

30 August 2001

Public Information and Records Branch (PIRIB)  
Information Resources and Services Division (7502C)  
Office of Pesticide Programs (OPP)  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

RE: Docket No. 00678B

To Whom It May Concern:

As directed by the public notice entitled "Announcement of Public Meeting; Opportunity to Comment on Implications of Revised Bt Crops Reassessment for Regulatory Decisions Affecting These Products, and on the Potential Elements of Regulatory Options,"<sup>1</sup> the Center for Food Safety (CFS) submits the following comments and attachments to the Environmental Protection Agency ("EPA" or "Agency"). These comments supplement other oral and written comments made by CFS, and the Genetically Engineered Food Alert coalition, in various EPA fora concerning the registration, use and safety of genetically engineered Bt crops (hereinafter "Bt Crops").

CFS believes that the EPA does not have the proper data available to support the re-registration of any genetically engineered Bt crop. The Agency's "Biopesticides Registration Action Document" ("BRAD") has, *inter alia*, failed to (1) adequately assess the human health risks associated with the Bt crops; (2) thoroughly engage in environmental review, including compliance with the consultation requirements of the Endangered Species Act, (3) fully incorporate data about non-compliance into its Insect Resistance Management (IRM) requirements; and (4) properly assess the economic impacts associated with re-registration of Bt crops. Furthermore, re-registration of the Bt crops will be a violation of the public trust doctrine.

As a result, CFS believes that the EPA cannot support a finding that the re-registrations of Bt crops do not pose "unreasonable adverse effects on the environment."<sup>2</sup> Accordingly, the EPA should allow all existing Bt crop registration to lapse and should not grant any re-registrations to Bt crops (including a renewal of the registration of Cry1F Bt corn issued by EPA to Dow/Mycogen/Pioneer Hi-Bred).

#### I. Inadequate Human Health Assessment

In its reassessment of Bt crops, the EPA has failed to take account of several recent studies showing that

---

<sup>1</sup> 66 Fed. Reg. 37227 (July 17, 2001)

<sup>2</sup> This standard is actually stated as two standards in the statute: "[the pesticide] will perform its intended function without unreasonable adverse effects on the environment; and [ ] when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. §136a(c)(5)(C).

Bt proteins could act as antigenic and allergenic sources. In one of these studies, antibody responses consistent with allergic reactions were discovered in farm-workers exposed to Bt spray, which contains pesticidal proteins similar to those found in Bt corn (Cry1Ab) and cotton (Cry1Ac). According to the EPA's scientific advisors: "Only surveillance and clinical assessment of exposed individuals will confirm the allergenicity of Bt products or any other novel protein introduced into the diet of consumers..."<sup>3</sup> The EPA has not conducted such surveillance or clinical assessments, even though it has had access to serological agents that could be used to test farm-workers for allergic reactions to Bt proteins for two years.

Three other studies have shown that Cry1Ac, the Bt protein engineered into cotton, is a potent immunogen, an adjuvant and is bound by mouse intestinal cells (suggesting a possible mechanism of allergic sensitization). The EPA has also failed to follow up on these studies.

A fundamental problem is the Agency's failure to demand that biotechnology companies conduct their toxicity and allergenicity tests on the pesticidal proteins actually produced in plants and eaten by consumers. Instead, the EPA accepts standard tests conducted on bacterial surrogate proteins, which can differ substantially from their plant-produced counterparts. According to the National Academy of Sciences: "Tests should preferably be conducted with the protein as produced in the plant."<sup>4</sup> If this is difficult due to low levels of expression in the plant: "The EPA should provide clear, scientifically justifiable criteria for establishing biochemical and functional equivalency when registrants request permission to test non plant-expressed proteins in lieu of plant-expressed proteins."<sup>5</sup> The EPA has not provided such criteria.

