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13 May 2002

Docket No. 00-078-1
Regulatory Analysis and Development, PPD
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**COMMENT ON USDA/APHIS ENVIRONMENTAL ASSESSMENT
ACCOMPANYING APHIS DECISION ON MONSANTO PETITION 01-137-01P
SEEKING A DETERMINATION OF NONREGULATED STATUS FOR Bt *cry3Bb1*
INSECT RESISTANT CORN LINE MON 863**

To Whom It May Concern:

Pursuant to the USDA's March 14, 2002, Federal Register notice, 67 Fed. Reg. 11458, the Center for Food Safety (CFS) submits the following comments concerning the inadequacy of the agency's Environmental Assessment (EA) accompanying the "USDA/APHIS Decision on Monsanto Petition 01-137-01P Seeking a Determination of Nonregulated Status for Bt *cry3Bb1* Insect Resistant Corn Line MON 863" (MON 863 Petition).

Introduction

In general, CFS believes that the USDA should engage in a full environmental impact study (EIS) prior to allowing commercialization of Monsanto's genetically engineered MON 863. The petitioner Monsanto views genetically engineered MON 863 corn as a variety with which to replace the over 15 million acres of corn treated for control of the corn rootworm complex in 2000.¹ By granting a petition for deregulatory status to Monsanto, USDA would be taking the action of allowing such broad scale commercialization to occur. Such action is clearly a major federal action that will significantly impact the environment, and, as such, should trigger full EIS review.

¹ MON 863 Petition at 2.

Indeed, one major potential environmental impact that requires full impact review is the potential for the development of pest resistance to the *Cry Bb1* protein. Monsanto and the agency both admit that insect resistance management plans have not yet been established to control this problem. Nonetheless, the agency has gone forward with an EA despite this lack of fundamental information on how MON 863 will be deployed in the field. This is clearly a fatal omission to the MON 863 EA.

CFS also believes that the procedures used to allow public comment on the MON 863 EA are inadequate to meet the public involvement goals of the National Environmental Policy Act (NEPA). The agency's EA references material from Monsanto that is not available to the public, therefore making effective and informed commenting difficult, if not impossible, on many key environmental questions. For example, the EA's review of MON 863's impacts on non-target organisms is reference over five paragraphs on two pages.² The primary data for the USDA's conclusions, however, is not publicly available. All appendices to Monsanto's MON 863 Petition which contain the critical data and review of such non-target impacts are withheld as confidential business information and/or trade secrets. Thus, the public is unable to comment on the accuracy of USDA's characterizations of such data in the EA. Precluding such review is counter to the NEPA process. The Council on Environmental Quality (CEQ) regulations clearly state that a federal agency's NEPA procedures must insure information crucial to the agency's underlying decision is available to the public.³ USDA should cure this violation of NEPA by delaying consideration of Monsanto's petition, mandating public release of the information, and reopening the public comment period after such material is available.

Failure to Address Gene Stacking

The Monsanto MON 863 Petition EA falls to address the cumulative issue of allowing numerous genetically engineered corn varieties onto the market and the synergistic effects of that cumulative release. The NAS specifically points out this limitation in the APHIS review stating: "the current APHIS approach to deregulation does not assess the environmental effects of stacked genes for nonadditive or synergistic effects on the expression of individual genes, nor does it assess stacked genes for cumulative environmental effects at the field level. . . . There are at least two levels at which scientists and regulators must look for interactions between the inserted genes with regard to environmental effects: (1) the individual plant phenotype and (2) the whole-field or farming system level."

The EA is devoid of analysis concerning the possible stacking of genetically engineered traits through cross-pollination. In the Petition, Monsanto admits that, "Occasionally it has been found that corn pollen can travel up to 3.2 km (2 miles) by wind under favorable conditions."⁴ It seems likely that such pollen dispersal will lead to cross fertilization of MON 863 traits with other genetically engineered corn varieties. In addressing these issues, the EA is wholly inadequate and fails to fully address the impacts

2 MON 863 EA at 11-12.

3 See e.g. 40 C.F.R. §§ 1500.1(b), 1506.5(b); C.E.Q. issued its regulations implementing NEPA in response to President Carter's Executive Order 11991 (1977). See, Andrus v. Sierra Club, 442 U.S. 347, 357 (1979). The Executive Order directed federal agencies to "comply with the regulations issued by the Council." See *id.*, quoting Executive Order No. 11991. The E.P.A. has adopted the C.E.Q. NEPA regulations. 40 C.F.R. ' 6.100, *et seq.* (July 1, 1996); The Supreme Court has held that the regulations are entitled to substantial deference by the courts. Andrus v. Sierra Club at 358; See, also, Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 372 (1989).

4 Monsanto, "Petition for Determination of Nonregulated Status for Corn Rootworm Protected Corn Event MON 863," CBI Deleted version, May 15, 2001, at 27.

caused by MON 863's ability to create new hybridized varieties with multiple herbicide resistance and/or Bt traits.

