

The StarLink Case: Issues for the Future

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Abstract

The disclosure in September 2000 that StarLink™ corn had been found in the human food supply put food biotechnology in the public spotlight and caused concern among consumers and food system stakeholders alike that a product approved only for animal use could find its way to grocery shelves. The StarLink experience raises a number of issues that deserve study concerning the current regulatory system and public policies affecting genetically modified foods. The issues include how to manage allergenicity issues posed by biotech foods at the approval stage. Most of the issues, however, involve post-approval control of staple food crops that have been genetically modified. It may be increasingly important in the future to maintain the identity of genetically modified crops and segregate them from conventional ones, yet neither the grain trading system nor the government regulatory system were designed to ensure this. This paper is the first step in a case study that Resources for the Future is conducting for the Pew Initiative on Food and Biotechnology to identify and analyze the regulatory and public policy issues raised by the StarLink episode. In this paper, we pose questions concerning the adequacy of current legal authority, regulatory procedures, and institutional arrangements for post-approval control of biotech foods that we intend to analyze in depth during the balance of the study based on interviews and other research. We welcome comment on this paper and the planned study.

Key Words: agricultural biotechnology, food allergens, food regulation, food safety, genetically modified food, grain trading system, StarLink™ corn.

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Background and Purpose

The discovery of StarLink™ corn in human food was a seminal event in the evolving response of the American public to agricultural biotechnology. StarLink is the trademark for a variety of corn that has been genetically modified to produce its own pesticidal protein, Cry9C. This protein, like other Bt toxins,¹ is effective in controlling certain insects and thus can substitute for chemical insecticidal sprays. Because of unresolved questions about the potential human allergenicity of the Cry9C protein, the Environmental Protection Agency (EPA) approved StarLink in 1998 for use only in animal feed and other industrial, nonfood uses. Nevertheless, in September 2000, StarLink corn was found in the human food supply, initially in corn tortillas but later in other processed foods. This event and its aftermath received extensive publicity and heightened public awareness of the presence of biotechnology-derived foods in the American food supply.

These events also focused attention in the press and public on how biotech foods are regulated. The presence of StarLink in the human food supply was unlawful. It prompted a swift government regulatory response and the mobilization of an intensive effort by government and industry to contain the StarLink corn and prevent its further infiltration of the human food supply. This was important for legal compliance, public health, and economic reasons. Although it is still unresolved whether the Cry9C protein is a human allergen, everyone involved in the matter agreed that it was essential to gain control of StarLink and restrict it to its lawful uses in order to maintain consumer confidence and the confidence of the grain trade in the safety and integrity of the American food supply. All the players—EPA, the Food and Drug Administration (FDA), the Department of Agriculture (USDA), Aventis CropScience (StarLink's owner), the grain trading industry, and the food industry—actively cooperated to contain StarLink.

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¹ Bt toxins are produced naturally by the bacterium *Bacillus thuringiensis* and also by plants that have been genetically modified to contain the toxin-expressing gene from the bacterium.

Many observers, however, immediately questioned EPA's original decision to approve StarLink corn solely for animal use, citing the lack of an established market infrastructure for maintaining the identity of specific lots of corn and segregating them from others. Corn is traded as a commodity, and commingling is commonplace. In response to this concern, EPA has already said that it would no longer grant "split" approvals for genetically modified crops. Animal feed uses for crops like corn will be approved only if the human use is also approved. This is an important regulatory lesson from the StarLink experience.

StarLink raises a number of other regulatory issues at both the approval and the postapproval stages of the regulatory process. Though interesting as a *sui generis* exercise in crisis management, StarLink is fundamentally more important as a harbinger of issues that EPA, FDA, and USDA will be facing for years to come in their routine oversight of biotech foods, especially in the area of ensuring postapproval compliance with regulatory requirements. The purpose of this discussion paper is to identify some of those issues.

This paper is the first step in a case study of the StarLink episode that Resources for the Future (RFF) is conducting for the Pew Initiative on Food and Biotechnology. The next step will be to analyze the regulatory and policy issues raised by StarLink and how they might be addressed. The study will culminate in a paper that is intended to inform the Pew Initiative's stakeholder consensus process, as well as the public debate about how biotech foods should be regulated.

A chronology of the StarLink case, highlighting the events that help frame the regulatory and policy issues, is given in the Appendix. We have prepared the paper to define, at least preliminarily, the scope of our study and to stimulate thinking and discussion, especially among participants in the StarLink episode and other experts with whom we will seek interviews. We welcome comments from all readers.

The Regulatory and Technology Context

The regulatory and public policy issues identified in this paper arise in the context of the current regulatory framework for agricultural biotechnology and the special regulatory challenges posed by the nature of the technology. The regulatory and technology context will be analyzed in some depth during the course of the study, but they are summarized briefly here.

Regulatory Context

For purposes of this paper and the larger study, we consider regulatory oversight of agricultural biotechnology to have three broad purposes: (1) to protect health and the environment, (2) to ensure compliance with regulatory requirements, whatever their purpose, and (3) to provide a basis for public confidence in the safety of the technology. The third purpose is not explicitly within the charge of the regulatory system. It is included here, however, because it is what many consumers and commercial stakeholders want from the system so that they can decide whether to accept biotechnology on the basis of its costs, benefits, or other considerations they deem relevant, not on the basis of unresolved safety concerns. One issue our StarLink case study will address is how this “public confidence” purpose should influence regulatory standards and procedures and the allocation of resources to the regulatory effort.

StarLink corn was subject to premarket oversight by three agencies—USDA, EPA, and FDA. Under the Plant Protection Act, USDA evaluates whether a new, genetically modified crop poses a threat to existing crops and authorizes commercialization with or without continuing oversight, depending on the potential risk. In the case of crops modified to produce a pesticidal substance, EPA registers the crop (i.e., authorizes its use under specified conditions) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) if it finds that the crop causes no unreasonable adverse effects on the environment. EPA evaluates the safety of the pesticidal substance in food under the Federal Food, Drug, and Cosmetic Act (FFDCA) and allows its presence in food if it finds there is a reasonable certainty that no harm will result from consumption. FDA, also acting under FFDCA, reviews the assessment made by the new crop’s owner of the safety of its nonpesticidal components and informs the owner if it has any safety-related questions or objections.

