



Pesticides: Regulating Pesticides

You are here: [EPA Home](#) » [Pesticides](#) » [Regulating Pesticides](#) » [Biopesticides](#) » [Plant Incorporated Protectants](#) » [Starlink Corn Regulatory Information](#)

Starlink™ Corn Regulatory Information

Current as of April 2008

This page provides information on the regulatory activities involving the genetically engineered corn known as StarLink™.

On this page:

- [Starlink™ Regulatory History](#)
- [EPA Recommends to Cease Monitoring for StarLink™](#)
- [Allergenicity Assessment](#)
- [Science Advisory Panel \(SAP\) Information](#)

Resources

- [Plant-Incorporated Protectants](#)
- [Monitoring to Cease](#)

Starlink™ Regulatory History

StarLink™ refers to a variety of yellow corn genetically engineered to express the protein Cry9C, which is toxic to various insect pests of corn and acts as a pesticide (a plant-incorporated protectant). During the mid-1990s, the registrant, Aventis Agrosience, Inc., submitted data to EPA on the safety of StarLink™ and applied for approvals under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).

After reviewing the available data, EPA was unable to determine whether the Cry9C protein was a potential human allergen. All other information indicated that Cry9C would not pose any other types of risks to human health or the environment. Accordingly, in 1998, EPA registered StarLink™ for commercial use, provided that all grain derived from StarLink™ corn was directed to domestic animal feed or to industrial uses (e.g., biofuels).

The intent of requiring all StarLink™ to be segregated as either domestic animal feed or for industrial use was to preclude any occurrence of the potentially allergenic Cry9C in human food. The registration contained several specific requirements designed to ensure that no StarLink™ grain would enter the human food supply.

Following registration, relatively small quantities of StarLink™ were planted in the United States: 9,018 acres in 1998; 247,694 acres in 1999; and 350,000 acres in 2000, with the largest planting representing less than half a percent of the total acreage planted to corn in the United States. (Approximately 70 to 80 million acres of corn were planted in the U.S. in 1998 through 2000.)

In September 2000, residues from StarLink™ were detected in taco shells, indicating that it had entered the human food supply. In response to these detections, Aventis requested cancellation of the StarLink™ registration, and the Food and Drug Administration (FDA) recommended that dry grain mills processing yellow corn test for the presence of Cry9C. More than 4 million tests on 4 billion bushels of corn were performed from the time FDA first issued its recommendations and 2007, and there has not been a verified positive test of yellow corn for dry milling in the marketplace since 2003.

Laboratory testing using more sensitive test methods occasionally gives positive results at or near the level of detection for the analytical method. Such positive results may be from traces of corn dust or soil containing naturally occurring proteins that are either Cry9C or so similar to Cry9C that they give false positives due to limitations in the analytical method. In any case, if the positive detections are StarLink-derived Cry9C, the levels in the corn supply in 2007 are less than that determined to be acceptable for the wet milling process of corn grain allowed since 2001.

EPA Recommends to Cease Monitoring for StarLink™

- [Summary of Final White Paper on StarLink™ Corn](#)
- Federal Register Notice [EPA-HQ-OPP-2007-0832](#); [FRL-8145-7](#) EPA Final White Paper Regarding StarLink™ Corn Dietary Exposure and Risk;
- Regulations.gov Docket ID: [EPA-HQ-OPP-2007-0832](#) [EPA White Paper Regarding StarLink Corn Dietary Exposure and Risk \(PDF\)](#) (45 pp, 364 K, [about PDF](#))

Science Advisory Panel (SAP) information

The Scientific Advisory Panel (SAP) reviewed scientific information concerning StarLink Corn™. Information from SAP meetings is provided here:

- February 29, 2000 - [Food Allergenicity of Cry9C Endotoxin and Other Non-digestible Proteins](#)
- November 28, 2000 - [Assessment of Scientific Information Concerning StarLink™ Corn](#)
- July 17-18, 2001 - [Assessment of Scientific Information Concerning StarLink™ Corn](#)