Failure to Review Greater Susceptibility of MON 863 to Plant Pathogens

Monsanto's Petition reveals that in some preliminary field tests corn stunt disease appeared on MON 863 corn plants but not on control plants.⁵ The appearance of the disease in the MON 863 varieties was quickly dismissed by Monsanto in its Petition. It is inappropriate for the USDA to rely on such self-serving explanations. The EA makes no mention of such results and does not analyze whether the commercialization of MON 863 may create greater problems with corn stunt disease.

Failure to Address Concerns of Organic Farmers.

The MON 863 EA fails to adequately address the impacts of genetically engineered corn on those who handle raw and processed organic agricultural commodities. Many farmers and food processors have been economically damaged by the contamination of non-GMO corn stock and products by transgenic varieties. For example, Terra Prima Incorporated of Hudson, WI, is a supplier and exporter of certified organic ingredients for food products and animal feed. Several years ago testing revealed that a genetically engineered B.t. corn variety had contaminated a shipment of its corn, resulting in product recalls from seven European countries and damages of over \$100,000. The USDA has failed to analyze the socio-economic impacts on farmers and food processors seeking to avoid genetically engineered corn in their crops and commodities.

In a minor attempt to rectify this omission, the USDA makes cursory and unsupported statements concerning the impacts on organic farmers. First, the USDA states that: "(a) nontransgenic corn will likely still be sold and will be readily available to those that wish to plant it."⁶ This statement is purely speculative in nature. APHIS has provided no evidence that it has taken a "hard look" at the status of the corn seed market. No analytical information is present, inter alia, concerning: (1) the ability of non-transgenic seed producers to avoid transgenic contamination of their foundation seed; (2) the ability of seed sellers to ensure that seed being sold can be guaranteed to be non-transgenic corn seed; (3) the willingness of corporations such as Monsanto to produce and sell non-transgenic varieties that are currently under their patent control; and (4) fluctuations in nontransgenic corn seed production that may affect its availability and price. Absent such analysis and information, the EA cannot support its finding of no significant impact on organic farmers.

Failure to Address Other Economic Concerns.

The action of deregulating MON 863 will have a direct economic effect on U.S. farmers that has not been analyzed in the EA. The commercialization of this crop will likely exacerbate negative effects genetically engineered varieties are having on U.S. agricultural trade. 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

⁵ MON 863 Petition at 60.

⁶ MON 863 EA at 14.

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 US corn exports before 1998.⁷

Indeed, all the USDA 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, following has occurred to US corn exports to the EU:

United States Corn Exports to European Union 1994 - 2000							
Based upon: USDA, Foreign Agricultural Service							
BICO Export Commodity Aggregations (values in 1000 dollars)							
Commodity Category	1994	1995	1996	1997	1998	1999	2000
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 even stated, “The EU represents one documented loss of U.S. corn exports resulting from issues related to biotech products.”⁸ The USDA EA is devoid of any such analysis.

Failure of the EA to Address Agency’s Public Trust Duties

The EA also fails to address the environmental impacts associated with the approval of 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.”⁹ The Supreme Court has recognized the validity of the public trust doctrine.¹⁰

⁷ USDA/Economic Research Service, Economic Issues in Agricultural Biotechnology, February 2001, p. 33.

⁸ USDA/ Economic Research Service, Agricultural Outlook, April 2000, pp. 24-25.

⁹ Joseph L. Sax, The Public Trust Doctrine in Natural Resource: Effective Judicial Intervention, 68 MICH. L. REV. 471,

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.”¹¹ Federal or state governments hold in trust all land in resources in its possession for future generations.

As of 1996, the Environmental Protection Agency has recognized that susceptibility of pests to Bt toxins is a resource that is a “public good.”¹² Since the first deregulation of a Bt corn variety, the USDA has granted private corporations the ability to “use” up this public good and resource. 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. Commercialization of MON 863 crops will convey a proprietary interest in the publicly-owned genetic resource of susceptibility to Bt (specifically *Bt cry 3Bb1*) and ultimately will destroy Bt’s effectiveness. Indeed, Monsanto admits in its Petition, “The use of corn hybrids containing Cry3Bb1 protein will eventually result if selection of CRW that are tolerant to the toxin.”¹³ 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 USDA’s public trust fiduciary duty and may set a precedent with enormous environmental implications.

For these reasons, inter alia, CFS finds that the USDA’s EA for Monsanto’s MON 863 is substantively inadequate and is procedurally contrary to the mandates of NEPA.

Respectfully submitted,

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Legal Director

490 (1970).

10 Phillips Petroleum Co. v. Mississippi, 484 U.S. 469, 98 L.Ed.2d 877, 108 S.Ct. 791 (1988).

11 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).

12 July 24, 2001, EPA Technical Briefing Bt Plant-Incorporated Protectants Reassessment Presentation of Sharlene R. Matten, Ph. D., Insect Resistance Management, slide 5.

13 MON 863 petition at 81.