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Part VI

Environmental Protection Agency

Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant–Pesticide; Notice

ENVIRONMENTAL PROTECTION AGENCY

[PF–867B; FRL–6754–3]

Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-Pesticide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On October 25, 2000, Aventis CropScience (Aventis) submitted new information in support of its petition (PP 9F5050) for an exemption from the requirement of a tolerance for the genetically engineered ''plant-pesticide'' materials in StarLink corn. These materials are the *Bacillus thuringiensis* subsp. *tolworthi* Cry9C protein and the genetic material (DNA) necessary for the production of this protein. While the original petition requested an exemption covering both the Cry9C DNA and Cry9C protein in all food commodities, this submission limits the request only to foods made from StarLink corn. The Aventis submission specifically addresses the potential allergenicity of the Cry9C protein that may be present in human food made from StarLink® corn, a line of genetically modified corn developed by Aventis. This notice provides information on Aventis' submission and outlines the U.S. Environmental Protection Agency's process for seeking public comment on and external scientific review of the new information.

DATES: Comments, identified by docket control number PF–867B, must be received on or before November 27, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–867B in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Paul Lewis, Office of Science Coordination and Policy (7101C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5369; fax number: (703) 605–0656; e-mail address: hutton.phil@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are technical experts in human allergenicity, as well as those persons who produce or handle corn grain or processed food made from corn grain. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Biopesticide Internet Home Page at http://www.epa.gov/pesticides/biopesticides. The EPA Biopesticide Internet Home Page will, at a minimum, contain the body of Aventis' October 25, 2000, submission. To access this Notice on the Home Page, select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official docket in connection with this Notice under docket control number PF–867B. Associated public dockets exist for: (1) the initial Notice of Filing for the food use Cry9C tolerance petition, 9F05050 (docket control number PF–867); (2) the notice soliciting public comment on EPA data evaluation records, questions within an EPA background document regarding the use of amino acid homology, the Brown Norway Rat Model, and other items regarding the assessment for potential allergenicity, (docket control number PF–867A); and (3) the February 29, 2000 SAP meeting, (docket control number OPP–00641). The official record for EPA's review of the Aventis petition will include, in addition to the documents in the dockets listed above, any materials submitted to EPA in connection with this **Federal Register** Notice, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–867B in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–867B. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this

document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

Today, EPA is announcing the receipt and public availability of a submission from Aventis concerning its pending petition to establish an exemption from the requirement of a tolerance for the genetically engineered ''plant-pesticide'' materials in StarLink corn. These materials are the *Bacillus thuringiensis* subsp. *tolworthi* Cry9C protein and the genetic material (DNA) necessary for the production of this protein. The requested exemption would cover both the Cry9C DNA and Cry9C protein in all food commodities. In addition, EPA is inviting public comment on the submission as it relates to the petition. Further, EPA is announcing its intention to hold a public meeting of an independent, external scientific peer review group during the week of November 27 – December 1, 2000, to consider the potential allergenicity of Cry9C.

The following paragraphs provide background on the matters being announced today.

1. *Regulatory history*. On April 7, 1999, EPA announced the receipt of a pesticide petition (PP 9F5050) (64 FR 16965) (FRL–6069–8) from AgrEvo USA Company; (Aventis has since succeeded to the interests of AgrEvo USA Company; also, this petition superceded a petition for an exemption that was submitted in 1997 by AgrEvo at the time AgrEvo initially applied for registration.) The petition, 9F5050, proposed an amendment to 40 CFR 180.1192 to expand the exemption from the requirement of a tolerance for *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn. At that time and currently, the existing exemption covered these substances in corn, only when the corn was used for animal feed, and in meat, poultry, milk, or eggs resulting from animals fed such feed. The petition sought to extend the exemption for these substances to all food commodities.

