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Regulatory Analysis and Development, PPD
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COMMENT ON USDA/APHIS ENVIRONMENTAL ASSESSMENT ACCOMPANYING APHIS DECISION ON AVENTIS CROPSCIENCE, USA, LP (01-206-01P) SEEKING AN EXTENSION OF DETERMINATION OF NONREGULATED STATUS FOR MALE STERILE, FERTILITY RESTORATION, AND GLUFOSINATE TOLERANT CANOLA EVENTS MS1 AND RF1/RF2 & 60 DAY NOTICE OF INTENT TO SUE UNDER THE ENDANGERED SPECIES ACT

To Whom It May Concern:

Pursuant to the USDA's February 25, 2002, Federal Register notice, 67 Fed. Reg. 8509, 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 Aventis CropScience, USA, LP (01-206-01p) Seeking an Extension of Determination of Nonregulated Status for Male Sterile, Fertility Restoration, and Glufosinate Tolerant Canola Events MS1 and RF1/RF2" and the inadequacy of the underlying EA/FONSI "Response to AgrEvo Petition 98-278-01p for Determination of Nonregulated Status for Canola Transformation Events MS8 and RF3 Genetically Engineered for Pollination Control and Tolerance to Glufosinate Herbicide" (March 1999).[1] CFS finds that the EAs are inadequate because: (1) they are being used to support an illegal and overbroad deregulation of Aventis' genetically engineered canola varieties; (2) they do not comport with numerous procedural requirements of the National Environmental Policy Act (NEPA) and its implementing regulations; and (3) they contain an inadequate analysis of numerous potential impacts associated with the commercial use of

1 67 Fed. Reg. 8509 (Feb. 25, 2002)

genetically engineered canola. The agency must engage in supplemental NEPA compliance on all past transgenic canola EA/FONSI decisions and complete a full environmental impact statement (EIS) to address the full range of impacts associated with the commercial planting of all genetically engineered canola varieties.[2]

Additionally, in accordance with the citizen suit provision of the Endangered Species Act (ESA), 16 U.S.C. § 1540 (g)(1)(A), CFS, on behalf of itself and members, is notifying the Secretary of the Department of Interior (DOI), the Secretary of the Department of Commerce (DOC), and the Administrator of USDA/APHIS, regarding APHIS violation of section 7 of the ESA.[3]

Introduction

CFS believes that the EAs conducted supporting the deregulation of Canola events MS1 and RF1/RF2 (and events MS8 and RF3) are being used to relieve the petitioner of liability for the biological pollution of other canola varieties with these events. On October 8, 2001, Aventis submitted an "Application for and Extension of the Determination of Nonregulated Status for Glufinosate Tolerant Canola Transformation (98-278-01p): MS1/RF1/RF2 events with the antecedent organism MS8/RF3 petition 98-278-01p)" (hereinafter referred to the "MS1 Petition" and/or "MS1"). The MS1 petition seeks deregulation for the "adventitious presence" of any canola progeny derived from crosses of MS1/RF1/RF2 with (1) all traditional canola varieties; and (2) other transgenic canola varieties already deregulated by USDA.[4] As petitioned for, the granting of the MS1 Petition would broadly deregulate any new transgenic canola created by Aventis and any new transgenic canola created with event MS1 through the crosspollination of existing canola varieties with MS1. Granting of the MS1 Petition, therefore, will have the effect of deregulating all new transgenic canola varieties that contain genetic constructs obtained from MS1 events regardless of the manner of creation, including in-field hybridization not performed by Aventis. In no manner is the USDA/APHIS allowed to deregulate such speculative varieties. The MS1 Petition and the accompanying EAs cannot in any manner adequately assess the environmental and human health impacts associated with new varieties that have yet to even be created. As such, USDA approval of the MS1 petition would be contrary to law.