Responsibility for post-approval oversight is divided between EPA and FDA. EPA is responsible for ensuring that registrants and growers of a genetically modified crop market and use the crop in accordance with any conditions imposed by EPA at the time of registration. In the case of StarLink, this meant ensuring that the product was promoted by Aventis and its distributors and used by farmers only for animal feed. FDA is responsible for enforcing the use restrictions on food in commerce. In the case of StarLink, this meant taking regulatory action, as needed, to exclude StarLink corn from the human food supply.

Technology Context

For regulatory purposes, what makes biotech crops different from conventional crops and chemicals used to produce and process food? The Coordinated Framework for the Regulation of Biotechnology, issued in 1986 by the White House Office of Science and Technology Policy,² was based on the assumption that there were no fundamental differences and thus that the technology could be regulated effectively within existing statutes and frameworks. At a conceptual level, this assumption may make sense. In the case of StarLink corn, the Bt toxin expressed in the plant is a pesticide whose safety for health and the environment can be assessed and regulated under FIFRA and FFDCA.

At a practical level, however, there are important differences for regulatory purposes between biotech crops and conventional crops and chemicals—differences that are directly relevant to the StarLink case and, even more importantly, to future applications of agricultural biotechnology. They relate primarily to the practical problem of postapproval control.

One of the core concepts underlying the regulation of chemical pesticides and other conventional chemicals used in food production and processing is that these chemicals are evaluated and approved for specific uses that EPA and FDA have found to meet the applicable safety standard. This regulatory approach implies a need to control how the chemical is used by farmers and processors so that it enters the environment and food chain only under those circumstances that have been found safe. This mode of regulation also implies the ability of regulatory agencies to verify compliance with the approved conditions of use and to take effective action in the case of violations.

In the case of chemical pesticides, we have well-established tools for maintaining this control and verifying compliance. EPA prescribes in the product label how the farmer can use the chemical and generally sets a quantitative tolerance level that, based on extensive testing, reflects the maximum amount of residue that should be present in the food if the chemical has been used safely and in accordance with the label. The entry of the chemical into the environment and food supply is then controlled directly by the farmer, who has legal accountability to EPA. FDA can test food to determine whether the tolerance has been exceeded, and it can remove from commerce commodities or food products containing violative residues.

² 51 Fed. Reg. 23302 (June 26, 1986).

FDA has an established sampling and testing program for conventional pesticide residues in food, and this approach to control is well-accepted among U.S. trading partners.

In the case of crops genetically modified to contain the Bt toxin, such as StarLink, practical control of how the pesticide enters the environment and food supply presents new challenges. The pesticide is not applied externally to the plant by a farmer who is legally obligated to follow a label, but rather is incorporated into the plant itself and becomes an inherent part of a living organism and, subsequently, a commodity grain. This raises the possibility that, through the spread of pollen to nearby fields, the pesticidal trait might unintentionally be transferred (or “outcrossed”) to other corn varieties for which it is not approved and whose owner may be unaware it happened, as may have occurred in the case of StarLink (see Appendix, November 21, 2000; July 4, 2001). Outcrossing of pesticidal traits may also have environmental consequences that merit control of how the biotech crop is used in the field. For both farmers and regulators, the outcrossing potential of plants with pesticidal traits presents control challenges that differ from those posed by conventional chemical pesticides.

Incorporation of the pesticidal trait into a commodity grain also poses new control issues because of extensive commingling of corn throughout the trading chain. First, the fact that the Bt toxin is produced within the plant means that it is more likely to persist throughout the food chain simply because it lacks the tendency of externally applied chemicals to be washed or worn off or to degrade, to at least some extent. Second, the Bt crop is likely to end up being mixed with other varieties. Farmers, who may be planting more than one variety of corn, are not generally accustomed to segregating one portion of their corn crop from another for regulatory purposes. Moreover, the farmer, who is the one person in the chain of distribution who knows for sure what he or she planted and under what regulatory restrictions, controls only his or her practices and the first sale of the crop. After that, the grain trade is organized in a way that is likely to result in the commingling of corn, without regard to regulatory distinctions among various lots. Although we have well-established analytical methods and other measures for ensuring that violative levels of conventional chemical pesticides do not reach consumers, the StarLink case suggests we may lack adequate tools to provide similar controls for biotech crops.

The ability to control how biotech crops are grown in the field and distributed through the food chain is likely to become an even more compelling issue in the future. This is due in part to the divergence in regulatory approaches and consumer acceptance of products between the United States and some of its trading partners, such as Europe and Japan. An increasing number of crops lawfully grown and sold here cannot be lawfully sold into some foreign markets. The

regulatory system and the marketplace need to be able to tell the difference and ensure that only products approved for sale in the receiving countries are exported there.

It also is the nature of the technology itself, however, and what it is capable of doing that will heighten the need for postapproval control. Scientists envision modifying plants to improve their nutritional profile, either by reducing nutrients consumers seek to avoid or adding nutrients consumers or some special subpopulation seek in greater amounts. In either case, preserving the identity of these crops will be important for regulatory compliance and commercial reasons. For producers to avoid unlawful misbranding of the product and realize its commercial value, consumers will have to be told in a verifiable way what they are getting.

Scientists also envision modifying crops to produce pharmaceutical or other substances having industrial, nonfood uses. At the approval stage, regulators will set the conditions under which such crops can be grown so that the trait for which the genetically modified crop is being grown does not inadvertently spread to other plants. Regulators will also resolve in the approval process whether any portion of crops used for these purposes can be used for human food or animal feed. It will then be essential that regulatory agencies have the tools to verify compliance with these controls and take effective action when there are violations.

The StarLink case involved loss of control of a commodity crop that had been modified for agronomic purposes. It teaches important lessons about managing such products. The proponents of agricultural biotechnology envision future applications that will add value to food for consumers and create completely new uses for traditional crops. The StarLink case suggests that if these benefits are to be realized in a way the public can accept, we must take a hard look at a wide range of issues, but particularly how we control the use of these crops following their approval.

Issues for the Future

With that context in mind, we sketch below some of the regulatory and public policy issues concerning agricultural biotechnology that are suggested by the StarLink case and that we plan to address in our case study. Most involve postapproval control of the technology, although the one specific health issue—the possible allergenicity of novel proteins—affects the regulatory process at the premarket testing and approval stage.

Allergenicity

- What evidence should be required to resolve whether a novel protein introduced through genetic modification or other means is nonallergenic?