The importance of using the plant-produced proteins for testing is illustrated by the investigation into contamination of the food supply with StarLink™, a variety of Bt corn that was never approved for human consumption. According to EPA's scientific advisors, who include some of the nation's leading allergists, a key deficiency of allergy tests conducted on people with suspected reactions to StarLink™ was the use of such a bacterial-produced surrogate protein rather than the version produced in StarLink™ corn, possibly resulting in false negative results.<sup>6</sup>

Finally, the EPA has not even collected basic data that the Agency itself deems essential to a health impacts assessment. For instance, the EPA does not have data comparing the structure of the pesticidal Bt proteins to the structures of known allergens and toxins, despite the lapse of 5 years since the original registrations. Still worse, biotech companies have not even *confirmed* the structure of their plant pesticides through sequencing. In addition, Monsanto has failed to determine whether the pesticide produced in its Bt corn is heat-resistant, a characteristic of many food allergens.<sup>7</sup>

The EPA relies heavily on a supposed history of safe use of Bt crops, as well as data on Bt sprays, in judging Bt plants to be safe. There are two serious problems to this approach. First, the plant-produced pesticides are usually activated toxins, which are quite different than the inactive protoxins found in Bt sprays. Second, without controlled studies examining potential health impacts, and in the absence of labeling that would permit a consumer and his/her physician to trace back a presumed allergic reaction to its genetically engineered source, there is no scientific basis for claiming that Bt crops on the market have

---

<sup>3</sup> "Bt Plant-Pesticides Risk and Benefit Assessments," FIFRA Scientific Advisory Panel Report No. 2000-07, March 12, 2001, p. 76.

<sup>4</sup> National Research Council, "Genetically Modified Pest-Protected Plants: Science and Regulation," 2000, p. 66.

<sup>5</sup> Id.

<sup>6</sup> "Assessment of Additional Scientific Information Concerning StarLink Corn," FIFRA Scientific Advisory Panel Report No. 2001-09, July 17-18, 2001, p. 30.

<sup>7</sup> "Bt Plant-Pesticides Biopesticides Registration Action Document: Human Health Assessment," (hereinafter "BRAD") EPA, p. IIB3.

not hurt anyone. In fact, a growing number of scientists recommend labeling and post-market surveillance of genetically engineered foods, in part from concern over the rising incidence of food allergy in recent years.<sup>8</sup>

Given these oversights, CFS believes the Agency has not adequately assessed the human safety of Bt crops and re-registrations should not be granted.

## II. Inadequate Environmental Review Lack of Endangered Species Consultations

There are numerous unresolved environmental impacts that need further assessment and/or study before the EPA should allow re-registration.<sup>9</sup> Of particular concern is the EPA's failure to engage in meaningful Endangered Species Act ("ESA") consultations for threatened and endangered butterfly and moth species prior to the completion of any agency re-registration decision. On October 2000, CFS and numerous other individuals and organizations provided the agency with a 60 day notice of intent to sue letter for the Agency's failure to engage in consultation for the Bt crops.<sup>10</sup> (This notice followed one lawsuit - later voluntarily withdrawn because this re-registration process had begun- and a citizens' petition in which the Agency was asked to perform such consultation.) Despite a February, 2001 letter denying such consultation was necessary, the EPA recently announced it has entered into informal consultation with the Fish Wildlife Service over one species - the Karner Blue butterfly - that was mentioned in the CFS 60-day letter.<sup>11</sup> To date, no data has been presented to the public concerning this "informal consultation." CFS believes that such information must be made public immediately. Furthermore, CFS asserts that making any re-registration determination prior to the completion of the Karner Blue consultation is an abdication of the precautionary steps necessary to ensure that Bt crops do not pose unexpected, adverse environmental impacts on non-target species.

Moreover, CFS believes the Agency is legally obligated to engage in consultation as outlined in its October 2000, 60 day notice letter. Of particular concern, EPA must immediately embark on ESA consultation for the following species that may be in larval development during pollen shed:

**(Endangered) Butterfly, Mitchell's satyr (*Neonympha mitchellii mitchellii*)** Current Range of Species or Population: Michigan. Michigan counties with species and grain corn in acres in 2000: Jackson (53000), Kalamazoo (53000), Kent (40000) Lenawee (95000) St. Joseph (85000) Van Buren (31000) and Washtenaw (42000).

**(Endangered) Butterfly, Saint Francis' satyr (*Neonympha mitchellii francisci*)** Current Range of Species or Population: North Carolina. North Carolina counties with species and grain corn in acres in 2000: Cumberland (8800) and Hoke (1400).