Procedural Failures

The MS1 Petition EA and the underlying EA cannot support any decision to approve Aventis' MS1 Petition. The EA fails to conform to numerous regulatory requirements designed to implement NEPA. CFS has identified some of the procedural inadequacies below:

(1). General Inadequacy of the Environmental Assessment

Throughout the MS1 Petition EA, APHIS has failed to comply with standard NEPA terminology, formatting, and analysis requirements, and is procedurally inadequate.

2 This comment also incorporates by reference CFS comments concerning the inadequacy of USDA's EA's contained at dockets 01-02-006-1 and 01-100-1.
3 16 U.S.C. ' 1536(a)(2).
4 Aventis, Petition 01-206-01p at 2.

For example, in section V, the MS 1 Petition EA claims: "This EA is tiered to the original EA of 98-278-01p . . ."[5] This "original" EA was undertaken for an entirely different decision – the deregulation of transgenic glufosinate tolerant canola events MS8 and RF3. If the MS8 EA is adequate for the pending decision concerning the MS1 Petition, then USDA would have no need for attempting to provide new, additional NEPA analysis and compliance. The result of USDA's reliance on the MS8 EA is one of legal incoherence. Under NEPA, APHIS may not "tier" one EA to an earlier EA. The Council on Environmental Quality's (CEQ) NEPA implementing regulations definition of "Tiering," 40 C.F.R. § 1508.28, states:[6]

> Tiering refers to the coverage of general matters in broader environmental impact statements (such as national program or policy statements) with subsequent narrower statements or environmental analyses (such as regional or basinwide program statements or ultimately site-specific statements) incorporating by reference the general discussions and concentrating solely on the issues specific to the statement subsequently prepared.
>
> Tiering is appropriate when the sequence of statements or analyses is: (a) From a program, plan, or policy environmental impact statement to a program, plan, or policy statement or analysis of lesser scope or to a site-specific statement or analysis. (b) From an environmental impact statement on a specific action at an early stage (such as need and site selection) to a supplement (which is preferred) or a subsequent statement or analysis at a later stage (such as environmental mitigation). Tiering in such cases is appropriate when it helps the lead agency to focus on the issues which are ripe for decision and exclude from consideration issues already decided or not yet ripe.

This regulatory definition and every other reference to the term "tiering" in the CEQ regulations refers to "tiering" from a prior full "environmental impact statement" (EIS) and never a previous EA.[7] Furthermore, neither the definition of "environmental assessment"[8] nor any other part of the CEQ regulations support the proposition that one EA can be tiered to an earlier EA.

The required legal elements of an EA are listed in 40 CFR § 1508.9, which defines "Environmental assessment" as (in pertinent part; emphasis added):

> (b) Shall include brief discussions of the **need** for the **proposal**, of **alternatives** as required by section 102(2)(E), of the **environmental impacts** of the proposed action and alternatives, and a **listing of agencies and persons consulted**.

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5 MS 1 Petition EA at 5.

6 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).

7 See also 40 CFR §§ 1500.4(i), 1502.4(d), and 1502.20

8 40 C.F.R § 1508.9

The MS1 Petition EA, dated February 2002, lacks virtually all of these required elements. The EA lacks sections on "Need," "Alternatives" (including discussion of a "No Action Alternative) and "Listing of agencies and persons consulted." This is not just a matter of procedural form. For example, the EA's failure to list the "agencies and persons consulted" leaves the ultimate APHIS decisionmaker - and the public - to guess about who was involved in development of the EA.

While a section does exist in the EA entitled "Section V. Potential Environmental Impacts," as indicated, it relies on improper "tiering" to a previous EA. The section also fails to assess the impacts of different "alternatives" besides the Proposed Action. In Section V, USDA identifies potentially significant impacts of the Proposed Action on organic farming, but then dismisses them without analysis in one conclusory paragraph (see below). Conclusory statements that no impacts exist, such as those in Section V, are legally insufficient. EAs must take a "hard look" at potential impacts.[9] Clearly, the MS1 Petition EA fails to undertake such a "hard look" analysis. In fact, the entire MS1 Petition EA lacks citation to any scientific literature - or any other information at all - to support its "no impact" conclusion. This approach is symptomatic of the agencies refusal to perform its "hard look" and violates the basic NEPA requirement of using the best information available.