Discussion: EPA concluded that the unresolved questions about the potential allergenicity of Cry9C precluded a finding that the substance was safe under the FFDCAs “reasonable certainty of no harm” safety standard for pesticides in food (see Appendix, December 21, 1999; December 1, 2000; July 25, 2001; July 27, 2001). This precautionary approach—not allowing new pesticide residues in food unless the sponsor has first demonstrated safety to EPA’s satisfaction—is what FFDCAs contemplates. It is unresolved, however, what tests and what quantity and quality of evidence, if any, can resolve allergenicity issues such as the one posed by StarLink. This is likely to be an important question because future applications of biotechnology are widely anticipated to result in the addition of novel proteins to food.

- Who is responsible for developing the scientific principles and generating the data required to resolve allergenicity issues?

Discussion: The legal burden of proof to demonstrate the safety of a novel protein is on the product’s sponsor, who must generate and submit the data required to satisfy the standard of reasonable certainty of no harm. The debate about allergenicity in the StarLink case suggests there is further work to be done to develop the scientific principles and test protocols that should guide the generation of product-specific data. The industry has a commercial interest in developing this science. The public, too, has an interest so that the regulatory agencies can make sound, science-based decisions that protect public health. It is unresolved who has responsibility for developing the necessary science and how the necessary public and private resources will be marshaled. Failure to develop this science could slow the commercial development of agricultural biotechnology.

Split Approvals

- Do EPA and FDA have the legal authority to deny a split approval when the safety standard for animal use of a novel protein has been satisfied?

Discussion: Ordinarily, when EPA and FDA consider a product for which approval has been sought solely for animal use, the agencies evaluate the product for that use only and approve or disapprove it on the basis of whether it meets the applicable standards governing the animal use, as in the case of StarLink corn. It is not unusual for EPA and FDA to approve

products solely for animal use, and neither FIFRA nor FFDCFA contain provisions that explicitly authorize denial of approval for animal use based on concerns about the adequacy of postapproval controls to keep a product out of the human food supply. Is there a need to clarify EPA's policy on split approvals for biotech crops and the policy's legal basis?

- To justify a split approval in a future case, what degree of assurance should exist that the product approved only for animal use can be kept out of the human food supply?

Discussion: There may be cases in which a split approval is sought and justified on scientific and economic grounds. For example, a product could involve adding a substance that is safe and valuable for animal nutrition but undesirable in human food. On what basis should a policy against split approvals be modified to allow such an animal product while excluding it from the human food supply?

Conditional Approvals to Increase Compliance with Use Restrictions

- Do EPA and FDA have legal authority to impose conditions on approvals to facilitate compliance with use restrictions?

Discussion: In the StarLink case, EPA conditioned registration on the agreement of the original registrant (Plant Genetic Systems) to obtain written agreements from farmers to use StarLink corn only for animal feed. Under FIFRA and FFDCFA, EPA and FDA routinely impose conditions on approvals of pesticides and food additives to ensure safe use. Do the agencies have adequate authority to condition approval on more active undertakings by the sponsor to ensure that the product is not put to unapproved uses? Can they condition approval on the existence of effective marketplace mechanisms to preserve the identity of lots and channel commodities to specific uses?

- Should EPA and FDA require, as a condition of approval, that every sponsor provide a practical analytical method that regulatory agencies can use to detect a genetically modified crop in the food supply?

Discussion: EPA normally requires that a method be available to enforce the tolerances (the legal limits) it sets for pesticide residues. Cry9C was exempted from the requirement of a tolerance, however, on the ground that a tolerance was not required to ensure the safety of the Bt toxin; thus EPA did not require that an analytical method be provided. When the press reported in September 2000 that StarLink had been found in human food, FDA had no method it could use immediately to verify this finding and conduct its own surveillance of the human food supply

for the unlawful presence of StarLink. It eventually developed a method with help from the sponsor of StarLink, Aventis CropScience. In light of StarLink, it is appropriate to consider whether EPA and FDA have the legal authority to require a method in every case and whether it would be good policy to do so.

Enforcement of Use Restrictions

- Do EPA, FDA, and the states have the legal authority they need to enforce use restrictions on the farm and throughout the food chain?

Discussion: Under FIFRA, states have the primary responsibility to enforce pesticide use restrictions, including those applicable to farmers, such as the restriction of StarLink's use to animal feed. FDA enforces EPA's pesticide tolerances and has jurisdiction to remove food from commerce if it contains an unapproved pesticide residue, food additive, or animal drug residue, except that the Food Safety and Inspection Service of USDA has jurisdiction over such substances in meat and poultry. The states have concurrent jurisdiction in these areas.

The enforcement authority of the many agencies involved varies, and there has been debate for some time about the adequacy of their authority in certain areas. The issues to be addressed include their authority to enter and inspect places where pesticides are used, require the maintenance and production of records relating to pesticide use and shipment of food products, detain violative products, and impose civil penalties on violators.

- Do EPA, FDA, and the states have the resources they need to enforce use restrictions on the farm and throughout the food chain?

Discussion: Enforcement of use restrictions for genetically modified food crops requires sufficient resources to conduct routine monitoring of usage practices, sample and test food for possible violations, investigate violations, and take enforcement action. EPA and the states have very limited and geographically variable resources for inspection, compliance, and laboratory efforts. FDA currently has no field resources for routine monitoring of biotech commodities and crops. There has been little public discussion of what constitutes an adequate level of effort to enforce use restrictions, the amount of money required to fund it, and the source of the money.

Role of Government on the Farm and Down the Food Chain

- As a matter of policy, what is the proper role of oversight and enforcement on the farm to ensure that biotech crops are planted in accordance with use restrictions and put only to lawful uses?

Discussion: EPA imposes planting restrictions on Bt-containing biotech crops to manage insect resistance, minimize impacts on nontarget species, and avoid environmentally harmful outcrossing. USDA has authority to impose restrictions on planting practices as needed to achieve the purposes of the Plant Protection Act. These restrictions, which obviously are meaningful only if observed, can impose economic costs on farmers that create pressure for noncompliance. Farmers, moreover, have traditionally resisted the presence of government inspectors on the farm to verify compliance. There is today little direct oversight of on-farm practices. Should there be more such oversight? How can it be done in a way that is acceptable to the agricultural community and feasible for the agencies?

- Beyond traditional regulation and enforcement, what role should government play in fostering market mechanisms that can segregate commodities and direct specific lots to designated uses?

