

# CRS Report for Congress

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## StarLink™ Corn Controversy: Background

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### Summary

StarLink™ is a corn variety that has been genetically modified to contain an insecticidal protein derived from a naturally occurring bacterium (*Bacillus thuringiensis*, or Bt). The Environmental Protection Agency (EPA) approved the gene-spliced variety of yellow corn in 1998 for use only as animal feed and set a zero-tolerance level for its use in human food based on the fact that this particular Bt protein does not break down easily in the human digestive system, is heat resistant, and could prove allergenic. StarLink corn was detected in taco shells in mid-September 2000. The StarLink variety constitutes between 0.4% to 0.5% of total U.S. corn production; however, a larger (and unknown) amount of corn currently in market channels may be commingled with StarLink corn. EPA is examining a request from Aventis, the manufacturer, to grant StarLink a temporary emergency exemption from the zero-tolerance standard. Japan, which imports 30% of total U.S. corn exports and does not permit StarLink to be imported for any use, has asked U.S. government officials to make sure that no incoming shipments contain StarLink-commingled corn. Several bills were introduced in the 106<sup>th</sup> Congress to require labeling of foods containing genetically modified organisms (GMOs). In addition, a bill was introduced at the end of the 106<sup>th</sup> Congress (S. 3184) to amend the Federal Food, Drug and Cosmetic Act to require pre-market consultation and approval for foods containing GMOs. This report will be updated as events warrant.

### Introduction

The presence of StarLink™ corn in food has become the first test case of contamination of the food supply by a genetically modified organism (GMO). Among the issues this raises for Congress are: What steps might help alleviate the immediate problems for farmers, grain elevators, exporters and trading partners? Are further changes in the current statutory or regulatory framework needed to address the food and environmental safety issues related to agricultural biotechnology? Can regulatory policies be changed in such a way that support for innovation in crop and food technologies is not undermined?

### StarLink™ & EPA: Regulatory Timeline

- **March 14, 1997.** EPA issues an experimental use permit (EUP) to Plant Genetics Systems (PGS) to test corn seeds containing the Cry9C protein in 3,305 acres in 28 States.
- **August 8, 1997.** EPA announces an application from PGS to register the Cry9C pesticide under FIFRA.
- **September 19, 1997.** EPA announces that PGS asked for a full exemption of a tolerance for Cry9C residues in or on all raw agricultural commodities under FFDCA.
- **November 26, 1997.** EPA announces PGS' request for a temporary "split" exemption of a tolerance for residues for Cry9C in corn for animal feed only under FFDCA.
- **April 10, 1998.** EPA issues a final rule establishing the temporary "split" tolerance exemption for Cry9C.
- **May 22, 1998.** EPA issues a final rule granting a "split" tolerance exemption to Cry9C.
- **April 7, 1999.** EPA announces that AgrEvo USA had filed a petition to exempt from tolerance residues of Cry9C in or on all raw agricultural commodities.
- **December 21, 1999.** EPA asks for input and comments on how to assess potential allergenicity of Cry9C in establishing "a reasonable certainty of no harm" before considering AgrEvo's request for a full exemption from tolerance under FFDCA.
- **February 29, 2000.** EPA's Scientific Advisory Panel (SAP) meets to consider and define the issues and methods in determining food allergenicity of Cry9C.
- **April 5, 2000.** A National Academy of Sciences (NAS) report states that Cry9C raises concerns of allergenicity.
- **August 9, 2000.** EPA announces new review process for plant-pesticide registrations, including Cry9C, in view of NAS recommendations.
- **October 31, 2000.** EPA announces Aventis' submission of additional data and outlines review process.
- **December 5, 2000.** EPA's SAP found

This report examines the events that led to the current situation and provides an overview of its impacts.

### What is StarLink™ Corn?

StarLink is a trademark for several genetically modified corn hybrids produced by Aventis Crop Science of Research Triangle Park, N.C. (a German-French life sciences consortium) and distributed through several seed companies. StarLink hybrids contain a plant pesticide protein (Cry9C) derived from a common soil microbe (*Bacillus thuringiensis*, or Bt), which kills certain destructive pests of corn such as the European corn borer. StarLink also is one of a handful of the currently approved genetically modified (GM) crop varieties that contains "stacked genes" (i.e., more than one commercially desirable transgenic trait at once.) StarLink contains: (1) the insecticidal Bt Cry9C protein; and (2) genes from the bacteria *Streptomyces hygroscopicus*, which makes StarLink tolerant to a commonly used broad-spectrum herbicide.