EPA completed its initial review of the data submitted in support of this petition and solicited public comment on the data evaluation records and on a list of questions regarding human allergenicity assessment for non-digestible proteins expressed as plant-pesticides (64 FR 74152, December 21, 1999) (FRL–6098–2). The evaluation of potential human allergenicity of non-digestible proteins expressed as plant-pesticides was also the subject of a February 29, 2000, FIFRA Scientific Advisory Panel (SAP) meeting (65 FR 5636) (FRL–6490–6). The SAP report was issued on June 29, 2000 and the SAP ''* * * agreed that based on the available data, there is no evidence to indicate that Cry9C is or is not a potential food allergen.''

In September of this year, the Cry9C DNA was first detected in processed food made from corn, indicating that Star-Link corn had been used directly in it's manufacture, contrary to the restrictions on the Aventis registration for StarLink corn. Following confirmation of this detection, the food product in which the Cry9C DNA had been detected was recalled by the manufacturer. Additional detections and recalls followed. On October 12, 2000, EPA announced that Aventis, in response to the Agency's strong urging, had requested voluntary cancellation of its registration for StarLink corn. Available information indicates that some portion of the 1999 StarLink crop entered the human food supply, but there is uncertainty about how much. Due to concerns that StarLink corn from the 2000 growing season might also directly enter the food supply, the U. S. Department of Agriculture took steps to bring all available StarLinkTM corn under its control. While these efforts continue, to date, USDA has successfully located and imposed controls on at least 88% of the 2000 StarLink crop; the government is confident that this portion of the 2000 StarLink corn crop is being handled so that Cry9C DNA and protein will not enter the human food supply. Nevertheless, there remains concern about the potential presence of the Cry9C protein in human food.

2. *Aventis submission concerning allergenicity*. Aventis has expressed its continuing interest in an exemption for the presence of Cry9C (DNA and protein) in human food. Given the actions that assure no future planting of StarLink corn, however, Aventis has narrowed the scope of its original petition. While the original petition requested an exemption covering both the Cry9C DNA and Cry9C protein in all food commodities, this submission limits the request only to foods made from StarLink corn. In addition, Aventis has asked that the exemption be granted only for a limited time of 4 years, which time, Aventis contends, is necessary to allow all processed foods potentially made from StarLink corn grown in 1999 or 2000 to pass through the channels of trade.

To support its contention that Cry9C is safe for human consumption for this period, Aventis has submitted new information regarding the potential allergenicity of the Cry9C protein that may be present in StarLink® corn. The Aventis submission contains an ''Introduction'' which appears to summarize the contents of the remainder of the document. This Introduction, which does not reflect the Agency's position, is reprinted below.

Introduction from Aventis Submission

A. Background

StarLink® corn was registered in 1998 for use by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use as animal feed and for industrial uses (production of ethanol, for example). In granting that registration, EPA concluded that Cry9C protein and related DNA met the safety standard under the FQPA for use in field corn for animal feed use. That is, EPA

concluded that ''based on the toxicology data cited and the limited exposure expected with animal feed use, there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children'' (U.S. EPA Bt Plant-Pesticides Biopesticides Registration Action Document, page IIB18, EPA Scientific Advisory Panel (SAP) website, October 2000 science assessment document). The EPA and the EPA's SAP were not able to conclude that the Cry9C protein was or was not an allergen (FIFRA SAP Report, Session I-A Set of Scientific Issues being Considered by the Environmental Protection Agency Regarding: Food Allergenicity of Cry9C Endotoxin and other Non-digestible Proteins, page 8, June 2000) and, thus, registration for human food use has not yet been granted.

StarLink® corn is a variety of corn modified through traditional and well-recognized techniques of genetic modification to contain the plant-pesticide *Bacillus thuringiensis* (''Bt'') subspecies *toliworthi* Cry9C protein and the genetic material necessary for the production of the protein (DNA). Bt proteins have insecticidal properties and have been used commercially for more than 30 years. Among these products are microbial sprays (Agree, XenTari) with the Cry9B protein, which is highly homologous with the Cry9C protein. Corn plants with the Bt protein have been widely and safely used for a number of years. These products thus have a long history of safe use.

