

Genetically Engineered Foods

StarLink Corn in Taco Shells

#3 in a series

A Series from Cornell Cooperative Extension's Genetically Engineered Organisms Public Issues Education (GEO-PIE) Project

STARLINK, A VARIETY OF "*Bt*" CORN UNAPPROVED FOR HUMAN CONSUMPTION, WAS FIRST DETECTED IN TACO SHELLS IN SEPTEMBER 2000. LATER ESTIMATES SUGGESTED IT MAY HAVE FOUND ITS WAY INTO MORE THAN 50 PERCENT OF THE U.S. CORN SUPPLY.

In September 2000, news headlines proclaimed that "StarLink," a variety of genetically engineered (GE) corn not approved for human consumption, had been detected in Taco Bell taco shells distributed by Kraft Foods, Inc. Kraft immediately issued a voluntarily recall of the taco shells that might contain processed StarLink corn.

In the months following the initial discovery, StarLink was detected in a wide variety of yellow-corn products, many even outside the United States. It has been estimated that as many as several hundred corn products may have been quietly recalled by individual manufacturers.

Frequently Asked Questions

What is StarLink?

StarLink is a variety of GE corn, developed by Aventis CropScience, that included two new traits, each coded by a different gene: (1) "*Bt*" based resistance to lepidopteran caterpillar pests such as the European corn borer and (2) tolerance to glufosinate herbicides such as Basta and Liberty. StarLink was unlike other *Bt* corn varieties because it produced a modified version of the *Bacillus thuringiensis* (*Bt*) toxin protein, known as "Cry9C," an Aventis proprietary technology.

StarLink was the only variety of GE food that had been marketed for animal feed but not also approved for human consumption. Aventis had assured regulators that appropriate precautions would be taken by StarLink growers to prevent the GE corn from entering the food supply, but those precautions were apparently inadequate.

How is StarLink different from other GE corn varieties?

If a GE plant produces a new protein, there may be some risk that the new protein could be an allergen to humans. For this reason, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) suggest that developers of new GE foods assess the foods' potential allergenicity. If the source of a GE protein is a common, known allergenic food (such as peanuts), then allergy testing of the new GE food is relatively straightforward using standard clinical methods.

If, however, the protein is from a source not normally in the food supply, then assessment of its potential allergenicity is much more difficult. Most known allergenic proteins have several chemical features in common (small size, resistance to heat, acid, and stomach enzyme digestion). The only available method of allergy assessment for "unknown" proteins is to subject them to similar chemical analysis.

Bt toxin proteins belong to the group of "unknowns." Because they are quickly degraded in the stomach, *Bt* toxins have not been considered an allergy risk. Tests submitted by Aventis to the EPA, however, suggested that the Cry9C version of *Bt* toxin in StarLink may be more heat stable and digestion resistant than other members of the *Bt* toxin family, making it a higher risk for allergenicity. For this reason, the EPA did not initially allow the use of StarLink in human food.

After StarLink was detected in foods, Aventis petitioned the EPA to consider allowing the "temporary approval" of StarLink corn for human consumption, based on new data provided by Aventis. The EPA's scientific advisory panel reviewed the new data and published its analysis on December 5, 2000, concluding that StarLink could pose a moderate allergy risk, although the likelihood of anyone having an allergic reaction was considered very small because of the low levels of exposure.

How did unapproved corn get into the food supply?

Regulators at first suspected that some StarLink growers may have ignored agreements not to sell StarLink corn to mills using the flour for human foods. Later interviews with growers, however, revealed that many farmers may not have been clearly instructed not to sell the corn for human use, or were told that the unapproved variety would be approved by harvest time. It is unknown at which points in the supply line corn was contaminated with StarLink, but it appears that many farmers simply sold the unapproved corn directly to the mills.

Although Aventis agreed to purchase all of the remaining 1999 and 2000 harvests of StarLink corn, several million bushels of StarLink corn were unaccounted for and probably entered the human food supply. StarLink represented only about 1 percent of the total corn harvest in 2000, but mixing of

StarLink with other corn varieties at individual mills caused a disproportionately larger number of corn products to be contaminated. Recent estimates suggest StarLink may have contaminated as much as 50 percent of that year's corn harvest.

What is the final word on StarLink?

After the discovery of StarLink contamination, two dozen people came forward claiming that they had had severe allergic reactions after eating corn products containing StarLink corn. Seventeen of the 24 allowed blood samples to be tested by the FDA and the Centers for Disease Control and Prevention (CDC). The CDC released a report on June 13, 2001, concluding that although the claimants did appear to have had severe allergic reactions to something, blood tests demonstrated that StarLink was not the cause. To date, there have been no documented cases of allergic reactions to StarLink corn.

On July 19, 2001 the EPA's scientific advisory panel (SAP) determined that although the CDC/FDA findings demonstrates that those individuals were not allergic to StarLink, it should not be used to conclude that no one could be allergic to StarLink. This new evidence did not affect the earlier SAP findings of moderate potential allergenicity of StarLink (see above). Furthermore, the SAP admonished the FDA and CDC to more actively investigate the possibility of other unreported cases of allergic reactions.

Following the advice of its SAP, the EPA ruled on July 27, 2001, that it would not accept Aventis' petition to allow traces of StarLink to remain in the food supply, and that its policy of zero tolerance would continue. Aventis has voluntarily withdrawn its regulatory approval to sell StarLink corn in the United States.

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