

# Biotech

## In focus



Cooperative Extension Service  
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## GMOs and Human Health III: The StarLink Corn Recall

The responsibility to regulate GE crops in the USA is divided among three federal agencies: the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Each agency deals with different components of the evaluation process. When genes—DNA recipes for proteins—are added to crop plants so that the plants make their own pesticides, EPA registers the approved uses of the pest-killing plant in the same way it registers synthetic pesticides, for example. FDA evaluates food safety components while the USDA examines the potential impacts of a release on the environment.



In 1997, a company called Plant Genetics Systems (eventually part of Aventis Crop Science) sought approval to deregulate (commercially release) StarLink corn, which was engineered with two bacterial genes. One of these genes provided resistance to the weed killer glufosinate, which is also called phosphinothricin and is sold as Basta®, Liberty®, and other trade names. The other gene was for Cry9c, a Bt protein toxic to several caterpillar pests. Cry9c is present in soil but hadn't been previously approved in a genetically engineered crop. Between 1998 and 2000, failure to follow an EPA decision that restricted the use of StarLink resulted in recalls, buybacks, and lawsuits costing hundreds of millions of dollars, contributed to a decline in U.S. corn exports to Japan and South Korea, and diminished the value of the U.S. corn crop by an estimated 7% for at least one year. Did this regulatory lapse also cause harm to human health?



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The EPA had found that the Cry9c protein didn't break down quickly enough during artificial digestion. This artificial digestion is designed to mimic the time that food spends in the human stomach. Few digestion-resistant proteins are allergens, but Cry9c's resistance to digestion increased the odds that it could be an allergen. For this reason, in 1998, EPA registered StarLink for commercial use in animal feed or industrial applications (for example, biofuels) but did not extend the registration to human food. Less than 10,000 acres of StarLink were planted in 1998; plantings increased to almost 250,000 acres in 1999 and about 350,000 acres in 2000 along with almost 170,000 acres as buffer areas to prevent cross pollination. At its most popular, StarLink still represented less than 0.5% of the annual total U.S. corn crop.

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# StarLink Mix Up

In September 2000, on behalf of Genetically Engineered Food Alert (a food safety organization), a laboratory called Genetic ID in Fairfield, Iowa, tested store-bought Taco Bell taco shells produced by Kraft Foods. The shells were found to contain StarLink corn DNA. Additional testing uncovered StarLink DNA or Cry9c protein in a wide variety of corn products. Industry infrastructure had not been established to keep specific corn varieties separate. While following standard practices, corn growers, shippers, and processors had mixed StarLink and food-grade corn; as much as 50% of the 2000 corn harvest may have been affected. How 50% of the corn crop became contaminated if StarLink was only 0.5% of the acreage that year is unclear. Hundreds of products containing Cry9c were recalled, and Aventis recalled corn harvests containing StarLink.



## Corn Allergies?

The FDA received reports from 51 consumers describing adverse reactions to StarLink corn-contaminated products. The Centers for Disease Control assessed these reports and concluded that 28 were consistent with a possible allergy: symptoms resembling an allergic reaction occurred within 12 hours of eating a corn product, were unexplained by other illnesses, and did not affect customers of dining companions who ate the corn product. This suggests a shared infection rather than an individual allergy.

None of the individuals with allergy symptoms who agreed to blood testing were found to have allergy-associated antibodies to Cry9c proteins. Blood samples from individuals with multiple known allergies were also negative for antibodies against Cry9c. These tests did not prove that Cry9c wasn't an allergen, only that the individuals tested were not allergic to Cry9c.

## Cry9c Protein Tests

After Aventis withdrew StarLink from the market in late 2000, FDA recommended that corn mills in the United States test yellow corn for Cry9c protein. EPA reported that the last verified positive test for StarLink at a U.S. corn mill occurred in 2003. The testing program was discontinued in 2010 according to the USDA website.



## StarLink Detected



Friends of the Earth reported that StarLink corn was found in U.S. grain aid to Bolivia in 2002 and in United Nations grain aid to several Central American nations in 2005: the USDA noted that the food aid was tested as required prior to shipment. In 2013, researchers using a commercial DNA testing kit from GeneScan Europe, that is no longer available, reported the presence of StarLink DNA in corn products purchased in Saudi Arabia in 2009 or 2010.

## Complex Findings

Interpretation of Cry9c protein or StarLink DNA findings in Saudi Arabia is made more complex by the presence of non-GM Cry9c protein in soil and by proprietary information relating to some testing kits, so these results should be regarded with caution



Allergic reactions to Cry9c protein have not been documented. The EPA has predicted the incidence of such allergies to be very low, given the low levels of human exposure to Cry9c. Remember that the initial concern in this regard was because the protein did not break down rapidly during artificial digestion, rather than in response to any reports of actual allergic reactions.

This example of a product being recalled and removed from the market illustrates how food safety measures aimed at ensuring genetically engineered crops are safe, have developed over time. Today, all new GE products are carefully screened for signs of allergens as discussed in a previous issue of Biotech in Focus. While it is unfortunate that the StarLink episode occurred, it did contribute to improved screening of new varieties for food safety.