(2). Inadequate Proposal Description

The MS1 Petition EA fails to provide an adequate proposal description of the activities proposed by Aventis and supported by the USDA EA. The MS1 EA states:

> This extension request is to address the adventitious presence of this event in commercially available seeds commercially sold in the U.S. until a Federal policy on this issue is developed. (Adventitious presence is the presence of events that have not been fully reviewed or approved by a regulatory agency and occurs in seeds and commodities as a result of either cross-pollination or commingling of experimental seeds with commercial seed).[10]

This description provides a previously unknown definition of "adventitious presence" that has no statutory or regulatory context. The EA makes no mention of the extent of MS1's presence in the current canola seed market nor does it provide any analysis on how this non-commercialized, non-deregulated genetically engineered canola variety has come onto the market. Thus, the EA inadequately describes the activities that are being analyzed in the EA.

Moreover, the Federal Register notice for the MS1 Petition EA provides inadequate notice as to the breadth the deregulation petition filed by Aventis. The notice speaks only to "certain canola events" but fails to mention that Aventis is seeking to extend the deregulation to all progeny derived from a transformation event using MS1 in any manner (including in field cross pollination). Absent such details, many of the ecological impacts associated with canola cannot be "meaningfully evaluated" as required by §1508.23.

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9 Kleppe v Sierra Club, 427 U.S. 390, 410 n.21 (1976).

10 USDA/APHIS Decision on Aventis CropScience, USA, LP Request (01-206-01p) Seeking an Extension of Determination of Nonregulated Status for Male Sterile, Fertility Restoration, and Glufosinate Tolerant Canola Events MS1 and RF1/RF2," Environmental Assessment, February 2002 at 2.

(3). Inadequate Notice of the Proposed Action on Localities.

A recent National Academy of Sciences report found that "[t]here is a need to actively involve more groups of interested or affected parties in the risk analysis process while maintaining a scientific basis for decisions."[11] Data derived from the USDA/National Agricultural Statistic Service indicate that since 1997 the overwhelming planting and harvesting of canola has occurred in the states of North Dakota and Minnesota. As such, the deregulation of MS1 canola and future crossbred progeny will be of particular concern to farming localities in these two states. APHIS should have sought to ensure active engagement from this particular geographic area, however, the USDA does not appear to have conformed to the suggested public involvement procedures. Had the agency adequately sought to involve the public in this matter it should have done so by seeking to notify farmers and other agricultural interests, per 40 CFR §1506(b)(3), in canola growing states such as Minnesota and North Dakota.

Substantive Inadequacies

In addition to the MS1 Petition EA's procedural failures, CFS finds the EA (and the underlying EA for AgrEvo (now Aventis) canola transformation events MS8 and RF3) inadequate for, *inter alia*, the following reasons: (1). failure to analyze the impacts of gene stacking and mischaracterizing of weediness; (2) failure to properly analyze impacts on pesticide use; and (3) improper analysis of the impact on organic farmers.

(1). Inadequate Assessment of Cumulative Impacts and "Gene Stacking."

The MS1 petition EA and underlying EA inadequately address the cumulative issues of allowing numerous genetically engineered 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 an 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 MS1 and underlying EA fail to take the NAS concerns into consideration. Indeed, the APHIS' failure to undertake such a review has led it to come to conclusions about control of volunteer canola and its weediness that contradict past experience. In January 2001, the Royal Society of Canada (RSC) specifically addressed the issue of particular GE canola varieties crossing with each other to yield volunteer canola with stacked genetic traits. The RSC stated:

> Many cultivated species, especially those involved in horticulture, forestry and rangeland agriculture, have only recently been brought under cultivation and consequently have been subjected to relatively little genetic alteration through conventional breeding. In this case, the degree of domestication may be quite

11 National Research Council/National Academy of Science, "Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation," (2002) at 175.