Pursuant to the registration, StarLink® corn was planted in 1998, 1999 and 2000. Approximately, 10,000 acres were planted in 1998, 250,000 acres were planted in 1999, and 350,000 acres were planted in 2000 out of the approximately 80,000,000 acres of corn planted in the United States in each of those years. Although StarLink® corn was not registered for use in human food, it now appears that through means not well known, not all of the corn has been kept within the scope of the registered uses (animal feed and non-food industrial uses). The significance to human health of the potential presence of the Cry9C protein and/or the DNA in human food is the subject of this analysis. The analysis relies on the best available data and information and conservative assumptions to assess the potential risks to human health, if any.

B. Approach of the Analysis

Human health assessments typically involve an evaluation of the potential hazard of the material in question and an evaluation of the magnitude of potential exposure to the material. The analysis set forth in this document follows that approach.

First, it identifies the material of potential concern. In the case of StarLink® corn, the only component of the corn that presents any potential for human health concern is the Cry9C protein and, only then, with regard to the potential for it to cause an allergic reaction in sensitized individuals. The EPA stated that there are no issues relative to the safety of food containing StarLink other than the potential allergenicity issue.

Concerning the allergenicity question, this assessment provides a comprehensive review of all available information and data and concludes that Cry9C is not an allergen.

After addressing the data and information pertinent to assessing the question of whether the Cry9C protein is likely to be an allergen, the analysis then turns to an assessment of the potential amount of the protein to which humans might be exposed. This analysis takes into account available information about:

(1) The amount of StarLink® corn planted in 1999 and 2000 and the known or probable disposition of that corn.

(2) Quantity of Cry9C protein in corn.

(3) The quantity of corn contained in different food products.

(4) The fate and disposition of Cry9C protein in food.

(5) Quantity of various foodstuffs which contain corn consumed by various population subgroups.

(6) Other relevant data.

This assessment considers the risk of adverse allergic responses as a result of a very low level and temporary dietary exposure to Cry9C protein. The strongly supported conclusion is that Cry9C is not an allergen. Furthermore, the assessment strongly concludes that even if Cry9C protein were allergenic, the low level and temporary exposures would neither sensitize individuals nor elicit an allergic response in sensitized individuals. The full basis for these conclusions is set forth below.

C. Context for the Assessment

In order to evaluate properly the potential human health consequences of the presence of Cry9C protein in human food, one must understand how corn is harvested and how it moves through various steps in the distribution chain before it is ultimately used in the production of food for human consumption. With that information, it becomes apparent that there is substantial dilution at each stage of the movement of corn from the farm to the table. To put it differently, the corn from one field or farm is commingled at each stage of the process with corn from other fields and farms.

This section sets forth a brief summary of that information. A full explanation of whole corn handling and grain processing at dry mills is contained in Appendix 1, Corn Handling and Grain Handling Discussion prepared by the North American Millers Association and the National Feed and Grain Association.

Whole corn handling operations from farm to elevator. Virtually all farmers harvest corn with a combine equipped with a corn header and transfer the harvested grain from the combine to a truck to deliver either to on-farm storage, a feedlot, or a commercial grain elevator. Farm trucks today typically hold 200 to 800 bushels with the average size about 400 bushels.

When the grain is delivered to a local elevator, it is dumped into a pit. From the pit, the grain is normally conveyed via a bucket elevator to the top of grain storage bins where it is dropped to the bottom of the bin, or onto other grain. Bin sizes at country elevators generally range from 10,000 bushels to 1,000,000 bushels with an average of 70,000 to 80,000 bushels.

Throughout this grain handling process, there is a continuous blending and commingling of the corn from any one farm. The farm truck often carries corn taken from different fields on the farm. When the farm truck arrives at the elevator at harvest, it is frequently one of many trucks in line to dump. In the binning of the grain, the contents of each truck are dumped on top of each other in continuous fashion.