**(Endangered) Butterfly, Fender's blue (*Icaricia icarioides fenderi*)** Current Range of Species or Population: Oregon. Oregon counties with species and grain corn in acres in 2000: Benton (300), Lane (300), Polk (1100) and Yamhill (2200).

**(Threatened) Moth, Kern primrose sphinx (*Euproserpinus euterpe*)** Current Range of Species or Population: California. California counties with species and grain corn in acres in 2000

---

<sup>8</sup> See e.g., Wal, J. M. "Strategies for Assessment and Identification of Allergenicity in (Novel) Foods," International Dairy Journal 8 (1998), p. 413.

<sup>9</sup> See, EcoStrat, "Critique of EPA's Environmental Risk Assessment," August 23, 2001. Attached with the permission of the Union of Concerned Scientists and Environmental Defense and incorporated by reference herein.

<sup>10</sup> Copy of 60 Day Notice Letter attached.

<sup>11</sup> See, EPA Discussion Paper, "Possible Options for Risk Mitigation for BT Incorporated Protectants," p. 6

Kern (13000).

A failure to engage and complete consultations on endangered and threatened species - including those listed here and in the CFS 60 day notice letter - prior to a grant of re-registration to Bt crops would be unlawful. A failure to engage in the consultations makes any Agency finding concerning the reasonableness of adverse environmental impacts incomplete, arbitrary and capricious.

### III. Resistance Management and Non-Compliance

One of the major concerns with the use of Bt crops is the development of insect resistance to the Cry toxins.<sup>12</sup> As the agency is well aware, Bt pesticides used in foliar spray are critical for many organic farming programs and have been identified by the EPA as a safer pest control method than chemical pesticide alternatives.<sup>13</sup> The agency has further recognized that foliar Bt pesticides have lower ecological risks when compared to the more hazardous alternatives that might replace foliar Bt pesticide should resistance develop.<sup>14</sup> The foliar Bt pesticides also are important in many Integrated Pest Management (IPM) programs for a variety of crops. Because of its effectiveness and safety, Bt is probably the single most important insecticide ever discovered and the loss of such a pesticide to insect resistance would cause growers to switch to more harmful synthetic pesticides.<sup>15</sup>

If exposed to continuous, massive doses of Bt toxins insects can develop resistance to it. Therefore, CFS believes that a central priority for EPA must be to prevent all potential for further development of Bt resistance. Anything less would cause an unreasonable adverse impact on the environment and be directly harmful to organic and sustainable agriculture.

Unfortunately, the EPA has admitted that registration of Bt crops will lead to pests that are cross resistant to foliar, convention Bt applications. Models analyzed by the EPA indicate that because of the use of genetically engineered Bt crops some pests now susceptible to Bt toxins may become resistant in as little as 3.46 years.<sup>16</sup> In order to manage this harm, the Agency has registered Bt crops with conditions that include the development and use of insect resistant management plans (IRM). The data show that the Agency is clearly unsure if such plans will be complied with or work. The EPA admits:

Grower compliance with refuge and IRM requirements is a critical element for resistance management . Significant non-compliance with IRM among growers may increase the risk of resistance for Bt corn. However, it is not known what level of grower non-compliance will compromise the risk of current refuge requirements.<sup>17</sup>

---

<sup>12</sup> See, New Science Shows that Current Bt-Corn and Cotton IRM Plans will Not Significantly Delay Resistance to By-Based Management Techniques,” August 20, 2001. Attached with the permission of the Union of Concerned Scientists and Environmental Defense and incorporated by reference herein.

<sup>13</sup> Janet L. Anderson, Acting Director Biopesticide and Pollution Prevention Division, Decision Memorandum, “Consideration of Section 3(c)(7)(B) Conditional Amendment for Nothrup King’s Bt Corn Plant-pesticide,” August 2, 1996, p. 2.

<sup>14</sup> Id.

<sup>15</sup> Id.

<sup>16</sup> BRAD at IID83.

<sup>17</sup> BRAD at IID9 (emphasis added).