Discussion: When commercial marketers of biotech crops and products have sufficient economic incentive to preserve the identity of specific lots and segregate them from others (such as to capture the value of a new consumer-oriented trait), they will presumably develop the necessary market infrastructure. Absent adequate economic incentives, such mechanisms may remain lacking, even if they are needed to meet domestic or international regulatory requirements, as in the case of StarLink. In light of the broad public interest in achieving regulatory compliance and maintaining public confidence in the safety and integrity of the food supply, what role should the government play in fostering development of market infrastructures for identity preservation and channeling of commodities? It could attempt to impose requirements through the regulatory process or simply encourage private sector efforts, perhaps through the collaborative involvement of USDA, including subsidies and technical assistance. The initial step might be to define the need for such market infrastructure and its feasibility.

Public Confidence and Economic Issues

- What is the proper role of the federal government in fostering public confidence in agricultural biotechnology?

Discussion: Maintaining public confidence in biotechnology and the safety of biotech foods is not one of the explicit charges given the regulatory agencies. The StarLink case demonstrated, however, that it is one of the demands placed on the agencies by many stakeholders, and it is clearly within the mandate of certain components of USDA, such as the Agricultural Marketing Service, the Foreign Agricultural Service (FAS), and the Grain Inspection, Packers and Stockyards Administration (GIPSA), which exist to advance the interests of the U.S. agricultural economy.

The regulatory agencies' core contribution to public confidence should be simply carrying out their environmental and food safety responsibilities competently. Should they also adopt regulatory policies and invest resources that may not be justified on safety grounds but that meet public expectations for the nature and intensity of government oversight of biotech foods?

USDA was pressed by the grain industry to intervene aggressively in the StarLink case to help minimize the sector's economic losses and ensure full recovery from Aventis CropScience (see Appendix, October 24, 2000; November 2, 2000). USDA offered to spend \$15 million to \$20 million to buy StarLink seed corn still in the hands of small dealers so that they would not sell it unlawfully (see Appendix, March 7, 2001). How far should USDA go in attempting to promote public confidence in the safety and integrity of the food supply?

- What is the proper role of the federal government in protecting the economic interests of American agriculture and technology providers, in both domestic and foreign markets?

Discussion: The economic interests of the private sector, in particular access to markets and public acceptance of products, can be substantially affected by public concerns about the safety of biotechnology and the effectiveness of government oversight. USDA went to considerable lengths to preserve U.S. export markets for corn in the face of concerns, especially in Japan and Korea, that unapproved StarLink corn might be exported. Preserving export markets is a legitimate role of government, but there is a need for greater clarity about the objectives and proper role of the government and the distinct roles to be played by the regulatory and promotional agencies.

Institutional Issues

- Is the government properly organized to manage and coordinate the activities of the many agencies involved in oversight of agricultural biotechnology?

Discussion: In addition to EPA, FDA, and USDA’s FAS, GIPSA, and Farm Service Agency, the State Department, the U.S. trade representative, and other White House staff offices played roles in managing the StarLink case. Day-to-day oversight of agricultural biotechnology also involves state agencies for agriculture, health, and the environment. Institutional complexity is built into the U.S. system of government, but the StarLink case suggests a need to examine whether the current institutional arrangements for biotechnology—including organizational structure, allocation of responsibilities, and cross-agency coordination—are meeting current and future needs.

Conclusion

The issues outlined here provide the starting point for RFF’s StarLink case study. We welcome comments and suggestions for other issues that we should address. Mike Taylor can be reached by e-mail at taylor@rff.org and by phone at 202-328-5066. Jody Tick can be reached at by e-mail at tick@rff.org and by phone at 202-328-5152.

Appendix

StarLink Corn: A Chronology of Events

On September 18, 2000, StarLink™ corn came sharply to public attention when the press reported that it had been found in the human food supply, despite having been approved by the Environmental Protection Agency (EPA) only for animal feed use. The subsequent efforts by the government and the food industry to manage this problem were highly publicized and elevated public awareness of the presence of biotech foods in the American food supply. The StarLink episode has led many to question the current regulatory system for genetically modified foods and call for policy change and strengthening of regulatory oversight.

Any attempt to draw lessons from StarLink about the need for and possible direction of regulatory change should be based on a complete picture of what happened, including the regulatory process that led to StarLink's approval, the efforts to contain the problem and limit its negative impact on the food chain, and the scientific review of the potential allergenicity of the Cry9C protein that is the active component of StarLink. The following chronology attempts to paint such a picture, at least in broad outline.

March 14, 1997: EPA issues an experimental use permit to Plant Genetic Systems (PGS) to test corn seeds containing the Cry9C protein on 3,305 acres in 28 states. (CRS Report 1/10/01)

April 4, 1997: PGS submits an application to EPA to register the Cry9C protein and the genetic material inserted in corn to produce it (cry9C DNA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The application requests that the Cry9C protein and cry9C DNA be registered for use in corn, without limitation on the corn's use in human food or animal feed. PGS simultaneously petitions EPA for an exemption from the requirement for a tolerance (legal residue limit) under the Federal Food, Drug, and Cosmetic Act (FFDCA) for the Cry9C protein and the cry9C gene.

August 8, 1997: EPA announces in the *Federal Register* the PGS application to register the Cry9C protein under FIFRA. (62 Fed. Reg. 42784)

September 19, 1997: EPA announces in the *Federal Register* the PGS petition for a full exemption from the requirement of a tolerance for Cry9C residues in or on all the raw agricultural commodities under FFDCA. (62 Fed. Reg. 49224)

November 26, 1997: EPA announces in the *Federal Register* the PGS request for a temporary “split” exemption from the requirement of a tolerance; this would allow the Cry9C protein to be present only in animal feed, based on unresolved questions about the human allergenicity of the protein. (62 Fed. Reg. 63168)

April 10, 1998: EPA issues a final rule establishing the temporary split tolerance exemption for Cry9C. (63 Fed. Reg. 17687)

May 12, 1998: EPA issues a registration for StarLink corn that limits its use to animal feed and nonfood industrial applications. This split registration is granted by EPA while more data are gathered to assess the potential allergenicity of the Cry9C protein. A condition of the registration is that PGS obtain signed agreements with growers that they will comply with the animal feed use restriction. (EPA Biopesticide Fact Sheet 03/01)

May 22, 1998: EPA publishes in the *Federal Register* a final rule granting a permanent split tolerance exemption for the Cry9C protein and cry9C DNA residues, allowing their use “only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.” (63 Fed. Reg. 28252)

October 1998: The registration of the Cry9C protein and its associated DNA is transferred from PGS to AgrEvo USA Company, which has bought the StarLink business from PGS.

November 1998: AgrEvo submits a new petition seeking to extend the tolerance exemption to all raw agricultural commodities.