As grain is dropped from the top of storage bins at the elevator, the grain forms an inverted conical shape, as the grain enters at the center and flows out to the sides of the bin. There is a ''layering'' effect of the grain from each individual truck.

When the grain is drawn from the bottom of the bin, a different flow pattern develops. The grain flowing out will form a ''core'' in the center. The center portion of the grain bin flows out first, then a cone develops, with the upper portions of the grain flowing out toward the early part of the removal process. As the bin empties, the grain at the sides of the bins starts to flow out of the bottom.

All the truck deliveries used to fill the bin are commingled in the storage/handling process. The degree of mixing of the grain will depend in part on the point at which the truck was dumped. Commingling further occurs as elevators often draw from multiple bins in order to ''blend'' grain for loading into one transport conveyance to meet quality specifications of different customers.

If an average farm truckload of 400 bushels of pure StarLink® corn were to be delivered to an elevator and placed into even a small 10,000 bushel bin, a commingling/dilution of that grain on the order of 3 to 5 times is a conservative expectation, with 3 probably a ''worst case'' situation (Appendix 1, Corn Handling and Grain Handling Discussion prepared by the North American Millers Association and the National Grain and Feed Association).

Grain processing at dry mills. Grain is delivered from elevators to dry corn mills via trucks or rail cars. Trucks typically haul 1,000 bushels with rail cars holding about 3,500 bushels. The initial receiving process is much like that at the elevator, dumping into a pit and elevating grain into storage bins, which hold the grain until it enters the processing stream.

Most dry corn mills are continuous process (rather than batch). Because the grain in a milling operation is being continuously mixed through tempering, milling, and handling, the degree of dilution at any one stage is probably much greater than the factor of three, considered to be the ''worst case'' at the elevator. Assuming conservatively that there are only seven handling and processing operations, each of which is assumed to dilute the grain by a factor of three, suggests that one truckload of pure StarLink® corn would be diluted by several orders of magnitude, prior to reaching the food processor or consumer.

Wet milling. Corn is received at wet milling plants via truck, railcar, or barge. Corn is stored at wet mills in a manner similar to dry mills or grain elevators.

The corn wet milling process separates corn into four basic components: starch, germ, fiber and protein. There are five basic

steps to accomplish this process. All processes in corn wet milling are continuous (rather than batch).

Incoming corn is inspected and cleaned. It is then steeped in a dilute sulfurous acid solution for 30 to 40 hours. This results in the breaking of the starch and protein bonds. The next step in the process involves coarse grind, which separates the germ from the rest of the kernel. Corn germ is subject to mechanical and solvent extraction to remove oil, which is then refined through degumming, alkali treatment, bleaching, winterization, and vacuum steam stripping deoderization. The remaining slurry consisting of fiber, starch and protein is finely ground and screened to separate the fiber from the starch and protein. Fiber is combined with the water from corn steeping to produce corn gluten feed. The remaining starch and gluten are separated into hydrocyclones. The separated gluten is dried to produce corn gluten meal. The remaining starch is repeatedly washed in fresh water. Water from this washing step flows back through the process countercurrently to the flow of corn. The starch is then converted to sweetners or fermentation products or dried and packaged as starch (Blanchard, 1992). Of the wet milled corn, approximately 60 percent is directed toward sweetner production, 25 percent toward alcohol production, and 15% toward starch production. In the latter case 80 percent is directed toward industrial purposes while the remaining 20 percent is used in food starches (Personal communication, Corn Refiners Association).

As in the case of the dry milling discussion, commingling of corn occurs. It is estimated that one truckload of pure StarLink® corn would be diluted by several orders of magnitude, prior to reaching the food processor or consumer. This extensive processing likely leads to, at least, degradation of protein.

