulatory agencies and other sources into one, interconnected story of *StarLink*'s regulation.

There are a few lessons already apparent from the *StarLink* saga. Twelve of these are briefly noted below:

Lesson 1: There are numerous stages at which the U.S. regulatory system for agricultural biotechnology assures that transgenic products like *StarLink* are safe for people and the environment, but not all products of biotechnology are subject to all avenues of scrutiny. For example, *StarLink* was subject to regulatory oversight by USDA-APHIS, FDA, and EPA as it moved from greenhouses to field trials and as it was commercialized. However, other genetically engineered crops not containing a plant-incorporated protectant would not trigger the EPA oversight resulting from pesticide registration requirements and the need to secure a pesticide residue tolerance or exemption.

Lesson 2: Federal regulations are really the heart of the regulatory system for biotechnology. This reliance on regulations, rather than on detailed statutes, provides needed flexibility to adapt the regulatory system to changing circumstances and assures the public an opportunity to participate in the important rulemaking process.

Lesson 3: The U.S. biotechnology regulatory system is focused on issues of health and environmental safety, not on issues such as the impact of biotechnology on the structure of agriculture and the concentration of economic power, or the religious or ethical dimensions of moving genes among organisms that do not mate naturally.

Lesson 4: On its surface, the regulatory system focuses on the "products" of biotechnology, not the process. Nevertheless, the "process" of biotechnology is often important as the trigger for special regulatory oversight. For example, because

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295. *Id. available at* http://vm.cfsan.fda.gov/~lrd/hhbioen3.html (last visited Feb. 2, 2002).

296. Guidance For Industry Food and Drug Administration, *Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, at* http://www.cfsan.fda.gov/~dms/biolabgu.html (last visited Apr. 6, 2002).

StarLink was produced through genetic engineering, it was a "regulated article" in the eyes of APHIS. *StarLink*'s plant-incorporated protectant was regulated as a "chemical pesticide" by EPA because it was produced through genetic engineering, but new rules exempt such substances from regulation if they are derived through the process of conventional breeding.[297] In addition, proposed rules would require that FDA be notified and provided safety assessment data prior to the distribution of foods derived from bioengineered plants.[298]

Lesson 5: The current U.S. grain marketing system has difficulty keeping a particular crop variety in "feed only" marketing channels, at least when the crop is planted on a rather large scale. Thus, as a general rule, there should be no split use approvals of transgenic crop varieties, such as *StarLink*, that will be grown on a large scale until there is better infrastructure for assuring that "feed only" products remain exclusively in "feed only" marketing channels.

Lesson 6: In retrospect, it was unwise for Aventis to request the split use approval of *StarLink*, and it was unwise for the EPA to register *StarLink* for feed use only unless food safety assessments also justified establishing a tolerance for traces of adventitious Cry9C protein in food products.

Lesson 7: The approval of *StarLink* for feed use only, and its subsequent discovery in food channels, has had significant economic consequences, but there is no documented evidence that any person has been hurt by the presence of *StarLink* in human food.

Lesson 8: Although the U.S. regulatory system for biotechnology relies on a mosaic of statutes originally enacted before the age of genetic engineering,[299] the years since 1986 have provided some opportunity to amend, consolidate, or replace the various acts forming the patchwork. For example, during the period when *StarLink* was being developed and commercialized, the Food Quality Protection Act amended both FFDCA and FIFRA, and the newly enacted Plant Protection Act superseded both the Plant Pest Act and the Plant Quarantine Act. Nevertheless, relying on the mosaic of laws can have unusual consequences. For example, because of *StarLink*'s pesticidal properties EPA became the key regulatory agency for *StarLink*, even when the key regulatory issue was allergenicity —a food safety issue where the FDA would be the key agency if the protein were not pesticidal. The corollary is that EPA may have no jurisdiction over a non-pesticidal bioengineered crop with potential for environmental consequences (unless EPA more aggressively asserts jurisdiction under the Toxic Substances Control Act).

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297. *See* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772, 37,772 (July 19, 2002) (to be codified at 40 C.F.R. pt. 152, 174).

298. *See* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. at 37,775.

299. *See* John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 823, 869 (2001).

Lesson 9: The transparency of the U.S. regulatory process, and the perception that the actions of specific agencies represent a truly coordinated approach to the regulation of biotechnology, would be enhanced by greater interagency efforts to link or otherwise coordinate the public information available on agency websites. For example, this paper has explained the contribution of APHIS, FDA, and EPA to that coordinated regulatory effort; the paper has also demonstrated that much *StarLink*-related information is available to the public from the websites of each agency. However, the story of *StarLink's* regulation by a coordinated "U.S. regulatory system" was very difficult to assemble because the wealth of information available from each agency was not linked, nor was there one "handle" for accessing the information.[300] The same would presumably be true for any other transgenic product that a consumer wanted to investigate.

