FDA Evaluation of Consumer Complaints Linked to Foods Allegedly Containing StarLink™ Corn

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Center for Food Safety and Applied Nutrition

Food and Drug Administration

Introduction

On September 19, 2000, FDA began receiving a cluster of reports from consumers alleging adverse events linked to foods allegedly containing StarLink™ corn. The initial reports of this cluster were received a day after an article appeared in *The Washington Post* (September 18, 2000) announcing that traces of StarLink™ corn had been detected in grocery store Kraft brand Taco Bell taco shells. When the cluster of reports was noted, FDA checked previous consumer complaints received and found two reports alleging adverse events linked to corn products, one each in July and August of 2000. No connection to StarLink™ was mentioned in either report.

In mid-October 2000, the Environmental Protection Agency (EPA) requested assistance from FDA in assessing the significance of the adverse event reports that both EPA and FDA had received. In late October, soon after the request was made by EPA, FDA contacted the Centers for Disease Control and Prevention (CDC) for assistance in reviewing the adverse event reports received up to that time. On November 8, 2000, FDA formally contacted CDC to recruit their expertise in launching a collaborative effort to study the clinical significance of the adverse event reports. This report summarizes FDA's assessment of the consumer complaints, FDA's role in the collaborative epidemiological effort with CDC, and the results of food product testing for samples collected from individuals who contacted FDA with consumer complaints.

FDA Evaluation of Consumer Complaints

Upon receiving the consumer complaints, FDA logged the reports into a centralized database (Field Accomplishments and Compliance Tracking System, FACTS). One or more medical officers then reviewed the reports to attempt to assess the likelihood that the consumer's illness resulted from a true allergic reaction. To make this assessment, medical professionals reviewed the forms for the following information: the exact symptoms reported; the time period between eating the food and the onset of symptoms; whether treatment was obtained and, if so, the nature of the treatment; and the course of the illness. The medical officers then assigned a rating of "compatible", "unlikely", or "unknown" for the likelihood that the reactions were allergic in nature.[1] For cases that were consistent with an allergic reaction, further work was needed to determine whether the possible allergic reaction was likely to have been triggered by ingestion of a corn product or by other possible causes and, if consistent with consumption of a corn product, whether the corn products consumed actually contained any StarLink™ corn.

FDA requested CDC's assistance in reviewing the complaints, and then, with CDC, launched a collaborative study of the clinical significance of the adverse event reports. The collaborative study was limited to those consumer complaints reporting adverse events occurring between July 1 and November 30, 2000. (Some of these complaints were submitted to FDA as late as December 11, 2000.) CFSAN medical officers submitted blinded copies of the consumer

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1 A number of different symptoms can raise suspicion that a reaction is allergic in nature. The most common IgE-mediated food hypersensitivity symptoms include gastrointestinal symptoms (vomiting and/or diarrhea), urticaria (hives), angioedema (swelling of the throat), rhinitis (runny nose), asthma, and even anaphylaxis.

complaints (i.e., reports with personal identifiers removed) to the Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC. FDA re-contacted all consumers who had submitted adverse event reports to FDA to request authorization to forward their names, addresses, and telephone numbers to CDC. For those who provided such authorization, a copy of the consumer complaint with personal identifiers was subsequently sent to CDC.

FDA continued to receive and evaluate consumer complaints in 2001, however, these reported adverse events did not occur within the time frame of the collaborative study and of CDC's case definition[2] (July 1 through November 30, 2000). Therefore, by mutual agreement, these later consumer reports were not forwarded to CDC.

Efforts to find additional consumer complaints were made through trade associations. In late October and early November 2000, FDA, EPA, and USDA jointly sent letters to various trade associations requesting their member companies to submit to FDA any information in their possession pertaining to possible allergic reactions reported by consumers that could have been related to the presence of StarLink™ corn in processed food. Insufficient data were presented in some of these submissions to allow follow-ups to be conducted in a manner parallel to that for reports that were submitted directly to FDA by consumers. For example, critical data, such as names, contact information and description of symptoms, were often missing. Consequently, consumer complaints obtained through these routes for which critical data were missing were not included in FDA's FACTS database, nor could they be evaluated for compatibility with an allergic reaction. In addition, some of the submissions received through EPA or in response to EPA FR Notice PF-867B lacked critical information, and also were not included in FACTS; these are summarized separately, below. Submissions that included names and contact information for complainants were included in the FACTS database.