April 7, 1999: EPA publishes in the *Federal Register* a notice announcing the filing of the AgrEvo tolerance exemption petition and seeking comment on the potential allergenicity of the Cry9C protein. This issue is raised because the Cry9C protein has been found in *in vitro* studies to have some of the characteristics of an allergen, including being heat resistant and potentially slow to digest—characteristics not possessed by other marketed Cry proteins. (64 Fed. Reg. 16965)

December 21, 1999: EPA publishes a notice in the *Federal Register* asking for scientific input and public comments on how to assess the potential allergenicity of Cry9C in establishing that the “reasonable certainty of no harm” safety standard for pesticide residues has been met. EPA wants this input before considering AgrEvo’s request for a full exemption under FFDCA. (64 Fed. Reg. 71452)

January 2000: A total of 33 StarLink hybrid varieties are available from 15 seed companies (Food Traceability Report, 2001).

February 29, 2000: A subpanel of Scientific Advisory Panel (SAP) of EPA is convened to define the issues and methods involved in assessing the allergenicity of Cry9C and to consider whether the Cry9C protein and other proteins having similar characteristics might be human allergens. (Meanwhile, Aventis has been formed by the merger of AgrEvo and Rhone-Poulenc Ag Company, and Aventis CropScience has assumed the FIFRA registration for StarLink corn.) (CRS Report 1/10/01)

April 5, 2000: The National Academy of Sciences (NAS) publishes a report initiated by its National Research Council addressing the health, environmental, and regulatory issues posed by genetically modified “pest-protected” plants, such as those modified to contain Cry9C and other Bt toxins. The report states that Cry9C raises concerns of allergenicity because of the protein’s relative stability in a simulated gastric environment. The NAS report advises EPA to improve testing for the human and environmental impacts of Bt crops and make the results of these tests, rather than just the agency’s evaluation, more available to the public. (NAS Report)

July 19, 2000: Genetically Engineered Food Alert (GEFA), a coalition of food safety and environmental organizations, announces a campaign “to take genetically engineered ingredients off American grocery shelves until they are fully tested and labeled” and calls specifically on the Campbell Soup Company to remove such ingredients from its products. (GEFA press release 7/19/00)

August 9, 2000: EPA announces new review processes for plant pesticide registrations, including Cry9C, in view of the NAS recommendations. (CRS Report 1/10/01)

September 18, 2000: The *Washington Post* reports that in tests conducted for the Genetically Engineered Food Alert, an independent laboratory (Genetic ID) has found traces of genetic material from StarLink corn in Kraft’s Taco Bell Home Originals brand taco shells in a metropolitan Washington, D.C. grocery store. The taco shells were manufactured in Mexico. Some government officials express skepticism about the testing process. Rep. Dennis J. Kucinich (D-Ohio) comments, “discovery of the unapproved corn shows that genetically engineered ingredients are not well regulated.” (*Washington Post* 9/18/00)

September 22, 2000: Kraft Foods recalls all taco shells sold nationwide in supermarkets under the Taco Bell brand after tests confirm they were made with StarLink corn. The nationwide recall covers Taco Bell packaged shells but not shells sold through Taco Bell restaurants, which use a different supplier. (*Chicago Tribune* 9/23/00)

Kraft's Taco Bell taco shells are made by chipmaker Sabritas (a unit of PepsiCo Inc.) at a plant in Mexicali, Mexico, with corn from the Dallas-based Azteca Milling plant in Plainview, Texas. (*Chicago Tribune* 9/23/00)

Azteca Milling says it buys corn only from farmers under contract to grow only varieties on a list issued by the company. No genetically modified corn is on the list. (*New York Times* 9/30/00)

Garst Seed Company is identified as the company that distributed StarLink seed. (*New York Times* 9/30/00)

September 26, 2000: Aventis announces that it told seed distributors to stop selling StarLink corn hybrids for the 2001 crop, as a way to minimize the chance that unapproved corn would enter the food supply. (*St. Louis Post-Dispatch* 9/27/00)

Sano Shimoda, president of BioScience Securities Inc., a brokerage, investment banking, and corporate advisory firm for industry sectors affected by agricultural biotechnology, says, "The taco shell incident illustrates the difficulty of keeping commodity grains separated for proper uses...Obviously the real world of agriculture created the problem...Right now it's almost impossible to track commodity grain through the entire processing chain." (*St. Louis Post Dispatch* 9/27/00)

Azteca Milling stops making and selling yellow flour, which accounted for 15% to 20% of its output, and says it will begin testing corn for presence of StarLink using a new test by Strategic Diagnostics. (*New York Times* 9/30/00)

September 27, 2000: GEFA writes to President Clinton criticizing the Food and Drug Administration (FDA) for inadequate oversight of biotech foods, including its lack of a method for detecting Cry9C in food, and calling for stronger premarket testing and postmarket oversight. (GEFA press release 9/27/00)

Environmentalists, food manufacturers, and biotech proponents call for an end to split registrations of genetically altered crops that have not been cleared for use in food. (*Los Angeles Times* 9/27/00)

EPA officials say they are considering ending the practice of granting partial, or split, crop approvals as part of a review of its policies for dealing with engineered crops.

EPA determines that licenses expiring the following year for eight genetically altered corn varieties will not be extended until EPA decides how to deal with relatively new types of

crops, according to Stephen Johnson, deputy assistant administrator, Office of Pesticides and Toxic Substances.

September 29, 2000: The U.S. Department of Agriculture (USDA) and Aventis begin taking steps to locate and direct all StarLink corn (and corn planted as a buffer around StarLink fields for resistance management purposes) to approved uses. Aventis informs growers of USDA's Corn Containment Program, under which the Commodity Credit Corporation will purchase StarLink and buffer corn at a price equal to the October 2, 2000, county price plus a \$.25 premium per bushel. Aventis will reimburse USDA for the full purchase price of the corn plus activities associated with storage, inspection, transportation, and auditing. (Aventis Petition for Tolerance)

October 1, 2000: The federal government's StarLink purchase program is estimated by industry experts to involve 45 million bushels of corn and cost approximately \$68 million. Securities analysts are confident that Taco Bell's core customers are unconcerned about StarLink and do not expect the incident to have a measurable effect on Taco Bell's sales. (*Chicago Tribune* 10/1/00)

October 4, 2000: ConAgra Foods recalls 12 cornmeal products by ConAgra Corn Processing. (FDA Enforcement Report 11/15/00)

October 6, 2000: USDA releases an alert reminding the grain trade that StarLink corn may not be lawfully sold for use in human food or for export.