### Government Review and Approval Process for StarLink

StarLink's journey through the regulatory review and approval process was typical for a GM crop in the United States.<sup>1</sup> As with all crops bioengineered

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<sup>1</sup> The Coordinated Framework for Regulation of Biotechnology of 1986 establishes agency responsibilities and regulatory policies for biotechnology products derived from existing statutes [Federal Register, June 26, 1986 (51 FR 23302)]. An in-depth discussion of regulatory issues (continued...)

to contain an insecticide, StarLink required regulation under two different authorities: (1) the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>2</sup> which requires EPA to register and label pesticides; and (2) the Federal Food, Drug and Cosmetic Act (FFDCA)<sup>3</sup>, which requires EPA to establish a safe tolerance level for pesticides used on (or genetically engineered into) foods, and vests enforcement authority in the Food and Drug Administration (FDA).

Although health safety tests had found that Cry9C did not resemble any known allergens, results from other tests did not allow experts to completely rule out the potential for allergenicity. There were two particular concerns: one test showed that Cry9C protein could survive cooking or processing, and another determined that Cry9C is hard to digest. When in 1997 the original patent holder asked EPA to allow Cry9C corn to be registered for use only for livestock feed and industrial purposes, EPA exempted the plant-pesticide from the requirement for a tolerance in animal feed, thus granting it a so-called split registration. EPA required the company to take all actions needed to prevent StarLink from getting into the human food chain. Giving split registration is a common practice with conventional chemical pesticides, as each registration (or tolerance) specifies the crops on which use is allowed.

In 1999, the AgrEvo USA seed company, the next owner of the StarLink patent, asked EPA to set a tolerance for use in food products. EPA responded by asking for input from industry and academia on methods to ascertain Cry9C's potential for allergenicity and by convening a Scientific Advisory Panel in early 2000 to review the issue. Meanwhile, in April 2000 the National Academy of Sciences issued a separate report reiterating

### Genetic Testing

Testing for GMO's has become central to determining the presence of StarLink corn. Two tests have been used:

**Strip Test** - confirms the presence or absence of *proteins* (like the Cry9C protein). The test costs \$5-7 and is used by grain elevators. Test can detect Cry9C down to 1 in 400 kernels (0.25%) and is used mainly for detection of GMOs in raw commodities.

**Polymerase Chain Reaction (PCR) test**- confirms the presence of *genetic material* or DNA associated exclusively with StarLink genes. This is the test used by environmental groups, and the FDA to detect StarLink. PCR test costs hundreds of dollars and can take several days to complete. The test can detect StarLink DNA down to 1 in 100,000 kernels, or less than 1 kernel in a bushel.

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<sup>1</sup> (...continued)

in food biotechnology can be found in CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*, by Donna Vogt & Mickey Parish.

<sup>2</sup> FIFRA (7 USC 136 et seq.) regulates the distribution, sale and use of pesticides in the United States. EPA defines registration as the formal listing of a pesticide before it can be sold and distributed in intrastate or interstate commerce. To register a pesticide the burden of proof is on the producer to demonstrate no "unreasonable" adverse effects on the environment.

<sup>3</sup> FFDCA requires that the EPA establish a tolerance level for pesticide residues in raw agricultural commodities (21 USC 346a). EPA may determine that a pesticide (e.g., Cry9C) is safe and exempt from the requirement of a tolerance if it finds, with "reasonable certainty" that aggregate exposure to residues will not cause harm.

concerns about Cry9C's possible allergenicity and advising the EPA to improve the testing on the human and environmental impacts of Bt crops.<sup>4</sup>

## How Events Unfolded

On September 18, 2000, the *Washington Post* reported that tests ordered by a coalition of groups opposed to biotechnology had found traces of genetic material from StarLink in Kraft's taco shells in grocery stores in Washington, D.C. Kraft voluntarily recalled all taco shells from grocery stores 4 days later, after confirming the finding. Several other recalls by retailers have taken place subsequently, and in November the FDA exercised its enforcement authority by recalling over 300 corn products.