Consumer Complaints—FDA's Evaluation

FDA continues to receive, track and evaluate consumer complaints. As of June 12, 2001, FDA has logged into FACTS 63 consumer complaints related to the alleged presence of StarLink™ food (Figure 1). The earliest consumer complaint, as discussed above, was received on July 25, 2000, and the most recent was received on April 20, 2001. The 63 complaints were ranked by medical officers as follows for compatibility of symptoms with those of a true allergic reaction:

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2 Case definition: "An adverse health event which occurred 1 July through 30 November 2000, temporally linking corn product consumption to anaphylactic symptoms within 1 hour of eating, dermatologic symptoms within 12 hours of eating, or gastrointestinal symptoms within 12 hours of eating. Excluded were those with gastrointestinal symptoms if more than one member of the group experienced similar symptoms after a common meal, considering these more likely due to an infectious or toxic foodborne etiology than to a food allergic reaction." (Winterton et al. 2000—EIS Meeting presentation slides).

- 37 (59%) were "compatible" with symptoms of allergic reaction;
- 12 (19%) were "unlikely;" and
- 14 (22%) were "unknown."

As of June 12, 2001, seven of the reports that were received through EPA, from industry, or in response to EPA FR Notice PF-867B, and that could be evaluated, were noted in our files, but were not included in FACTS. These 7 complaints were ranked by medical officers as follows for compatibility of symptoms with those of a true allergic reaction:

- 5 (63%) were "compatible" with symptoms of allergic reaction; and
- 2 (25%) were "unknown".

FDA also received four reports through industry for which critical information was missing, and thus these reports could not be evaluated.

Epidemiological Collaborative Study

The EPA FIFRA Scientific Advisory Panel, during their November 28 meeting, supported CDC's proposal to further address the clinical significance of the reported adverse events by utilizing a detailed questionnaire, obtaining medical records, as appropriate, and collecting blood samples for further testing with a still-to-be developed test.

FDA's involvement in the plan CDC had proposed involved developing a test to detect antibodies to Cry9C protein in human serum samples, and finally, to test the samples. Initially, FDA considered contracting with an outside laboratory to develop the method for testing, as well as to analyze the serum samples. Actual or apparent conflicts of interest on the part of some of the outside laboratories considered precluded their use. Additional considerations of timeliness and availability of qualified personnel led to FDA's decision to do the work in-house.

FDA then proceeded to develop a laboratory method to detect antibodies to Cry9C protein in animal (goat) serum and then adapted it to analyze human serum samples for the type of antibody (IgE) that would be most indicative of the potential for an allergic reaction to the Cry9C protein. The assay developed was an enzyme-linked immunosorbent assay (ELISA). When the assay was developed, CDC submitted coded serum samples to FDA for analysis. FDA analyzed the coded serum samples using the newly developed method. In addition, an independent laboratory of the University of Maryland repeated testing of the coded serum samples. Results were sent to CDC for decoding and analysis. Details of method development and the results of serum testing are presented in a separate report.

Food Sample Collection and Analysis

Under the direction of FDA's Division of Emergency and Investigational Operations (DEIO), FDA field personnel collected a total of eleven food samples from ten consumers who reported symptoms that FDA medical officers deemed were compatible with allergic reactions. For one of the consumer complaints, two physical samples were collected; one sample consisted of an

open container of cereal collected from the consumer, while a second unopened box of the same cereal was purchased from a local grocery store for analysis. The consumers who provided food samples also consented to have their contact information forwarded to CDC to be included in the collaborative epidemiological study, except for one person whom FDA could not re-contact for this authorization.

The food samples collected (three samples of corn cereals, one sample of taco shells, three samples of tortillas, and four samples of tortilla chips) were submitted to the Center for Food Safety and Applied Nutrition (CFSAN), the Pacific Regional Lab - Northwest (PRL-NW), or the Southeast Regional Lab (SRL) where they underwent polymerase chain reaction (PCR) testing for the presence of *cry9c* DNA, the gene encoding the pesticidal Cry9C protein. In addition, most of the samples were tested for the presence of Cyr9C protein using a recently validated EnviroLogix ELISA kit. Details regarding both of these methods are presented elsewhere. The last sample collected (# 124952) is still being analyzed using both methods.

As of June 12, 2001, StarLink™ corn has not been detected in any of the ten food samples tested using the PCR methodology (Table 1). In addition, Cry9C protein was not detected in eight of the nine samples tested using the ELISA method. As noted in Table 1, FDA considers the result for one sample inconclusive because the result was close to the estimated level of detection for the method; the inter-laboratory validation study did not address this specific region. Material was not available for testing one sample. CDC was informed initially of the results of the testing of the first ten samples during phone conversations, and was informed more formally on June 1, 2001.