October 12, 2000: The press reports that the Safeway supermarket chain has recalled its store-brand taco shells after GEFA found StarLink corn in them. The Safeway shells are produced by Mission Foods Corp. of Irving, Texas, a subsidiary of Mexico's Gruma Corp. The recall extends into Canada. (*Washington Post* 10/12/00)

October 12, 2000: Aventis announces the voluntary cancellation of its registration of StarLink in response to urging from EPA. (Statement by Stephen Johnson, EPA deputy assistant administrator for pesticides)

Mid-October 2000: EPA requests FDA's assistance in evaluating reports from consumers alleging adverse effects associated with foods thought to contain the Cry9C protein. FDA subsequently enlists the Centers for Disease Control and Prevention (CDC) in the evaluation.

October 18, 2000: The press reports that StarLink is again found in taco shells made for Safeway supermarkets by Mission Foods Corp. The company recalls all foods made with yellow corn and begins to use white corn in all its products. (*San Francisco Chronicle* 10/18/00)

John B. Sanfilippo & Son Inc., recalls Creamy Chicken Noodle Soup and Corn Chowder Soup after Cry9C was detected in the bulk dry soup mixes. (Food Traceability Report, 2001)

October 19, 2000: The press reports an assertion by Aventis that corn from the 2000-year crop apparently was sold by farmers to dozens, and perhaps hundreds, of grain elevators across the country, which unknowingly distributed it to millers and processors for use in making food. (*Washington Post* 10/19/00)

John Wichtrich, vice president and general manager of Aventis CropSciences, estimates that 88% of StarLink corn is being either stored on farms or used for feed, but an additional 9 million bushels has already left farms this year. Aventis is trying to track that corn and buy it back, at an estimated cost of \$100 million. The company is paying to test commingled corn in many grain elevators.

Wichtrich says some growers did not know the StarLink corn was approved only for animal or industrial use, or they forgot restrictions. "A lot of this corn was grown on a small section of larger farms, and sometimes farmers just harvested it all together."

October 20, 2000: Chicken processor Tyson Foods announces it will not use StarLink for chicken feed. (Food Traceability Report 2001)

October 22, 2000: The press reports that Mission Foods is pulling all its corn-based products from stores other than Safeway, including Kroger, Albertson's and H-E-B. (*Houston Chronicle* 10/22/00)

October 22, 2000: The press reports that the Kellogg Co. has shut down a Michigan plant because it cannot guarantee corn used in production is free of a genetically modified grain approved only for animal consumption. Big grain suppliers are unable to certify that their corn is not mixed with genetically altered corn. StarLink was mixed with regular corn in several sites around the country. Nine million bushels of StarLink are reportedly still unaccounted for by Aventis. (*Chicago Tribune* 10/22/00)

October 24, 2000: Four grain industry organizations (American Farm Bureau Federation, National Corn Growers Association, North American Export Grain Association, and the National Grain and Feed Association) write to Agriculture Secretary Dan Glickman calling for urgent

government action to define the terms under which StarLink corn may be exported in order to protect U.S. export markets. (Grain industry letter 10/24/00)

October 24, 2000: Aventis asks EPA to convert its pending petition for an exemption from the requirement of a tolerance into a petition for a time-limited exemption that would apply to (and legalize) only the unapproved human uses of the StarLink corn already in the food supply. Aventis also submits new evidence to support its case that the grain is safe, including new information about the speed at which the Cry9C protein breaks down in the human stomach. Aventis says that new tests and risk assessments have concluded that consumer exposure to foods containing the corn is, even under worst-case scenarios, “many thousands of times smaller than that required to sensitize individuals and lead to a later allergic reaction.” (Aventis CropScience letter 10/24/00)

October 26, 2000: The press reports that the Japanese Consumers’ Union has detected StarLink corn in snack foods and animal feed—the first indication that StarLink has spread overseas. StarLink is not approved for any use in Japan. (*Washington Post* 10/26/00 and *New York Times* 10/26/00)

October 26, 2000: The business section of the *Toronto Star* reports that StarLink is spilling over into Canada but that no one is telling consumers. (*Toronto Star* 10/26/00)

Canadian Food Inspection Agency officials say that StarLink has not crossed its borders. (*The Gazette* 10/27/00)

October 26, 2000: The U.S. government lifts export restrictions on StarLink so that exporters can ship corn with “trace amounts” for use as animal feed only to countries where it is approved for that use. (USDA/FDA/EPA notice to exporters 10/26/00)

October 26, 2000: FDA issues instructions to its field offices to collect samples of selected processed foods made from yellow corn and analyze them for the presence of cry9C DNA for the purpose of removing products containing the Cry9C protein from interstate commerce. The assignment is accorded top priority, with sampling and analysis to be completed by December 15, 2000. (FDA memo October 26, 2000)

October 27, 2000: Government officials report having tracked down all but 1.5% of the StarLink crop, leaving 1.2 million bushels of the 80-million-bushel crop unaccounted for, down from 4.5 million bushels that could not be traced earlier in the week. EPA also announces that it is unlikely the agency will grant any more split registrations. (*Los Angeles Times* 10/27/00)

October 31, 2000: EPA announces that Aventis has submitted additional data on the potential allergenicity of Cry9C and outlines the process the agency will follow to review the data and reach a conclusion. EPA makes the information available to the public with a 30-day comment period. (CRS Report, 1/10/01)

November 2, 2000: The same grain industry associations that wrote to Secretary Glickman on October 24 write again, calling for strong government intervention to enforce Aventis's financial obligations to the grain trade, prevent further commingling of StarLink with other corn, and provide "assurances to consumers in the U.S. and globally that the U.S. supply of corn and corn products is safe and reliable." (Grain industry letter 11/2/00)

November 2, 2000: USDA finalizes a test and documentation protocol to assure the government of Japan that corn imported from the United States does not contain detectable StarLink corn.

November 3, 2000: Japan accepts the USDA StarLink testing plans.

Wilson Foods, a Utah company, recalls its corn products sold in grocery stores in Utah, Idaho, and Montana.

