

27 November 2000

Administrator Carol Browner
c/o Public Information and Record 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

**Comments to Docket Control Number PF-867B and Docket Control Number OPP-00678
Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-
Pesticide**

Dear Administrator Browner, *et al.*:

Pursuant to the public notice given at 65 Federal Register 65246 (October 31, 2000), the Center for Food Safety provides the following comments concerning the Environmental Protection Agency's ("EPA" or "Agency") Assessment of Scientific Information Concerning StarLink® Corn Cry9C Bt Corn Plant-Pesticide.

The Center for Food Safety ("CFS") is a public interest and environmental advocacy organization which works to address the impacts of our food production system on human health, animal welfare and the environment. CFS is a member of Genetically Engineered Food Alert, a coalition of organizations which conducted tests confirming (for the first time) the presence of StarLink® Bt corn in foods destined for human consumption. To date, the coalition has positively identified StarLink® in Taco Bell® *Home Originals* Taco Shells, Safeway® brand taco shells, and Western Family Foods taco shells. As a result of StarLink® adulteration, these products, and many more, are currently subject to Class II product recall by the Food and Drug Administration ("FDA").^[1] FDA Enforcement Report, Oct. 4, 2000 and Nov. 1, 2000. CFS expects that the FDA will continue to publish and enforce such recalls so long as StarLink® and Cry9C are detected in the human food supply.

Introduction.

The safety of our food supply is an issue of critical importance to the public. Among the key components in the public of a safe food supply is strict oversight and regulation by the federal government. In the area of genetic engineering, the federal government has been grossly inadequate in its regulatory oversight.^[2] Currently, the Food and Drug Administration's ("FDA") 1992 Policy allows genetically engineered food and food ingredients into interstate commerce without labeling and mandatory analysis of the potential safety risks associated with genetic instability. These risks include increased toxicity, nutritional alterations, impacts on therapeutic antibiotics and the potential for new and novel allergens, the issue currently confronting the EPA.

The EPA should use the StarLink® situation to initiate a federal commitment to properly regulating,

assessing and labeling the agricultural products of genetic engineering. Accordingly, the EPA should not allow Aventis to justify its actions regarding StarLink® in light of the difficult situation that its own conduct has in large measure brought about. A granting of an exemption from tolerance to Aventis for StarLink® and Cry9C would further erode consumer confidence in the government's ability to adequately ensure the safety of our food supply from the potential hazards of genetically engineered food, and more directly it will further establish the precedent that the American public bears the potential health consequences caused by a corporation's misdeeds and a federal agency's unwillingness to uphold its legal mandate to ensure a food supply free of dangerous contaminants.

Accordingly, the Center for Food Safety believes that the Aventis CropScience petition for a four year tolerance exemption for the human consumption of StarLink® corn and Cry9C should not be approved based upon the evidence submitted by Aventis.[3] Additionally, CFS finds, inter alia, the following deficiencies in the EPA's current evaluation of the Aventis information submission:

- (1). Inadequate assessment of the acreage quantity of StarLink® and other Cry9C corn;
- (2). Inadequate assessment of protein sensitization to Cry9C especially in children; and
- (3). Failure to include legally required safety assessment of a ten-fold Cry9C exposure threshold for children.

A failure to rectify these deficiencies means that the EPA cannot make the legal finding that presence of StarLink® and Cry9C creates a reasonable certainty of no harm to the public necessary to grant Aventis a tolerance exemption. Should a tolerance exemption be granted by the EPA, CFS will be compelled to take all legal steps necessary to ensure that U.S. food consumers do not bear the impacts of the Agency's failure to uphold the law.

Finally, the Center for Food Safety believes that the short time provided to assess this information fails to provide the public with a reasonable opportunity to comment on the StarLink® issue. Should the EPA make a final decision concerning the Aventis petition the agency must comply with the law and provide for another sixty (60) public comment period.

I. Erroneous Quantity and Exposure Assumptions.

The data submitted by Aventis and the EPA's Preliminary Evaluation of Information Contained in the October 25, 2000 Submission from Aventis CropScience ("Preliminary Evaluation") underestimated the potential exposure of the public to StarLink® and Cry9C. Both Aventis and the Agency fail to consider the extent to which StarLink® can be spread throughout the environment through routes of seed contamination and/or cross pollination. As such, the quantity of StarLink® corn (or corn containing Cry9C) is underestimated and, thus, potential exposures levels to Cry9C are also underestimated.