Table 1 Consumer Samples of Processed Food Analyzed for StarLink™ Corn

FDA Complaint Number	FDA Sample Number	Product	Product Lot Number	PCR Test Result	EnviroLogix ELISA Test Result
BLT-5197	65819	Kelloggs Corn Flakes (consumer)	-	Not detected	Not detected
BLT-5197	67988	Kelloggs Corn Flakes (store)	KLC 001	Not detected	Not detected
746	103311	Kraft Taco Bell Brand Taco Shells	07DEC002XSB7	Not detected	Not detected
SAN-2578	103968	La Cumplidora Corn Tortilla, non-consumed home made chicken enchilada	-	Not detected	Not detected
136	104671	Don Pancho Authentic Mexican Foods Corn Tortillas	Consumer removed lot code	Not detected	NT*
275	105055	Santitas White Corn Tortilla Chips	Dec51.7913229055	Not detected	Not detected
SEA-7552	107254	Kraft Taco Bell Brand Home Style Originals	09NOV001XSB7	Not detected	Inconclusive**
480	110194	Doritos Nacho Cheese Flavored Tortilla Chips	56525214/DORI-0014C**2379	Not detected	Not detected
765	110939	Tyson Mexican Original Enchilada Style Corn Tortilla	Use by Nov 02 00 506	Not detected	Not detected
291	117019	Kelloggs Crispix Cereal	2001 KLC 007 Exp. 7/31/01	Not detected	Not detected
3228	124952	KASH N' KARRY White Corn Tortilla (Chips)	May2301HAS	In analysis	In analysis

* NT: Not tested using the EnviroLogix ELISA kit because no sample remained.

** Inconclusive: Close to the estimated level of detection. The inter-laboratory validation study did not address this specific region.

Reference

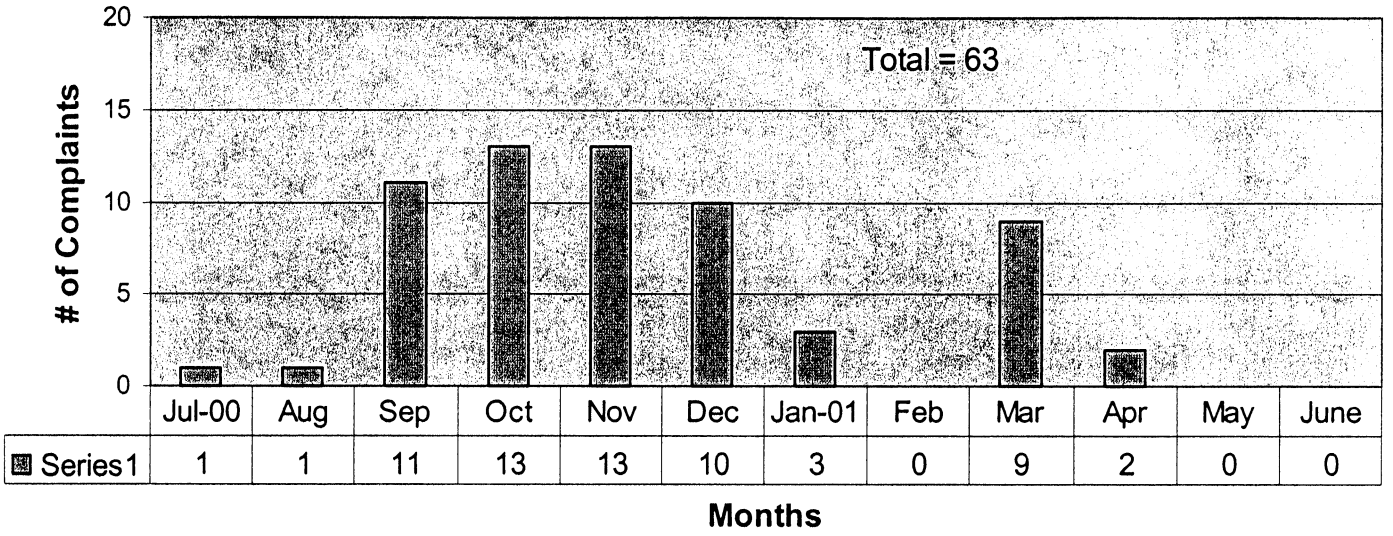
Environmental Protection Agency. PF-867B. Assessment of Scientific Information Concerning StarLink Corn Cry9C Bt Corn Plant-Pesticide; Notice; 65FR 211:65245-65251, October 31, 2000.

Figure Legend

Figure 1:
Top: Tracking of Cry9c Consumer Complaints Received by FDA as of 6/12/01
Bottom: Cry9C Consumer Complaints from Industry, EPA, or EPA FR Notice, (Not Included in FACTS), as of 6/12/01

Figure 1.

Tracking of Cry9c Consumer Complaints Received by FDA as of 6/13/01



CRY9c Consumer Complaints from EPA, or EPA FR Notice as of 6/13/01 (not included in FACTS)