November 9, 2000: After an internal review, the board of management of Aventis CropScience issues a status report on the effort to contain StarLink and its financial impact on the company. Aventis says that it voluntarily withdrew its StarLink registration after discussion with EPA because it wanted to ensure that "in the future no new StarLink corn will be grown for any use in the U.S. or for export until a new registration for both food and feed use has been obtained." (Aventis press release)

November 13, 2000: EPA issues a preliminary evaluation of Aventis's submission on the allergenicity of Cry9C, concluding that the potential dietary exposure to the Cry9C protein is quite low but that existing evidence is insufficient to determine whether it is a human allergen. (*Washington Post* 11/14/00; Aventis Petition for Tolerance)

November 13, 2000: GEFA writes to EPA Administrator Carol Browner to express concern that the process for reviewing the latest Aventis submission on allergenicity does not provide the public sufficient access to data and adequate time to comment meaningfully on the evidence. GEFA asks EPA to take additional steps to ensure "transparency and public involvement" in the process.

November 14, 2000: The press reports that South Korea has recalled 32,000 pounds of tortillas based on the presence of StarLink corn; USDA officials say the corn may have been exported to Korea through a third party. (*Washington Post* 11/14/00)

November 14, 2000: Sixteen state attorneys general call on Aventis to do more to reduce economic loss to farmers, including an expedited claims process, increased transportation and storage capabilities, staff to answer questions, more testing resources, and further steps to accept responsibility for financial losses. (Letter from attorneys general; *Washington Post* 11/16/00)

November 15, 2000: Aventis announces plans to divest Aventis CropScience as part of a plan to focus the company on its pharmaceuticals business. (Aventis press release)

November 17, 2000: U.S. corn sales are reported to have declined part because of StarLink concerns in South Korea and Japan (*New York Times* 11/17/00)

November 20, 2000: USDA issues final Protocol for Food Corn Exported to Japan.

November 21, 2000: Garst Seed Company announces that “limited quantities” of a single, non-StarLink corn hybrid produced by Garst in 1998 appears to contain “a small percentage” of the Cry9C protein. Garst asks Aventis CropScience to include this corn within its StarLink containment program. (Garst and Aventis press releases)

November 22, 2000: Aventis reportedly faces “enormous” legal liabilities because of the StarLink recalls. (*Washington Post* 11/22/00)

Bunge Lauhoff Grain Company recalls 50-pound bags of Lauhoff CCF100 Tiny Flakes used in the brewing industry. (Food Traceability Report, 2001)

November 28, 2000: EPA’s Science Advisory Panel meets to consider the evidence on the allergenicity of Cry9C, including summaries to date of the ongoing FDA-CDC joint investigation of reported adverse events.

December 1, 2000: SAP concludes that there is a “medium” likelihood that Cry9C is a potential allergen but that the levels of Cry9C possibly in the human food supply present a “low” likelihood of eliciting an allergic reaction in exposed individuals. Children may be more sensitive than adults. The panel emphasizes that further study of those persons reporting an allergic reaction would be valuable and recommends other actions already begun by EPA, including containment efforts, evaluation of new data on the effects of processing on Cry9C residues, and review of new and existing analytical methods for measuring StarLink corn in processed food. (SAP Report No. 2000-6)

December 10, 2000: The press reports that growers who got caught up in the StarLink episode will choose to plant conventional corn, based on a concern that the StarLink controversy will affect consumer confidence and farmers' credibility; companies such as Frito Lay and Gerbers are refusing to use genetically modified organisms in their products. (*St. Louis Post Dispatch* 12/10/00)

December 18, 2000: The U.S. Embassy in Tokyo issues a Statement of Intent with Respect to the Export of U.S. Corn, reaffirming the U.S. commitment to the testing and documentation protocol agreed to earlier to ensure that no StarLink corn will be exported to Japan.

January 23, 2001: Aventis agrees to contracts with 17 states, including Nebraska and Iowa, to reimburse farmers and elevators for their costs related to detecting, sorting, shipping, and marketing StarLink. Farmers and grain elevators that have incurred StarLink costs can sign up for the reimbursement program until 2/15/01. The executive director of the Nebraska Corn Board says the StarLink case has affected farmers' ability to export U.S. corn as much as anything in the past. (*Omaha World-Herald* 1/24/00)

February 15, 2001: The press reports that Taco Bell's sales have been hurt by consumer concern about the taco shell recall and that its parent company, Tricon Global Restaurants Inc., has set up a \$15 million loan pool to help franchises; earlier reports had indicated that Taco Bell's sales would not be hurt by the StarLink recall. (*Los Angeles Times* 2/15/01)

February 21, 2001: Japan and the United States agree to strengthen measures already in place to ensure that no StarLink corn is exported to Japan. The agreement between Japan's Ministry of Health, Labor, and Welfare and USDA is intended to tighten a screening system approved in November, according to a statement by the US Embassy in Tokyo. (*St. Louis Post-Dispatch* 2/22/01)

March 1, 2001: USDA reports that Cry9C has been detected in non-StarLink seed intended for planting in 2001 (Food Traceability Report, 2001)

March 7, 2001: USDA announces plans to purchase corn seed containing the Cry9C protein from small seed companies to ensure that it is not used in the spring planting; the cost will be \$15 million to \$20 million. (USDA press release)

March 7, 2001: EPA announces that in the future it will not grant split registrations of biotech products. EPA also releases a draft report on the effects of processing on Cry9C, indicating that wet milling virtually eliminates the protein but dry milling does not.

March 8, 2001: The press reports that new lab tests commissioned by Greenpeace find that vegetarian burgers and meat-free corn dogs made by Morningstar Farms contain genetically modified soy as well as StarLink corn. (*Los Angeles Times* 3/8/01)

March 9, 2001: USDA cuts its projection for U.S. corn exports for the fourth time in the past four months, forecasting 2 billion bushels, down from 2.05 billion bushels the previous month. Private analysts say the estimates may be reduced by another 50 million bushels in the coming months. Before the first StarLink detection, projected corn exports were 2.175 billion bushels. (*Chicago Tribune* 3/9/01)

March 31, 2001: American farmers are expected to plant more genetically engineered soybeans and cotton this year than ever before, despite the uncertainty surrounding the issue and the difficulty of segregating genetically engineered crops. (*Los Angeles Times* 3/31/01)

April 3, 2001: Thailand's prime minister instructs the Ministry of Agriculture and Cooperatives not to approve new field trials of bioengineered crops which could mark the end of ongoing field trials for biotech cotton and corn by Monsanto. (Food Traceability Report, 2001)

April 18, 2001: USDA acting Deputy Undersecretary Hunt Shipman announces that at least 78 U.S. seed companies had found some degree of contamination of their seed corn with the Cry9C protein.

April 19, 2001: Aventis petitions EPA for a time-limited tolerance to allow human consumption of StarLink corn provided that corn delivered to dry mills contain no more than 20 parts per billion of the Cry9C protein.

