ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2007–0832; FRL–8145–7]

EPA Draft White Paper Regarding StarLink® Corn Dietary Exposure and Risk; Availability for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is seeking comment on a draft 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, the FDA is publishing for comment a notice in the **Federal Register** that FDA is considering withdrawing its guidance.

DATES: Comments must be received on or before December 3, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2007–0832, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2007–0832. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available in regulations.gov. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. 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 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.

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 anagricultural 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. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a

Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

What Action is the Agency Taking?

EPA is seeking comment on a draft 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. StarLink® refers to a variety of corn genetically engineered to express the protein Cry9C. Because Cry9C is toxic to various insect pests of corn, Cry9C acts as a pesticide and was regulated by the U.S. Environmental Protection Agency (EPA or Agency) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Under FIFRA and FFDCA, a company seeking to sell or distribute a pesticide must submit data demonstrating that it will not cause unreasonable adverse effects on the environment and that any residues in food will be safe, i.e., there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

Aventis Agroscience, Inc. (Aventis) submitted data on the safety of StarLink® and applied for approvals under FIFRA and FFDCA. EPA concluded that the available data did not provide enough information to support a conclusion that Cry9C was not a potential human allergen, but that all other information indicated that it 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 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 entered 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.

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, *http://www.epa.gov/fedrgstr/EPA-PEST/2001/January/Day-18/p1522.htm*. In addition, working with U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), EPA, and the food industry, Aventis undertook a program to remove all StarLink® from the food supply. Among other measures, FDA recommended that facilities engaged in the dry milling or masa production of yellow corn test all incoming shipments of yellow corn for the possible presence of Cry9C and that they divert all shipments testing positive to domestic feed or industrial use.

At the same time, Aventis also requested that EPA reconsider its position that the available data did not provide enough information to support a conclusion that Cry9C was not a potential human allergen. Aventis provided additional data and analysis to support its position that the allergenic risks of Cry9C were very small. Most of the arguments advanced by Aventis involved the assertion that exposure to Cry9C was so low, especially after the full implementation of the containment and removal program, that there would be no threat to public health. In 2000 and 2001 EPA held a series of meetings of its FIFRA Scientific Advisory Panel (SAP or Panel) to evaluate the scientific issues raised by the new data, analysis, and arguments.

Following the cancellation of the StarLink® registration, Aventis established a separate corporate entity, StarLink Logistics Inc. (SLLI), as the successor to Aventis' interest in StarLink® products. SLLI oversees the StarLink®. Enhanced Stewardship Program, through which SLLI and the U.S. corn millers have continued the efforts to contain and remove Cry9C from the human food supply. SLLI also maintains a monitoring database containing the test results from more than 4 million tests from over 4 billion bushels of corn collected by dry milling facilities and other corn handling operations. These tests were carried out according to guidance developed by FDA and USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA), and the federal government considers the data reliable.

In 2005, SLLI commissioned Exponent, Inc., to prepare a new exposure assessment of the levels of Cry9C present in the U.S. food supply for submission to EPA. SLLI provided supplemental information in 2006 that updates the 2005 exposure assessment and that quantitatively characterizes the impact of the monitoring and diversion program on exposure to Cry9C. The USDA's Agricultural Research Service (ARS) provided the analytical data on Cry9C concentrations in corn grain used in Exponent's exposure analysis. In addition, the ARS provided results from testing corn seeds from the 1970s and 1980s (that is, before Cry9C was ever bioengineered into corn) for the possible presence of naturally occurring Cry9C or other proteins that give a positive reaction in the Cry9C test. GIPSA conducted additional testing to verify the results of the ARS laboratory.

The draft EPA White Paper 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 FDA withdraw its guidance recommending testing yellow corn grain for Cry9C at dry mills and masa production facilities. A full copy of the draft EPA White Paper is available in the docket and at *http://www.epa.gov/pesticides/biopesticides/pips/star-link-white-paper.pdf*.

List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests.

Dated: October 3, 2007.

James B. Gulliford,

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

[FR Doc. E7–20381 Filed 10–16–07; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0025 (formerly Docket No. 01D–0025)]

Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Comments on Possible Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is 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.'' FDA is considering withdrawing its guidance in response to the release by the Environmental Protection Agency (EPA) of a draft ''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: Submit written or electronic comments by December 17, 2007.

ADDRESSES: Submit written comments on this notice to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

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 issued final guidance for industry 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 United States 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.

EPA has developed a draft ''White Paper Concerning Dietary Exposure to Cry9C Protein Produced by STARLINK Corn and the Potential Risks Associated with Such Exposure'' (draft White Paper), which it is making available for comment elsewhere in this issue of the **Federal Register**. In the draft White Paper, EPA 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 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 recommends 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.

FDA is now 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.''

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: September 6, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–20379 Filed 10–16–07; 8:45 am]

BILLING CODE 4160–01–S