On September 26, 2000, Aventis (the third and current owner of the StarLink patent) instructed its seed distributors in the United States to stop sales of StarLink seed corn for planting in 2001; shortly thereafter the company voluntarily agreed to cancel its EPA registration of StarLink for feed and industrial use, thus taking the product off the market. On October 25, Aventis submitted new safety information and asked EPA to grant a time-limited approval of up to 4 years for the presence of the corn in human food. According to Aventis, four years is how long it could take for all StarLink-contaminated corn to clear food channels.

On September 29, Aventis agreed with the U.S. Department of Agriculture (USDA) and EPA to purchase all of the 2000-crop year StarLink corn, offering farmers a 25-cent premium over the price of corn on October 2, which was \$1.9925/bushel. Under the program, USDA will purchase the corn from the farmers and assure that it is distributed into feed and industrial channels only. Aventis will reimburse USDA for the cost. Early estimates of the cost to the company of implementing the buy-back program have ranged between \$60 to \$100 million and involve close to 80 million bushels.

International repercussions concerning StarLink began on October 24, 2000, when the Consumers Union of Japan found traces of the variety in snack foods and in animal feed. Under Japanese regulations, StarLink is not approved for any use and there is a zero tolerance threshold for StarLink in corn imports. Korea, the second largest market for U.S. corn, also has recalled corn products after finding StarLink traces in imported taco shells in early November. No immediate repercussions are expected in Europe, where imports of U.S. corn are small (0.1% of U.S. exports.)

## The Current Situation

**StarLink down on the farm.** According to Aventis, farmers planted StarLink on 248,000 acres in 26 states in 1999. In 2000, farmers planted the variety on 352,000 acres in 29 states. These figures represent 0.32% and 0.44% of corn acreage in the United States in 1999 and 2000, respectively. Production estimates for StarLink are 38 million bushels (1999) and 54 million bushels (2000), which represent between 0.4% to 0.5% of U.S. crop production. However, in accordance with EPA rules, an additional 30 to 40 million bushels of non-StarLink corn harvested from buffer acres must be included in total

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<sup>4</sup> National Research Council. April 2000. Genetically modified pest-protected plants: Science and Regulation. National Academy Press. Washington, D.C. 260p.

production figures.<sup>5</sup> As of late October, Aventis had located all but 1.2 million bushels of the 2000 StarLink crop. The 1999 crop is so far along in the marketing chain that Aventis cannot determine its whereabouts. At the farm level, most producers already have sold their 1999 StarLink crop; they will be paid for the 2000 crop at the level set in the USDA-Aventis buy-back program (see above).

**StarLink in the market.** Aventis maintains that about 12% of the 2000 crop, 9.6 million bushels, could be illegally present in food products. Aventis is working to forestall further contamination by designating specific elevators for delivery and distribution into approved feed and industrial use outlets. However, the extent of commingling of StarLink with non-StarLink corn in food channels is harder to pin down. Media reports vary and high estimates abound because it does not take very much StarLink in a sample to result in a positive finding (see box on Testing). For example, experts at Iowa State University claim that a large proportion of corn in Iowa elevators may contain traces of StarLink.<sup>6</sup> Most experts agree that factors such as the handling of the corn from buffer strips and the possibility of StarLink pollen drifting into neighboring fields could elevate contamination estimates substantially. In addition, there is suspicion that the prevalent StarLink contamination in food currently on the shelves could be from the 1999 StarLink crop.<sup>7</sup> According to USDA, 1.8 billion bushels from the 1999 season remain in elevators as carryover. This represents close to 20% of that year's crop.

**StarLink exports.** In early November 2000, USDA and Japan's Health Ministry implemented a plan to assure that no commingled corn is shipped to Japan. The plan provides that USDA will test for the presence of StarLink at domestic shipping locations, again on barges and railcars, and finally at export points. The protocol pertains to corn imports for food and feed use. Meanwhile, in response to a request from USDA and the U.S. grain industry, the Japanese Agriculture Ministry has agreed to review the safety of StarLink corn as an animal feed. The United States sold 600 million bushels of corn to Japan in 1999 with an estimated value of \$1.45 billion. Sales to Japan represent 30% of U.S. corn exports. Late in 2000, USDA reports showed that corn sales to Japan were decreasing, but an agreement between the government of Japan and USDA in December promised to reverse the trend. Under the agreement, Japanese inspectors monitor tests of corn feed shipments and certify them as StarLink-free.