This admission is rather astounding. Under the existing Bt crop registrations it has become clear that compliance data is lacking to the extent that the EPA cannot understand whether IRM programs can even work to prevent or delayed Bt resistance. Remarkably, in the area of Bt corn there are only two sources for what can be considered actual data of in-the-field compliance. All of the other surveys attempt to be predicative, but provide no analysis of actual compliance rates.<sup>18</sup> The data providing actual numbers are:

(1) Yearly Reporting (1999) on the Insect Resistance Management Plan of StarLink™ Corn, EPA registration No. 45639-221, Aventis Crop Science USA LP, January 25, 2000; and

(2) Bt Corn Insect Resistance Management Survey, 2000 Growing Season, Agricultural Biotechnology Stewardship Committee, prepared by Market Horizons, Inc., December 2000.

Both reports show significant non-compliance with IRM requirements. The final agency BRAD does not review the Aventis documents, presumably because they also show that the Agency was on notice as of January 27, 2000, that a percentage of StarLink™ was entering the food supply.<sup>19</sup> Significantly, the Aventis 1999 Report states that, “A large majority of growers (84.3%) reported planting non-Bt corn within 2,000 feet of StarLink acres to fulfill refuge requirements.”<sup>20</sup> This means that at a minimum 15.7% of surveyed StarLink™ did not plant refugia. Moreover, the report conflicting adds, “Overall, 87.5% of the StarLink™ corn growers who planted a refuge planted a sufficiently large refuge. Among all StarLink growers surveyed, 73% planted a sufficiently large refuge.”<sup>21</sup> Thus, combining the non-compliance rate with the inaccurate refugia plantings suggests that well over 25% may not have complied with IRM requirements.

The EPA does correctly characterizes the ABTSC survey which found that “71% of growers apparently followed the complete refuge requirements outlined for the 2000 season.” ABTSC survey at 10.

Together, the two “actual” figures presented show that non-compliance is somewhere between 20%-29%. However, the EPA correctly asserts that end results of surveys “may increase ‘false positives,’ which may artificially inflate estimates of grower compliance.”<sup>22</sup> Therefore, it seems reasonable to assume that non-compliance will be well over the 30% range suggested by EPA.<sup>23</sup> Regardless, the non-compliance figure has not been taken into account when the Agency has established or proposed new IRM requirements. Even the Agency concludes that:

Many of the models that have been developed to evaluate refuge and resistance scenarios assume 100% compliance. However, based on existing surveys of grower compliance (discussed later in this section), it is unlikely that 100% compliance can be achieved. On the other hand, research and modeling may show that some level of non-compliance can be tolerated without significantly increasing the risk of pest resistance. Models tend to assume 100% adoption of Bt technology. Compliance

---

<sup>18</sup> Any such survey material must be mandated by the Agency to be fully released to public in its entirety.

<sup>19</sup> See, Domestic Feed and Industrial Non-Food Uses Plan Report for StarLink™ Corn, EPA Registration No. 45639-221, Aventis, January 27, 2000.

<sup>20</sup> *Id.* at 8.

<sup>21</sup> *Id.* at Annex 5.

<sup>22</sup> BRAD at IID11.

<sup>23</sup> BRAD at IID56.

and adoption are both important factors that should be considered. Ultimately, models will need to be updated to reflect some degree of non-compliance, so that the potential impact can be more thoroughly understood.<sup>24</sup>

Furthermore, at the July 24, 2001, EPA Technical Briefing Bt Plant-Incorporated Protectants Reassessment, CFS, the Union of Concerned Scientists and others asked the Agency technical staff whether the models the Agency has used to help build its IRM requirements have been run to consider non-compliance rates. The answer was, “no.” Remarkably, while acknowledging IRM non-compliance rates, the Agency has failed to incorporate non-compliance rates into its calculation of refugia size requirements. Ultimately, the Agency cannot base its re-registration of Bt crops upon IRM modeling that uses 100% compliance when it has data showing that over 30% of farmers are likely to ignore such requirements.

Therefore, CFS believes it is unacceptable and illegal for the agency to go forward and claim that re-registration of the Bt crops does not create any unreasonable adverse effects when the Agency acknowledges that it does not know, and has not incorporated into its requirements, the impact of non-compliance to IRM plans on the development of Bt insect resistance. Without such an analysis, the Agency’s attempts to either delay or prevent such resistance are inherently flawed. Users of conventional Bt applications should not be asked to bear the injury created by such oversights, and the Agency should cancel the registrations until such oversights are corrected.