Lesson 10: Because civil liability costs can be staggering, a company has a powerful incentive to comply with the conditions imposed by a regulatory agency when the transgenic product is approved, conditions such as keeping the product out of export or food marketing channels.

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300. APHIS information about its Determination of Nonregulated Status (and its Environmental Assessment concerning that action) is available at http://www.aphis.usda.gov/biotech/dec_docs/. However, accessing this information required one to know the Petition number (Petition No. 97-265-01). The word *StarLink* was not a useful "handle" in accessing that info. Similarly, *StarLink* was not a good handle for accessing field trials information at http://www.isb.vt.edu/cfdocs/fieldtests1.cfm. To access that information, one needed to employ the following criteria: Organism - CORN; Institution - PLANT GENETICS SYSTEMS; Phenotype - LEPIDOPTERON RESISTANCE. The key to accessing FDA information at http://vm.cfsan.fda.gov/~lrd/biocon.html was to know the BFN No. -- BFN No. 41 for StarLink. The word *StarLink*, by itself, was not a good handle for accessing the FDA data. Regarding EPA's regulation of StarLink's pesticidal protein, sometimes the key for getting data was to search for *StarLink*; other times, the key was Cry 9C or Bacillus thuringiensis, etc. There was no one website linking all the regulatory activity of all the agencies that participated in the coordinated regulation of *StarLink*. An analogy may help to illustrate the point being made by the author. Under the Coordinated Framework, the U.S. regulatory system for biotechnology fielded a team of three agencies, APHIS, FDA, and EPA to regulate a particular product -- StarLink. But if one wishes to analyze how the team played in this regulatory effort (or how the product fared as it was subjected to regulation by this regulatory team), one doesn't find the game film. One can find three films – each highlighting the role of one agency-player; but even assembling the three films for sequential viewing is difficult. This is because these films are not cataloged in ways that link the efforts of the three players (or the comprehensive, sequential regulatory hurdles that this particular transgenic product had to surmount as it was released into the environment and ultimately approved as a commercial product). Would it be desirable to routinely produce "game films" concerning regulatory approval of biotechnology product? If so, who is best positioned to assemble all the data? Might it be the lead agency in the regulatory effort, or the company hoping to commercialize the product? Would such an effort be difficult? What might its benefits be? Would the benefits include greater transparency concerning the coordinated regulatory effort, greater consumer confidence in the regulatory system, and perhaps greater effectiveness in the regulatory effort (because, in developing the "game film," the players actually function in a more integrated and coordinated way)?

Lesson 11: When transgenic products are approved subject to conditions imposed by a regulatory agency, the agency may need to take additional steps to assure that the conditions are actually being met post-approval. If, for example, the approval is conditioned on farmers acting in a particular way (e.g., keeping a transgenic crop out of food/export channels, or planting insect refuges as part of an insect resistance management plan), the agency may need to develop effective post-approval monitoring strategies. Such action will complement the incentive created by civil liability risks, and could give the public greater confidence in the regulatory system.

Lesson 12: The regulatory system for biotechnology is dynamic and continues to evolve. An early step in the evolutionary process was resolving what regulatory oversight should apply to research in the laboratory or greenhouse. A subsequent major step involved how to regulate field trials or other releases of genetically engineered organisms, and how to coordinate the oversight of multiple regulatory agencies. More recently the regulatory system has encountered different challenges, including unresolved *StarLink* issues, such as how to deal with the potential allergenicity of a novel protein entering the food chain. The evolution of the regulatory system continues, fueled in part by the lessons of *StarLink* and the interest it has spawned.

Today, in the wake of extensive regulatory oversight by three federal agencies, the recall of various food products containing *StarLink*, the cancellation of *StarLink*'s pesticide registration, the expenditure of millions of dollars by Aventis in buying corn containing Cry9C protein and channeling it into non-food uses, continuing scientific review and debate regarding issues of allergenicity, the filing of numerous lawsuits alleging *StarLink*-related damages to corn producers and consumers, and newly initiated assessments of the regulatory system, the *StarLink* saga has become an important milestone in the evolution of U.S. regulatory policy toward biotechnology. The *StarLink* saga, including contemporaneous assessments of the regulatory process, has already resulted in some changes in the regulatory system for biotechnology. *StarLink*'s impact will continue to unfold as new insights are gleaned from the saga, and as these insights are transformed into further improvements in the regulatory system. It is hoped that this case study, one step in the assessment process trailing the *StarLink* saga, will contribute to the progressive evolution of U.S. regulatory policy.