minor and cultivated genotypes may resemble their wild ancestors in many respects. In these cases, cultivars are more likely to persist outside of cultivation, and under certain circumstances could become invasive (see below). GM species with a short domestication history are more likely to pose environmental problems than our major crop plants. However, invasiveness will occur only if the genetic modifications increase the survival and reproduction of cultivars in natural ecosystems. Little work in this area has been conducted. In the future, as the range of target organisms for genetic modification widens, it may not be safe to assume that all cultivated species have been genetically crippled through intense artificial selection. Indeed, recent experience in Canada with herbicide-tolerant canola (oil seed rape), discussed next, provides a warning that some crop plants have the potential to become serious weeds of agriculture.

Canola is a relatively recent plant domesticate compared with many of our major cereals (e.g. corn, wheat, rice). Unfortunately, two wild traits that persist in many canola cultivars are weak seed dormancy and a degree of seed shattering. As a result of these traits, large numbers of seeds enter the soil after cropping and can persist in the seed bank to emerge in subsequent seasons as volunteer plants (Pekrun et al., 1998; Derksen and Watson, 1999; Downey, 1999). Traditionally, volunteer crop plants occur at relatively low densities and are eliminated from crops by selective herbicides. However, this management tool is complicated if volunteers are herbicide resistant. Unfortunately, herbicide-resistant volunteer canola plants are beginning to develop into a major weed problem in some parts of the Prairie Provinces of Canada. Indeed, some weed scientists predict that volunteer canola could become one of Canada's most serious weed problems because of the large areas of the Prairie Provinces that are devoted to this crop. Of particular concern is the occurrence of gene exchange via pollen among canola cultivars resistant to *different* herbicides. This can occur through crosses between volunteer plants and the crop, or between different volunteer plants. Three classes of herbicide-resistant canola (resistant to glyphosate, glufosinate and imidazolinone) are currently grown in western Canada. Recent evidence indicates that crosses among these cultivars have resulted in the unintentional origin of plants with multiple resistance to two, and in some cases three, classes of herbicide (Derksen andWatson, 1999; Downey, 1999; Topinka et al., 1999). Such "gene stacking" represents a serious development because, to control multiple herbicide-resistant volunteer canola plants, farmers are forced to use older herbicides, some of which are less environmentally benign than newer products. This example involving the origin of multiple herbicide-resistant canola serves to illustrate the dynamic nature of weed evolution within managed agroecosystems. It also demonstrates that crops plants are not immune from becoming weeds of agriculture under the appropriate selection regimes.

Because of the large areas devoted to herbicide-resistant canola in the Prairie Provinces, it is not surprising that opportunities for the genetic mixing of different varieties occur. Despite the best efforts of growers, seeds may often be transported accidentally between fields containing different herbicide-tolerant canola varieties by farm machinery, or simply be blown from trucks transporting

> seeds to and from fields (Gray and Raybould, 1998). Indeed, it has been argued that seed spillage, a form of gene dispersal, may be a much more common mechanism resulting in hybridization between varieties than is likely by long-distance pollen flow by animal pollinators (McHughen, 2000, p. 166). Regardless of the mechanisms giving rise to multiple herbicide-tolerant canola varieties, this example illustrates the problems in trying to predict the likelihood of gene flow from small-scale test plots involving relatively small numbers of plants. In addition, it emphasizes the inherent difficulties in areas of the landscape. Industry argues that as long as "good farming practices" are followed, these problems should not occur. This perspective may be unduly naïve. Environmental assessments associated with the release of GM crops should take account of the fact that in the real world human error and expediency may often compromise guidelines for the growing of such crops. (emphasis added)[12]

The RSC is not the only scientific body with high concern over canola and gene stacking. In 2002, the European Environment Agency study "Genetically Modified Organisms: The significance of gene flow through pollen transfer" concluded that:

> Oilseed rape can be described as a high risk crop for crop-to-crop gene flow and from crop to wild relatives. At the farm scale low levels of gene flow will occur at long distances and thus complete genetic isolation will be difficult to maintain. <u>This particularly applies to varieties and lines containing male sterile components, which will outcross with neighbouring fully fertile GM oilseed rape at higher frequencies and at greater distances than traditional varieties.</u> Gene stacking in *B. napus* has been observed in crops and it is predicted that plants carrying multiple genes will become common post-Gm release and consequently volunteers may require different herbicide management. Oilseed rape is cross compatible with a number of wild relatives and thus the likelihood of gene flow to these species is high.[13] (emphasis added)

In addressing these issues, in particular the heightened concerned cause by male sterile components such as those in the MS1 Petition, the EA's are wholly inadequate and fail to fully address the impacts caused by greater outcrossing distance of these genetically engineered canola lines and their ability to create new hybridized varieties with multiple herbicide resistance. In no manner has the USDA analyzed the impacts of large scale development of volunteer canola with "stacked" herbicide, the associated use of chemicals for burn off, and the impacts it may have on future crop rotations. Indeed, farmers have already complained that controlling these new resistance forms of canola have created severe management problems and harmed yields of crops planted the following year.[14]

12 The Royal Society of Canada, "Elements of Precaution: Recommendation for the Regulation of Food Biotechnology in Canada," (January 2001) at 122-23.

13 European Environment Agency, "Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer," (March 2002) at 7.

14 See e.g., Ian Bell, "Zero-Till Farmers Air Roundup Ready Concerns," Western Producer, (December 6, 2001) available at http://www.producer.com/articles/20011206/news/2011206news08.html

(2). Failure to Address Cumulative Pesticide Use.

As the NAS recently concluded, "APHIS assessments of petitions for deregulation are largely based on environmental effects considered at small spatial scales. Potential effects from scale-up associated with commercialization are rarely considered."[15] The MS1 Petition EA and underlying EA fail to address how genetically engineered canola variety deregulations have impacted the growth in U.S. canola planting. For instance, since 1997 the growth in the number of acres of canola planted has grown from 671,000 acres in 1997 to 1,554,000 acres in 2000.[16] The significant increase in canola planting appears to parallel the introduction of genetically engineered varieties. Thus, new GE varieties are not displacing existing canola planting but adding to the cumulative total of canola acres planted. The EAs fail to address how the increased planting of canola affects larger agroecological systems, the existing crops canola may be displacing, and the quantity of new agricultural land placed into canola production. Furthermore, the increased use of canola means that glufosinate-tolerant canola will not reduce the pesticide load applied to canola acreage. To the contrary, the increased acreage resulting from increased use of new genetically engineered varieties will increase the overall number of canola acres treated with herbicides.

(3). Failure to Adequately Address Concerns of Organic Farmers.

The MS1 Petition EA and underlying EA failed to adequately address the impacts of genetically engineered canola on those who handle raw and processed agricultural commodities. The EAs concluded that the use of glufosinate tolerant canola "will not cause damage to raw or processed agricultural commodities."[17] Such a conclusion failed to address the socio-economic impacts associated with the introduction of MS1 and other genetically engineered canola varieties. Many farmers and food processors have been economically damaged by the contamination of non-GMO canola stock and products by transgenic varieties. The USDA has failed to analyze the socio-economic impacts on farmers and food processors seeking to avoid genetically engineered canola 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) USDA's National Organic Program . . . requires farmers to plant certified (nonengineered) transgenic seeds."[18] The National Organic Program does not require farmers to plant transgenic seed.

Second, the agency claims there will be no impacts on organic farmers because the National Organic Program final rule only requires farmers to demonstrate they do not use genetically engineered seeds. This analysis is incomplete and devoid of any analysis about the current organic marketplace. During the implementation of the Organic Food Production Act the USDA made it clear that the agency views the organic rule as a marketing standard based upon consumer expectations. This approach was stated in its treatment of "excluded methods" (i.e. genetic engineering). The USDA has stated:

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15 NAS at 189.