D. Safety of Cry9C DNA and DNA Generally

With respect to the safety of Cry9C DNA and DNA in general, EPA has concluded that:

DNA is common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption as components of food. These ubiquitous nucleic acids as they appear in the subject plant pesticide have been adequately characterized by the applicant and supports (sic) EPA's conclusion that no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the Cry9C protein. (63 FR 28259, May 22, 1998).

There is an EPA proposed exemption from the requirement of a tolerance for nucleic acids produced in plants as part of a plant-pesticide (Plant Pesticides; Subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA): Proposed Rule, 59 FR 60505, November 23, 1994). This proposal states:

Residues of nucleic acids produced in living plants as part of a plant-pesticide active or inert ingredient, including both deoxyribonucleic acid and ribonucleic acids, are exempt from the requirement of a tolerance.

More recently, EPA confirmed its views concerning the safety of nucleic acid in its background materials from the October 18–20, 2000 SAP meeting; Biopesticides Registration Action Document: Bt Plant-Pesticides (http://www.epa.gov/scipoly/sap/).

DNA is common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption as a component of food.

In addition, the U.S. Food and Drug Administration (FDA) has also concluded that DNA is generally recognized as safe (1992, FDA Food Policy).

Based on these EPA and FDA statements, the presence of Cry9C DNA in food is not relevant to the safety assessment of StarLink® corn because it is recognized as safe.

E. Assessment of Potential Toxicity of Cry9C Protein

Based on the history of the use of Bt microbial pesticides and available toxicity data on Cry9C protein, it is reasonable to conclude that, other than possible allergenicity, there are no toxicity issues related to the food and feed use of Cry9C protein. EPA concurs with that conclusion.

In the final rule establishing the exemption from the requirement of a tolerance for Cry9C protein and genetic material in feed EPA stated:

Bt microbial pesticides, containing Cry proteins other than Cry9C, have been applied for more than 30 years in food and feed crops consumed by the U.S. population. There have been no human safety problems attributed to the specific Cry proteins. An oral dose of the tryptic core Cry9C protein of at least 3,760 mg/kg was administered to 10 animals without mortality demonstrating a high degree of safety for the protein. (63 FR 28258, May 22, 1998).

The lack of acute oral toxicity of Cry9C protein is consistent with the lack of toxicity and established safety of other Cry class proteins previously approved for use by the Agency. Furthermore, additional toxicity studies submitted to EPA support this conclusion (MRID #44734302 and 44734303). Thus, general toxicity issues are not considered further in this assessment.

F. Assessment of Potential Allergenicity of Cry9C Protein

Given that DNA is recognized as safe, and that there are no general toxicity issues related to Cry9C protein, the only remaining issue relative to the safety of StarLink® corn is the potential allergenicity of Cry9C protein and the associated level of potential risk.

In regard to the use of StarLink® corn in animal feed, the EPA concluded that

The Cry9C protein would not likely cause an allergic reaction to man when used in feed corn because; (1) it was not from allergenic sources and (2) the best available information indicates that edible products derived from animals such as meat, milk and eggs intended for human consumption, have not been shown to be altered in their allergenicity due to changes in the feed stock utilized. (U.S. EPA Bt Plant-Pesticides Biopesticides Registration Action Document, page IIB18, EPA Scientific Advisory Panel website, October 2000 science assessment document.)

This document provides a brief background on food allergy and, drawing on new information and analysis, provides a risk assessment regarding the potential allergenicity for StarLink® corn expressing Cry9C protein in food. A discussion of the new information relevant to the allergenic potential of the Cry9C protein is also included. Based on a review of all available information and data, this assessment concludes that there is a reasonable certainty that Cry9C protein is not an allergen, and is not likely to become an allergen even if there were long-term consumption.

