

ENVIRONMENTAL PROTECTION AGENCY**[EPA-HQ-OPP-2007-0832; FRL-8358-7]****EPA White Paper Regarding StarLink® Corn Dietary Exposure and Risk; Availability****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: EPA is making available a final White Paper that reviews data on the level in the human food supply of Cry9C protein from StarLink® corn grain. It concludes that the protein has been sufficiently removed from the human food supply to render the level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no added public health protection. The White Paper therefore recommends that the Food and Drug Administration (FDA) withdraw its guidance recommending testing yellow corn grain for Cry9C at dry mills and masa production facilities. Concurrent with this notice, FDA is publishing a notice in the **Federal Register** withdrawing their guidance.

FOR FURTHER INFORMATION CONTACT: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8715; fax number: (703) 308-7026; e-mail address: mendelsohn.mike@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer or food manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to

certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0832. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>.

II. Background

EPA is making available a final White Paper that reviews data on the level in the human food supply of Cry9C protein from StarLink® corn grain.

The Agency notified the public regarding the availability of a draft version of the White Paper in the October 17, 2007 **Federal Register** (72 FR 58978) (FRL-8145-7), with a docket identification number of EPA-HQ-OPP-2007-0832. The open comment period from October 17, 2007 to December 3, 2007, was held to allow members of the general public to submit letters and/or documents to the Agency on this White Paper. The Agency received comment from the North American Export Grain Association, Inc., the Corn Refiners Association, the Biotechnology Industry Association (BIO), the National Grain and Feed Association, the U. S. Grains Council, the North American Millers’ Association, the Food Corn Industry Coalition, the National Corn Growers, and two unsigned comments. These comments are addressed in the final White Paper.

The final White Paper concludes that the Cry9C protein has been sufficiently removed from the human food supply to render the level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no added public health protection. The final White

Paper therefore recommends that FDA withdraw its guidance recommending testing yellow corn grain at dry mills and masa production facilities. A full copy of the final EPA White Paper is available in docket EPA-HQ-OPP-2007-0832.

List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests.

Dated: April 21, 2008.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2008-D-0229 (formerly Docket No. 2001D-0025)]

Guidance for Industry on the Food and Drug Administration Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance document entitled “FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues.” FDA is withdrawing its guidance in response to the release by the Environmental Protection Agency (EPA) of its final “White Paper Concerning Dietary Exposure to Cry9C Protein Produced by STARLINK Corn and the Potential Risks Associated With Such Exposure,” the availability of which is announced elsewhere in this issue of the **Federal Register**.

DATES: April 25, 2008.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin or Samir Assar, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1639 or 301-436-1636, respectively.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 22, 2001 (66 FR 6627), FDA announced the availability of a guidance document entitled “FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues.” Cry9C is a pesticidal protein in the STARLINK variety of yellow corn that makes the corn more resistant to certain types of insects. EPA authorized STARLINK corn only for use in animal feed. EPA did not authorize the use of STARLINK corn in human food because of unresolved questions about the allergenic potential of the Cry9C protein. Although restricted to animal food use, some STARLINK corn was commingled with yellow corn intended for human use. In addition, in certain limited cases, the Cry9C protein was also detected in corn seeds of a non-STARLINK variety of corn or in corn from such seeds. In response to these findings, Aventis S.A. (the developer of STARLINK corn), EPA, FDA, the U.S. Department of Agriculture, and the food industry undertook efforts starting in 2000 to remove all STARLINK corn from the food supply. Among other measures, FDA issued guidance recommending that corn dry milling and masa operations screen yellow corn (and milled yellow corn in certain situations) to minimize the production of human food products with corn containing the Cry9C protein. Corn containing the Cry9C pesticide is adulterated under

section 402(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(2)(B)) if such corn is for human food use because there is no tolerance or exemption from the need for a tolerance under section 408 of the act (21 U.S.C. 346a). Therefore, FDA recommended that manufacturers who detected Cry9C-containing corn in any lot should divert the lot to animal feed or industrial use.

In the **Federal Register** of October 17, 2007 (72 FR 58978), EPA announced the availability of its draft “White Paper Concerning Dietary Exposure to Cry9C Protein Produced by STARLINK Corn and the Potential Risks Associated with Such Exposure” (draft White Paper), in which it concluded that the Cry9C protein has been sufficiently removed from the human food supply to render the level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no additional human health protection. EPA reached that conclusion based on information including results from more than 4 million tests for Cry9C at corn handling operations over the past 7 years and an exposure assessment by Exponent, Inc., of the levels of Cry9C still present in the U.S. food supply. Based on its analysis, EPA recommended in its draft White Paper that FDA withdraw its guidance on the sampling and testing of yellow corn grain for Cry9C at dry mills and masa production facilities.

In response to the EPA recommendation that FDA withdraw its

guidance on the sampling and testing of yellow corn grain for Cry9C at dry mills and masa production facilities (72 FR 58978), FDA announced that it was seeking comment on whether to withdraw its guidance document entitled “FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues” (72 FR 58980, October 17, 2007). FDA received five comments, all from trade associations, that supported withdrawal of the guidance document.

In its final “White Paper Concerning Dietary Exposure to Cry9C Protein Produced by STARLINK Corn and the Potential Risks Associated With Such Exposure,” EPA continues to recommend, as reflected elsewhere in this issue of the **Federal Register**, that FDA withdraw its guidance. Based on EPA’s recommendation, the comments that FDA received that support withdrawal of the guidance, and its own evaluation of these circumstances, FDA is withdrawing its guidance document entitled “FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues.”

Dated: April 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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