## Emerging Issues

**Liability.** The most frequently asked question is who is responsible for StarLink's illegal appearance in food products. EPA officials have said that Aventis, as a condition for its license, had the responsibility to ensure that the corn did not get into the human

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<sup>5</sup> The 2000 StarLink Bt Grower Agreement states that: "In accepting StarLink corn, grower agrees to direct the harvested grain and grain grown within 660 feet of the StarLink grain towards domestic feed (e.g. animal feed) and/or non-food industrial purposes. Grower agrees not to use this grain for food use or allow it to enter grain export channels."

<sup>6</sup> Personal Communication with Dr. Charles Hurburgh, Professor at the Department of Agricultural & Biosystems Engineering. Iowa State University. November 2, 2000.

<sup>7</sup> Associated Press. November 3, 2000. *Corn recall expands to stores, restaurants across country.* Washington Post p.A5.

food supply. Aventis has said that it required farmers who grew StarLink to sign agreements to use the corn only for animal feed or industrial use and to treat non-StarLink corn harvested from buffer strips as part of the StarLink crop. In addition, Aventis has claimed that seed bags carried a label detailing these requirements. Many agree that the issue of liability is likely to be under judicial review for a long time, as farmers, elevators, processors, and others seek redress from losses that have been estimated in the hundreds of millions of dollars.<sup>8</sup>

**Split Approvals for GM Crops by EPA.** Critics have questioned EPA’s decision to grant StarLink approval for animal feed and not for human food. Some are asking EPA to withhold approval of biotechnology crops until they have clearance to be used in food. These critics point to the StarLink incident as an example of how the “split” approval policy has gone wrong and threatens the confidence of consumers and foreign markets.<sup>9</sup> Others have argued that split registrations for GM varieties should be permitted on a case-by-case basis – for example, for those containing edible vaccines or for industrial-use-only cultivars, and where segregation from food varieties can be better ensured.

**Mandatory Pre-Market Approval and Review.** This incident has raised serious questions about the adequacy of the current system, especially in the areas of monitoring and enforcement. Some are calling for requiring a fully validated testing procedure for identifying DNA in crops and finished goods as a precondition to approval by EPA. Others are calling for a mandatory review of each new GM variety before it reaches the market by panels composed of state and federal agencies, industry, exporters, academia and other interest groups. Critics of these proposals argue that it would become increasingly difficult to register or introduce biotechnology innovations under such a system, and that the increasing genetic complexity of second and third generation GM crops would make testing for individual traits an expensive proposition.

## Legislation

Several bills were introduced in the 106<sup>th</sup> Congress which addressed the issue of mandatory labeling of GM foods.<sup>10</sup> In response specifically to the StarLink events that began in September 2000, Senator Durbin introduced a bill late in the 106<sup>th</sup> Congress that would have amended the Federal Food, Drug and Cosmetic Act to require pre-market consultation and approval for GM foods (S. 3184). The bill proposed to codify the existing system of voluntary consultations with the Secretary of Health and Human Services, giving FDA the authority to regulate genetically engineered food and to require public participation in the decisions. Bill provisions would have also authorized FDA to test products on the market to determine whether unapproved genetically engineered materials are present.

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<sup>8</sup> K.T. Arasu, Reuters News Service. “Anger in Iowa over gene-altered corn controversy.” November 2, 2000.

<sup>9</sup> See Kraft Foods (September 22, 2000) Official Statement; Grocery Manufacturers of America. (September 22, 2000) Press Release; National Corn Growers Association. (September 29, 2000) “Hot of the Cob: Grains Council, NCGA Respond to Corn Concerns in Japan.”

<sup>10</sup> Bills include H.R. 3377 (Kucinich) and S. 2080 (Boxer). For overview see CRS Report RS20507, *Labeling of Genetically Modified Food*, by Donna Vogt & Brian Jackson.