On November 21, 2000, Aventis CropScience admitted that Cry9C had been found in a non-StarLink® Garst Seed Co. hybrid produced in 1998.[4] Neither the October 25th Aventis information submission nor EPA's Preliminary Evaluation consider this additional volume of corn containing Cry9C entering the food supply. As a result, the total acreage figures for corn containing

Cry9C is underestimated substantially. At this time, the total acreage of the contaminated Garst Cry9C hybrid is unknown and any attempt to quantify exposure rates to all Cry9C corn cannot be completed. Accordingly, the Agency must revise its exposure figures to accurately reflect the Garst seed contamination issue prior to any analysis supporting a granting of a tolerance exemption to Aventis.

Additionally, the EPA inadequately accounts for potential cross pollination of conventional, neighboring corn fields with StarLink® and the newly found Garst Cry9C hybrid. While the EPA does calculate buffer zone areas as containing a portion of Cry9C, the agency fails to address cross pollination beyond the buffer zones. Recently, the National Academy of Science addressed this issue stating:

Most pollen is deposited within a few meters of its source, but a small proportion can be carried more than 1km away. . . . In addition, the extent of long-distance gene flow is highly variable and depends on local conditions, the relative sizes of donor and recipient populations, and synchrony of flowering. Once pollen from a crop has spread to wild plants, further gene flow occurs in a ripple effect through both pollen and seed dispersal.[5]
(estimate added)

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator--

(i) shall assess the risk of the pesticide chemical residue based on--

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall--

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.(emphasis added)

Both the Aventis submission and EPA's "Preliminary Evaluation of Information Contained in the October 25, 2000 Submission from Aventis CropScienced" ("Preliminary Evaluation") fail to address a number of key questions about protein sensitization in children and do not assess Cry9C exposure scenarios with a tenfold margin of safety.

(1). Protein Sensitization.

The incidence of all allergic diseases appear to be on the increase in industrialized societies.[6] The prevalence of food allergy is much higher for infants and children than adults. The true prevalence of food allergy is believed to be between 2% and 8% for infants and children and approximately 1% for the adult population.[7]

In its submission, Aventis makes an inappropriate assertion that because there is no history of significant consumption of Cry9C there is no potential for allergic sensitization to the protein. 65 Fed. Reg. 65249. This assertion is unsupported and contradicted by other data. As the Agency pointed in its Preliminary Assessment, Hourihane, et al. have shown that even extremely low doses of an allergenic protein can trigger food allergies.[8] If low doses can trigger reactions, such low doses likely can sensitize the population to a potentially allergenic protein. Moreover, Aventis fails to even address the issue of sensitization in infants and children even though the EPA is mandated by law to assess such information when considering an exemption from tolerance.

The early onset of food allergies in children reasonably indicates that repeated exposure to an allergic protein need not occur over a long duration for a child to develop allergic sensitivity. In children, repeated exposure to small quantities of food allergens may lead to recurrence of symptoms and delay resolution of food allergy.[9] And generalized allergic reactions to as little as one drop of milk have been reported in children.[10]

Failure to address adequately the sensitization issue (especially in infants and children) is a fundamental and fatal shortcoming of the Aventis' submission. In making its determination on an exemption, the EPA must address the issue of susceptibility of infants and children to Cry9C residue. 21 U.S.C. § 346a(b)(2)(C)(i)(II). Additionally, the EPA must assess the cumulative effects of Cry9C on infants and children. 21 U.S.C. § 346a(b)(2)(C)(i)(III). Both the Aventis submission data and the EPA's Preliminary Assessment fail to take such actions. Therefore, the granting of a tolerance exemption without such analysis would be an arbitrary and capricious agency action.

(2). Exposure Data.

Similar to the issue of protein sensitization, Aventis provides no information addressing the issue of exposure rates of Cry9C to infants and children. The EPA's Preliminary Evaluation does provide some exposure rate projections for infants and children. See Tables 9-13. However, EPA states that it is providing some estimate exposure rates to infants because of public concern about this age group. Preliminary Assessment, at 20. The Agency should recognize that public concern over infant exposure has resulted in making such assessment data mandatory under law. See 21 U.S.C. § 346a(b)(2)(C)(i)(I).

(3). Precautionary Assessment for Children.