#### IV. Inadequate Benefits and Economic Review

By its own admission, the EPA reassessment of the Bt crops registration fails to include effects the re-registration may have on commodity prices, shifts in the benefits among producers and consumers, impacts on foreign trade, registrant profitability and incentives for product development.<sup>25</sup> These oversights skew the Agency’s benefits analysis in the favor of grants of re-registration.<sup>26</sup> The Agency must correct such oversights and take into consideration, *inter alia*, the loss of export markets caused by the continued allowance to use certain Bt crops and the impacts re-registration will have on organic farmers.

At the July 24, 2001, technical briefing CFS posed the Agency the question as to why changes in foreign trade and exports had not been considered in the BRAD document. The Agency replied it did not have any data on that issue. The data on this subject are easily found and admission of such an oversight is remarkable. Accordingly, the EPA cannot grant the re-registration to Bt crops based upon such a flawed benefits analysis.

The data available on the loss of the European Union (“EU”) as an export market for U.S. corn is dramatic. A recent USDA, Economic Research Service report stated that:

Because some GE varieties had not been approved for sale in the EU, US corn exports to the EU fell from \$190 million in 1997 to a mere \$35 million in 1998 and \$6 million in 1999. This phenomenon has affected all US corn exports to the EU, even exports destined for animal feed (US corn exports to the EU were only about 4 percent of total

---

<sup>24</sup> BRAD at IID9-10.

<sup>25</sup> BRAD at IIE2.

<sup>26</sup> See, “EPA Continues to Overstate the Benefits of Bt Crops and Ignores Important Costs,” August 20, 2001. Attached with the permission of the Union of Concerned Scientists and Environmental Defense and incorporated by reference herein.

US corn exports before 1998.<sup>27</sup>

Indeed, all the EPA staff need do to obtain export data and information on this subject is visit the USDA Foreign Agricultural Service website. Had the Agency done so, it would have found:

(1) based upon USDA, Economic Research Service, FATUS Export Aggregation US corn exports to the EU declined from 305,168 (1000 dollars) in 1996 to 8,101 (1000 dollars) in 2000. That is a decrease in (1000 dollars) of 97%; and

(2) based upon USDA, Foreign Agriculture Service, BICO Export Commodity aggregations, as compiled by the Center for Food Safety,<sup>28</sup> following has occurred to US corn exports to the EU:

<b>United States Corn Exports to European Union 1994 - 2000</b>							
<b>Based upon: USDA, Foreign Agricultural Service</b>							
<b>BICO Export Commodity Aggregations (values in 1000 dollars)</b>							
<b>Commodity Category</b>	<b>1994</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>
Yellow Corn	N/A	N/A	9,203	2,278	1,120	190	2,347
#1 Corn, Ex SD	63	2,543	562	11	0	132	0
#2 Corn, Ex SD	63,964	106,702	146,031	32,802	11,884	607	4,922
#3 Corn, Ex SD	136,726	292,857	148,172	154,662	22,219	0	0

Clearly, the export market for U.S. corn has decreased dramatically, and a main cause of this downturn is the continued use of genetically engineered crops by the US farmers, including the allowance of farmers to use genetically engineered Bt corn varieties that are not approved for use in the European Union. As the USDA has stated, "The EU represents one documented loss of U.S. corn exports resulting from issues related to biotech products."<sup>29</sup> Accordingly, the EPA's benefit analysis misses a clear part of the economic analysis - that the EPA re-registration of Bt crops - particularly Bt corn - will continue to cause the loss of millions of dollars in export markets to the EU. Clearly, any benefits analysis that does not include such readily available data is flawed. Moreover, such an incomplete analysis poisons the Agency's weighing of economic impacts in making a final determination on the adverse effects such re-registration will have on the environment.

In addition, the EPA benefits review fails to provide any data on how the continued re-registration of Bt crops will impact organic farmers. As stated previously, the potential loss of Bt foliar sprays because of insect resistance development would cause a significant interruption in organic production. The Agency fails to factor in the potential cost of organic (and conventional) crop loss because of a loss in effectivity of foliar Bt spray.