April 24, 2001: The press reports that data submitted by Aventis in support of its petition show that traces of StarLink corn are reported to have been found in additional products, such as cornbread, polenta, and hush puppies. Aventis officials say the levels detected are very low. FDA is testing the blood of about 20 people who believe they may have suffered allergic reactions. (*Washington Post* 4/24/01)

April 30, 2001: USDA reports that Illinois farmers plan to plant 59% of their soybean acres with genetically modified crops; however, farmers plan to cut back slightly on biotech corn. The biotech beans reduce the number of times farmers must cultivate their fields in summer, when fuel prices are high. (*St. Louis Post-Dispatch* 4/30/01)

May 4, 2001: Missouri Attorney General Jay Nixon is reported to be suing the maker of StarLink corn. Nixon says the company marketed the corn to Missouri farmers but did not tell them about the restrictions and failed to label the seed properly. The suit seeks to have Aventis

pay Missouri farmers, grain elevators, and others for their losses, and to fine the company up to \$1,000 for each violation. (*St. Louis Post-Dispatch* 5/4/01)

June 9, 2001: Tricon Global Restaurants Inc. agrees to pay Taco Bell franchises \$60 million for sales lost after the recall of Taco Bell taco shells that contained StarLink corn. Taco Bell franchises maintained sales were hurt by the recall, even though the affected taco shells were supplied only to supermarkets. (*Dallas Morning News* 6/9/01)

June 12, 2001: FDA reports to EPA on the results of its joint study with CDC on the adverse effects allegedly associated with Cry9C. FDA and CDC did not find any evidence that hypersensitivity to the Cry9C protein was responsible for the self-reported allergic responses that people experienced in fall 2000. Samples had been taken from 17 people—too few to resolve the allergenicity issue, according to some observers. (AgNet. Reuters and Associated Press 6/13/01)

June 14, 2001: Grain importers in Japan and Korea, the two top U.S. corn buyers, say the CDC study will not change their position against importing StarLink corn. South Korea's Korea Corn Processing Industry Association has asked foreign suppliers since late last week to replace U.S. corn with South American corn. (AgNet. Reuters Jae Hur 6/14/01)

June 21, 2001: Some farmers are reported to be establishing systems to produce “identity-preserved” crops and cattle—farm products whose chain of custody can be documented from beginning to end—so that they can satisfy market demand and potentially get a premium price for identity-preserved products, such as food free from genetically altered crops. A representative of the Missouri Corn Growers Association comments, “if any good comes from the StarLink episode, it will be from emphasizing the need to move farmers and millers toward an identity-preserved system.” (*Kansas City Star* 6/21/01)

June 26, 2001: A survey by Zogby International for the Pew Initiative on Food and Biotechnology reports that of the 1,231 adults surveyed more than half (52%) are confident that government regulators are prepared to manage genetically modified foods and ensure consumer safety while a significant percentage (45%) are not.

July 4, 2001: StarLink is found in a white corn product for the first time. FDA has discovered genetic material from StarLink corn in Kash n' Karry White Corn Tortilla Chips. In response to the 2000 recall of Taco Bell products, many manufacturers had switched from yellow to white corn. (AgNet. *Washington Post* and Reuters 7/4/01)

Food Lion and Kash n' Karry grocery chains pull their store-brand corn tortilla chips in response to FDA concerns about the genetically modified corn used in the chips. Both chains are

owned by Delhaize Group, which has notified its food chains in Belgium, Greece, and the Czech Republic. (Associated Press 7/4/01)

July 6, 2001: Frito-Lay Inc. says it is confident that white corn products do not carry traces of StarLink yellow corn. A representative says the corn is tested before it leaves the farms and is strip-tested before it comes into the processing plants—practices initiated following the fall 2000 recall of Taco Bell products. (AgNet. Reuters 7/6/01)

July 11, 2001: U.S. government tests were cited as finding that 10 of the 11 samples collected from consumers who complained of allergic reactions to StarLink corn did not contain the genetically modified corn. Wise Foods Inc. says there was no StarLink corn in tests of its white corn tortilla chips; however, extra tests on all white corn shipments are being performed as a precaution. (AgNet. *New York Times* and Reuters 7/11/01)

July 17, 2001: At the SAP meeting convened to evaluate the new information on the allergenicity of Cry9C submitted by Aventis, EPA, CDC, FDA, and USDA, Aventis urges EPA to set a standard of 20 parts per billion of the Cry9C protein in human food, and to remove from sale any foods with more than that amount. Aventis also maintains that it is inevitable that the corn will find its way into the human food supply but that processing the corn removes 82% to 99% of the protein. (AgNet. Agence France Presse English 7/17/01)

July 18, 2001: Keith Finger, a Florida optometrist, tells SAP scientists that he is allergic to StarLink grain despite a negative government blood test. Some SAP scientists have questioned the effectiveness of the test and asked why the government did not seek out more potential victims by contacting doctors around the country. Federal officials say they lacked the money for wider-ranging tests. (Associated Press and Reuters 7/18/01)

July 18, 2001: The SAP subpanel tells EPA that the studies did not provide enough data for them to suggest a safe tolerance level for the Cry9C protein in food. (AgNet. *Wall Street Journal* and Associated Press 7/19/01)

July 24, 2001: Seventeen states say they have entered into a second agreement with Aventis to compensate farmers whose crops were tainted by the company's gene-altered StarLink corn. Two food companies from South Korea announce plans to buy 52,500 tons of corn for human food use, but not from the United States because of concerns over StarLink. (AgNet. Reuters 7/24/01)

July 25, 2001: SAP issues its report to EPA based on its July 17–18 meeting. The SAP reaffirms findings from previous scientific assessments that there is a “medium” likelihood that

the Cry9C protein is a potential allergen. The SAP scientists agree that there is inadequate information to establish a reasonable scientific certainty that exposure would not be harmful to public health. (SAP Report No. 2001-09)

July 27, 2001: Based on the SAP conclusion, EPA announces that “establishing a tolerance for StarLink in human food products is not currently supported.” (EPA press advisory)

September 4, 2001: The press reports that according to a government document, the U.S. government and Aventis had at least some indication that StarLink may have entered the human food supply more than half a year before GEFA discovered it in taco shells. A survey commissioned by Aventis CropScience, conducted in December 1999, reported that 2 of 230 farmers growing StarLink had sold the corn for food use or export, and another 12.6% said they did not know what happened to the corn after they sold it. (*New York Times* 9/4/01)