The potential risks of a rushed EPA decision are especially high among sensitive populations such as children. Investigators of food allergies believe that the frequency of fatal and near fatal food-induced anaphylactic reactions has risen over the past several years. With increasing use of protein additives in commercially prepared foods, it is believed that food-induced anaphylactic reactions will continue to rise.[11] While the EPA's Preliminary Assessment have revised upwards the possible exposure rates of StarLink® corn in the human food, the agency has failed to take the additional step of providing a worst case scenario for exposure rates to infants and children. As mandated by law, an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. 21 U.S.C. § 346a(b)(2)(C). In making its final assessment the Agency must

revise the data in Tables 9-13 to reflect an additional tenfold exposure rate. In doing so, the exposure rates for micrograms of Cry9C protein would be revised to range from a high of 170 mcg (Table 9, Children 7-12, 99 percentile) to a low of .8 mcg (Table 13, Children 7-12, 99 percentile). As revised, the potential Cry9C exposure rates of 170 mcg would fall well within the range of amounts that *Hourihane, et al.* found could trigger allergic reactions. Therefore, it would appear that the Aventis cannot present with a reasonable certainty that presence of Cry9C in the human food supply will be safe.

(4). Potential Evidence of Human Health Impacts.

The Agency should also be on notice that there are several public health incidents allegedly associated with consumption of StarLink® and Cry9C. These incidents include the hospitalization of a child for allergic reactions including stomach ache, diarrhea, headache and hives, and other similar reactions. See Attach. 1 and 2. Additional adverse reactions concerning StarLink® and Cry9C have been reported to the Centers for Disease Control and Prevention and the FDA. These incidents must be investigated prior to any agency decision concerning the Aventis petition. An epidemiological study of these events may reveal specific concerns with Cry9C such reactions in particularly susceptible populations like children, elderly or immuno-suppressed communities.

III. Procedural Failures and Issues.

A. Assessment Review Process Has Failed to Provide Meaningful Ability to Comment.

CFS again expresses its concern over the Agency's October 31st Notice. The Agency's process for regulatory reconsideration of Aventis' petition for an exemption of a tolerance for foods made from StarLink® corn, *inter alia*, fails to provide the public with a meaningful opportunity to comment on this matter. In order to address these shortcomings in the EPA's process, we again request that the EPA take the following actions: (1) provide for public access to all information upon which the EPA's review will take place; (2) extend the public comment period to ninety (90) days; (3) begin the tolling of such a comment period after all information concerning the StarLink® review is publicly available; and (4) take other steps to ensure public representation in the review process.

Despite the Agency's response letter received on November 24, 2000, CFS again strongly urges the EPA to grant the requests outlined above, otherwise the validity of EPA's decision on the matter would be subject to challenge because of potential violations of the APA. 5 U.S.C. § 553 (2000). Courts have repeatedly recognized the laudable goals of § 553's notice and comment requirement to increase public participation and fairness in agency decisionmaking. The law is well settled that the APA requires the EPA "to provide notice of its proposed rulemaking adequate to afford 'interested parties a reasonable opportunity to participate in the rulemaking process.' Such notice must not only give adequate time for comments, but also must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." *Florida Power & Light Company, et al. v. NRC*, 846 F.2d 765, 771 (D.C.Cir. 1988). *See also, Connecticut Light & Power Co. v. NRC*, 673 F.2d 525, 530-31 (D.C.Cir.), cert. denied, 459 U.S. 835, 103 S.Ct. 79, 74 L.Ed.2d 76 (1982); *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (D.C.Cir.), cert. denied, 434 U.S. 829, 98 S.Ct. 111, 54 L.Ed.2d 89 (1977).

B. Any Granting of a Tolerance Exemption Requires Rulemaking

The Center for Food Safety does not consider that the notice and comment provided in the Federal Register concerning StarLink® on October 31, 2000 and November 7, 2000, satisfy the procedural requirements for EPA to issue an exemption of tolerance to Cry9C. Should EPA make an arbitrary and capricious decision to grant Aventis a tolerance, the Agency must still proceed with a rulemaking and formal notice and comment period. Such a requirement are statutory. In pertinent part the statute states:

(A) In general. The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator--

Accordingly, CFS expects the Agency to comply with this notice and comment prior to the

tolerance exemption for the human consumption of StarLink® corn and Cry9C should not be approved based upon the evidence submitted by Aventis. Additionally, CFS finds, inter alia, the following deficiencies in the EPA's current evaluation of the Aventis information submission:

- (1). Inadequate assessment of the acreage quantity of StarLink® and other Cry9C corn;
- (2). Inadequate assessment of protein sensitization to Cry9C especially in children; and
- (3). Failure to include legally required safety assessment of a ten-fold Cry9C exposure threshold for children.

A failure to rectify these deficiencies means that the EPA cannot make the legal finding that presence of StarLink® and Cry9C creates a reasonable certainty of no harm to the public necessary to grant Aventis a tolerance exemption. Should the EPA grant a tolerance exemption to Aventis, CFS will be compelled to seek other means to redress its concerns over the StarLink® issue.

Respectfully submitted,

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Attatch