The Agency analysis also fails to consider another impact on organic farmers and producers - the economic impacts associated with contamination of organic corn with genetically engineered Bt varieties. As proven by the event surrounding StarLink™ corn, the cross contamination of corn crops with unintended, genetically engineered varieties is a real risk. The granting of registration renewals for the Bt crops will continue to cause genetic drift and the contamination of organic crops and seed. This will

<sup>27</sup> USDA/Economic Research Service, Economic Issues in Agricultural Biotechnology, February 2001, p. 33.

<sup>28</sup> See attached USDA/FAS statistical printouts.

<sup>29</sup> USDA/ Economic Research Service, Agricultural Outlook, April 2000, pp. 24-25.

directly impact organic growers' ability to export their products. It may also directly affect individual farmers' ability to remain certified as organic under the standards adopted by the National Organic Program (which consider the use of genetic engineering an "excluded method" see 65 Fed. Reg. 80548 (December 21, 2000)). Any cost-benefit analysis of the Bt crop re-registrations must include an analysis for such impacts.

#### V. Violation of the Public Trust.

CFS also objects to any re-registration of Bt crops as an illegal grant of the publicly owned, genetic resource of insect susceptibility to private corporations. Under federal common law the Public Trust Doctrine has a long history of preventing federal and state governmental entities from expropriating natural resources in a manner contrary to the public interest. The doctrine's central tenet is that "when a state holds a resource which is available for the free use of the general public, a court will look with considerable skepticism upon any governmental conduct which calculated either to reallocate that resource to more restricted uses or to subject public uses to the self-interest of private parties."<sup>30</sup> The Supreme Court has recognized the validity of the public trust doctrine.<sup>31</sup> Ultimately, the doctrine stands for the proposition that the "public domain is held by the Government as part of its trust. The government is charged with the duty and clothed with the power to protect it from trespass and unlawful appropriation."<sup>32</sup> Federal or state governments hold in trust all land and resources in its possession for future generations.

As of 1996, the EPA has recognized that susceptibility of pests to Bt toxins is a resource that is a "public good."<sup>33</sup> Since the first registration of Bt crops, the Agency has granted private corporations the ability to "use" up this public good and resource. As noted earlier, the widespread use of Bt foliar sprays in organic and other types of agriculture demonstrates that the susceptibility of insects to Bt has a tremendous value. Any re-registration of Bt crops will convey a proprietary interest in the publicly-owned genetic resource of susceptibility to Bt and ultimately will destroy Bt's effectiveness. This transfer of genetic resources from the public trust into the possession of commercial entities causing harm to the resources with little if any direct public gain or benefit violates the Agency's public trust fiduciary duty.

For the reasons contained herein, and the numerous other issues brought to the Agency's attention in all fora discussing the re-registration of Bt crops, the Center for Food Safety requests that the EPA deny the re-registration of all Bt crops.

Respectfully submitted,

Joseph Mendelson, III  
Legal Director

August 30, 2001

---

<sup>30</sup> Joseph L. Sax, *The Public Trust Doctrine in Natural Resource: Effective Judicial Intervention*, 68 MICH. L. REV. 471, 490 (1970).

<sup>31</sup> *Phillips Petroleum Co. v. Mississippi*, 484 U.S. 469, 98 L.Ed.2d 877, 108 S.Ct. 791 (1988).

<sup>32</sup> *United States v. Beebe*, 127 U.S. 338, 342, 32 L.Ed. 121, 8 S.Ct. 1083 (1888); See also, *Light v. United States*, 220 U.S. 523, 537, 55 L.Ed. 570, 31 S.Ct. 485 (1911) (public lands held in trust of all of the people); *United States v. Trinidad Coal Company*, 137 U.S. 160, 170, 34 L.Ed. 640, 11 S.Ct. 57 (1890) (United States land held in trust of all of the people).

<sup>33</sup> July 24, 2001, EPA Technical Briefing Bt Plant-Incorporated Protectants Reassessment Presentation of Sharlene R. Matten, Ph. D., *Insect Resistance Management*, slide 5.

Attach.