In an independent review by Dr. S.L. Hefle of the Food Allergy Research and Resource Program, University of Nebraska, Dr. Hefle concluded that ''the data shared by Aventis, taken in total, while not conclusive provide evidence that (sic) of low probability of allergenicity of Cry9C'' (Appendix 2). A written statement submitted by Dr. S.L. Taylor of the same organization to EPA's SAP (October 20, 2000) supports this conclusion (Appendix

G. Food Allergens and the Use of the Peanut for Comparison Purposes

Food allergy affects 1–2% of adults and 6–8% of children in the United States (Sampson, H.A. et al., 1996; Metcalfe, D.D. et al., 1996). Protecting food allergic patients from unexpected exposure to food allergens is a critical priority. Food allergy assessments ensure that food allergic patients are protected from unexpected exposure to the allergens that might cause them harm. In addition, food allergy assessment evaluates the potential of any new protein to become a new allergen, and to create a newly sensitized population.

In his written submission to the SAP (October 20, 2000), Dr. S.L. Taylor stated that sensitization to foods requires multiple exposures over an extended time period and at a relatively high percentage of total protein content (Appendix 3).

For StarLink® corn, there is no history of significant consumption, and hence no real potential for allergic sensitization. Furthermore, based on available data and information, the amount of Cry9C protein that could potentially be present in corn products would be present at levels far below those required to cause sensitization. Therefore, it is reasonable to conclude that there are not now and will not be in the future any ''at risk'' consumers. Furthermore, the EPA has previously concluded that after more than 30 years of commercial use of microbial products containing a variety of Cry proteins, including proteins from the Cry9 class, no allergy has been attributed to Cry proteins (McClintock et al., 1995; EPA, 1999).

Most allergenic proteins are present in levels of 1 to 40% of the total protein of the allergenic food (Metcalfe, D.D., et al., 1996; Yunginger, J.W et al., 1997; Li-Chan, E. and Nakai, S., 1989; Murphy, P.A. and Resurrection, A.P., 1984; Kalinski, A. et al., 1990; Carpentier, B.A. and Lemmel, D.E., 1984; Goldberg, R.B. et al., 1983; Burks, A.W.

et al., 1992; Lotan, R. et al., 1975; Crouch and Sussex, 1981). In contrast, there is an extremely low percentage (0.0129%) of the Cry9C protein in StarLink® corn grain (Table 1) (MRID #45025701).

Even lower levels of Cry9C protein might be expected in foods containing corn as an ingredient since, following dry or wet milling, the protein is redistributed into individual commodities. Thereafter food processing exposes the protein to a range of potential degradation procedures which in some instances could completely destroy the protein. In taco shells, for example, no protein was detected (Preliminary Study for Detection of Cry9C Protein in Taco Shells, FIFRA 6(a)(2) report, submitted to EPA on 10/16/00; MRID #44384301 and Analysis of Taco Shells for Cry9C Protein submitted to EPA on 10/24/00).

TABLE 1.—QUANTITIES OF CRY9C PROTEIN IN PROCESSED COMMODITIES OF STARLINK® CORN (CBH351) EXPRESSED AS PERCENT OF CRUDE PROTEIN (MRID #45025701)

Process	Commodity	Crude Protein (All Types) in Matrix (%)[a]	% Cry9C in Crude Protein	
			Transgenic Unsprayed[b]	Transgenic Sprayed[c]
	Whole corn	8.9 – 10	0.0116	0.0129
Dry Mill	Composite Grits	7 – 10.3	0.00861	0.0111
	Hull Material	8	0.0130	0.0163
	Meal	7.5 – 9.0	0.00989	0.0118
	Flour	5.2 – 7.8	0.0149	0.0147
	Solvent Extract Germ	12–25	0.0345	0.0298
	Crude Oil	0	NA[d]	NA
	Refined Oil	0	NA	NA
Wet Mill	Steepwater Concentrate	41–62	0.000034	0.000078
	Hull Material	8	0.00719	0.0146
	Gluten	41–60	0.00015	0.00011
	Starch	0.6	NA	NA
	Solvent Extracted Germ	22.6	0.00056	0.00063
	Crude Oil	0	NA	NA
	Refined Oil	0	NA	NA

[a] Range of data from Wolff, I.A. 1982; Ensminger, M.E. et al., 1990; McGregor, C.A. 1994.
[b]Unsprayed = Not treated with Liberty® Herbicide
[c]Sprayed = Post emergent treatment with Liberty® Herbicide
[d]NA - concentration was below limit of quantitation (LOQ) for these samples.