16 Statistics Obtained from National Agricultural Statistics Service available at http://www..nass.usda.gov (last visited March 7, 2002)

17 USDA/APHIS, "Response to AgrEvo Petition 98 278-01p for Determination of Nonregulated Status for Canola Transformation Events MS8 and RF3 Genetically Engineered for Pollination Control and Tolerance to Glufosinate Herbicide, Finding of No Significant Impact," March 1999, at 1.

18 MS1Petition EA at 5

> Products created with modern biotechnology techniques have been tested, approved by the appropriate regulatory agencies, and can be used safely in general agricultural production. At the same time, consumers have made clear their opposition to use of these techniques in organic food production. This rule is a marketing standard, not a safety standard. Since use of genetic engineering in the production of organic foods runs counter to consumer expectations, foods produced through excluded methods will not be permitted to carry the organic label. 65 Fed. Reg. 13534-35 (March 13, 2000) (emphasis added).

Therefore, it is not clear whether the marketplace in organic will accept any "adventitious presence" of genetically engineered canola or other crops. Indeed, many manufacturers and farmers undertake significant efforts (and financial burdens) to ensure that their seed or products do not use canola contaminated with "adventitious presence." If the USDA is going to make such an assertion, it needs to analyze whether the marketplace and market-based standards will actually tolerate "adventitious presence" and the impact that such a tolerance will have on organic agricultural producers, processors, and consumers.

Sixty (60) Day Notice of Intent to Sue for Inadequate ESA Consultation

Section 7 of the ESA requires every federal agency to conserve species listed as endangered or threatened.[19] It also mandates that in consultation with and with the Assistance of the Secretary, each federal agency shall "insure that any action authorized, funded or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species. . ."[20] This prohibits an agency from proceeding with an action that may impact a listed species before the analysis required by Section 7 is complete.

Despite the ESA's section 7 requirements, the MS1 Petition EA reveals that APHIS has done nothing to consult with other relevant agencies to consider the impacts of allowing hundreds of thousands of acres to be planted with the MS1 genetically engineered canola varieties and any of its progeny. Instead, the agency seeks to rely on the ESA consultation conducted for the MS8/RF3 EA. As with the "tiering" of the MS1 Petition EA to the past MS8/RF3 EA (see above), the agency cannot rely on past consultations to meet the ESA's requirements for a new proposed action.

Unless APHIS commits in writing within the next sixty days that the agency will fully and completely comply with the ESA's section 7 statutory requirements concerning the impacts on threatened and endangered species from MS1 (and all its progeny) genetically engineered canola, then CFS will have no alternative but to seek relief in federal court.

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19 16 U.S.C. § 1536(a)(1).

20 Id. §1536(a)(2). If the Director of the FWS or NMFS determines that any action by the federal agency may affect a listed species, the Director may request a consultation if the federal agency fails to d so. 50 C.F.R. § 402.14(a).

Conclusion

NEPA's procedures are both required and useful for structuring the analysis to determine whether potentially significant impacts exist. No agency has the discretion to violate NEPA or to ignore the CEQ's implementing regulations, which are entitled to substantial deference.[21] USDA/APHIS has never prepared a full EIS, neither on its dozens of prior approvals for broad releases of crops and other GE products, now covering tens of millions of hectares, nor on the cumulative effects of APHIS' decisions. Analytical bias is obvious and it is reinforced here by APHIS's failure to comply here with basic NEPA procedural requirements. The agency must immediate engage in supplemental NEPA compliance for all existing transgenic canola EA/FONSI decisions, including the MS8/RF3 EA, and complete a full EIS governing the agency's deregulation actions allowing numerous genetically engineered canola varieties to be commercial grown in the United States.

In addition, the agency must immediate rectify its failure to engage in the require consultation processes under the ESA for the proposed actions contained in the MS1 deregulation petition..

Finally, in granting the MS1 Petition for Deregulation the agency would be allowing the creation of numerous new canola varieties without any regulatory oversight and with only inadequate and speculative environmental assessment. USDA/APHIS must deny the Aventis' MS1 Petition.

Sincerely,

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21 See Andrus v. Sierra Club, 442 U.S. 347, 348 (1979); Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 372 (1989).

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