Since allergy to Cry9C protein does not already exist, the extremely low level of Cry9C protein estimated to be consumed using a reasonable, worst case exposure assessment leads to the conclusion that the Cry9C protein present in StarLink® corn is very unlikely to become an allergen.

Peanuts account for the majority of fatal and near-fatal, food-induced, anaphylactic reactions in the United States (Yunginger JW, et al., 1988; Li, X-M, et al., 2000). About 1.5 million Americans (Li, X-M, et al., 2000) are allergic to peanuts. Given the severity, prevalence, and frequently lifelong persistence of peanut allergy, a comparison of the potential allergenicity of a new protein, such as Cry9C protein, with peanuts, one of the most potent known human food allergens, provides an extremely conservative and protective assessment.

This concludes the quotation of the Introduction from the Aventis submission of October 25, 2000.

3. *EPA Review Process—Public and External Scientific Peer Review.* EPA intends that its decisions involving biotechnology and public health be based on the best available scientific information and expertise. Moreover, EPA is committed to conducting its regulatory decision-making in a transparent and participatory manner. Therefore, EPA has decided it would be prudent to seek independent scientific peer review of the information submitted by Aventis in support of the petition for a time-limited exemption for Cry9C in human food, as well as other available and relevant information.

The Agency has not yet determined who will participate in the peer review group, and therefore cannot set a specific date or location for the public meeting of the peer review group. Pending determination of the availability of experts and meeting space, EPA expects to hold a one or two day meeting during the week of November 27 – December 1 (or possibly earlier)at a location in the Washington, DC metropolitan area. EPA also recognizes that new data may become available in the coming weeks, and the date of the public meeting may need to be adjusted to allow full consideration of all relevant information. As is its practice, EPA will develop and provide to the peer reviewers a ''charge,'' that is a series of questions raising scientific issues on which EPA will seek the members' advice. EPA will also provide to the members various documents as background for the consideration of these issues.

By November 3, 2000, EPA will make available on the web and public docket (PF–867B) the Agency's initial evaluation of the new information, as well as announce the actual peer review meeting date/location and charge to the peer review group. The Aventis

submission is available on our website as of the publication of this notice.

In addition, consistent with its practice and because of the widespread public interest in these particular matters, EPA is providing an opportunity for the public to comment on the Aventis submission. EPA will accept comments submitted on or before November 27, 2000. In order for comments to be considered in the peer review process, EPA does not anticipate granting any requests for an extension of time to comment. As discussed above, during the comment period, EPA also expects to make available additional information that it will be providing to the scientific peer review group. The public is welcome to comment on these materials as well. Finally, EPA will make any public comments available to the members of the scientific peer review group.

In addition, anyone having information concerning any allegations of adverse effects in humans from ingestion of food that may have contained StarLink corn should submit such information for consideration by the government. This information should be sent to: Food and Drug Administration, Office of Field Programs, Division of Enforcement Programs, Outbreak Coordinaiton Staff, HFS-605, 200 C St., SW., Washington, DC 20204. FDA will share this information with EPA as soon as it is received.

B. What is the Agency's Authority for Taking this Action?

The Agency is soliciting input to aid in determining whether there is a reasonable certainty of no harm for the proposed amendment of the existing exemption from the requirement of a tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA). EPA is also acting under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

List of Subjects

Environmental protection, Pesticides and Pests.

Dated: October 27, 2000.

Susan B. Hazen,

Acting Deputy Director, Office of Pesticide Programs.

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