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Docket No. APHIS-2007-0044
Regulatory Analysis and Development
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Comments to USDA APHIS on Draft Environmental Impact Statement (DEIS) for the Determination of Regulated Status of Glyphosate-Tolerant Alfalfa Events J101 and J163

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Docket No. APHIS -2007-0044

In 2004, Monsanto Company and Forage Genetics International (FGI) petitioned the Animal Plant Health Inspection Service (APHIS) for a determination of non-regulated status for two lines of alfalfa, designated as J101 and J163, genetically engineered to be resistant to the herbicide glyphosate. APHIS prepared an Environmental Assessment (EA) and took public comments on the EA and the petition for deregulation. APHIS received 663 public comments, 520 of which opposed deregulation.¹ On June 27, 2005 (70 FR 36917-36919, Docket No. 04-085-3) APHIS announced its decision to grant non-regulated status to Monsanto and FGI lines J101 and J163. Despite the many public comments indicating that Glyphosate-tolerant alfalfa (GT Alfalfa) may significantly affect the quality of the human environment, the decision was made without the benefit of an Environmental Impact Statement (EIS).

In 2006, Center for Food Safety (CFS) along with farmers and other environmental and consumer organizations filed suit against the United States Department of Agriculture

¹ *Geertson Seed Farms v. Johanns*, 2007 WL 518624, *2 (N.D.Cal. 2007) *aff'd*, 541 F.3d 938 (9th Cir. 2008).

(USDA) for violating the National Environmental Policy Act (NEPA), the Plant Protection Act (PPA) and the Endangered Species Act (ESA) in approving GT Alfalfa. Judge Breyer of the Federal District Court, Northern District of California agreed and on February 13, 2007 granted summary judgment in favor of plaintiffs and ordered APHIS to prepare an EIS. This DEIS responds to that order.

CFS is a non-profit, membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture.² CFS represents over 100,000 members throughout the country that support organic agriculture and regularly purchase organic products. CFS members support the public's right to choose GE-free food and crops. These comments incorporate by reference other CFS organizational comments submitted to the docket concurrently. Concurrently, CFS is submitting 51,710 comments from CFS True Food Network members opposing the deregulation of GT Alfalfa (Docket No. APHIS-2007-0044).

SUMMARY

The DEIS is arbitrarily and capriciously flawed in structure, process and substance.

The DEIS is flawed in structure because it is overly narrow in scope and stripped of any alternatives besides complete, unconditional deregulation. This contravenes NEPA and the PPA.

The DEIS is arbitrarily and capriciously flawed in process because, rather than informing APHIS's deregulation decision on GT alfalfa, the DEIS's analysis is predicated on the pre-determined and separate conclusion that APHIS will deregulate GT alfalfa, making the entire NEPA analysis a foregone conclusion – a meaningless paper exercise.

The DEIS is arbitrarily and capriciously flawed in substance because its analysis on numerous impacts is inadequate to comply with NEPA, because it entirely fails to address other significant issues, and because its conclusions that GT alfalfa will lead to no significant impacts to the environment, U.S. agriculture and public health are contrary to the record evidence. Deregulation of GT alfalfa would have numerous significant impacts on U.S. agriculture and the environment that must be acknowledged, analyzed, and meaningfully considered.

APHIS should have consulted with the Fish and Wildlife Service (FWS) about the significant impacts of deregulating GT alfalfa on protected species. By failing to adequately assess the foreseeable impacts to protected species and failing to consult, APHIS violated the Endangered Species Act (ESA).

The APHIS decision to deregulate GT alfalfa does not comply with the Plant Protection Act (PPA) and is not based on sound science. The Roundup Ready alfalfa system

² See generally www.centerforfoodsafety.org.

violates the PPA in that it promotes the proliferation of plant disease agents; noxious, herbicide-resistant weeds; and economic impacts that will harm the agricultural economy.

COMMENTS

The National Environmental Policy Act

The National Environmental Policy Act (NEPA) requires a federal agency such as USDA APHIS to prepare a detailed EIS for all “major Federal actions significantly affecting the quality of the human environment.”³ NEPA “ensures that the agency ... will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience.”⁴ NEPA requires APHIS to take a “hard look”⁵ at the environmental consequences of deregulation of GT alfalfa, including a reasonable range of alternatives and the cumulative impacts of past and future deregulation of GE crops.

An agency first prepares an Environmental Assessment (EA) to determine whether a Federal action will have a significant affect on the quality of the human environment. “An environmental assessment is a ‘concise public document’ that ‘[b]riefly provide[s] sufficient evidence and analysis for determining whether to prepare an [EIS] or a finding of no significant impact.’”⁶ Once an agency (or a court upon review of an agency’s EA) determines the Federal action will have a significant affect, an EIS must be prepared. Here, the district court established that deregulation of GT alfalfa will have a significant affect on the quality of the human environment and required APHIS to prepare this DEIS.

An EIS serves different purposes from the EA already prepared by APHIS.⁷ “An EA aims simply to identify (and assess the ‘significance’ of) potential impacts on the environment.” An EIS, on the other hand, balances “different kinds of positive and negative environmental effects, one against the other” and “weighs negative environmental impacts against a project's other objectives.”⁸ “Preparation of an EIS thus ensures that decision-makers know that there *is* a risk of significant environmental impact and take that impact into consideration.”⁹ APHIS’ decisions must be “complete, reasoned, and adequately explained.”¹⁰

The Council on Environmental Quality (CEQ)

³ 42 U.S.C. § 4332(2)(C).

⁴ *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349(1989).

⁵ *Kleppe v. Sierra Club*, 427 U.S. 390, 410 (1976).

⁶ 40 C.F.R. § 1508.9(a); *Anderson v. Evans*, 371 F.3d 475, 488 (9th Cir.2004).

⁷ *See Anderson v. Evans*, 314 F.3d 1006, 1022 (9th Cir. 2002).

⁸ *Sierra Club v. Marsh*, 769 F.2d 868, 875 (1st Cir. 1985).

⁹ *Anderson v. Evans*, 314 F.3d at 1022.

¹⁰ *Northwest Coalition for Alternatives to Pesticides v. U.S. E.P.A.*, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008).

NEPA also established the Council on Environmental Quality and charged CEQ with the duty of overseeing the implementation of NEPA.¹¹ The regulations subsequently promulgated by CEQ, 40 C.F.R. §§ 1500-08, implement the directives and purpose of NEPA, and “[t]he provisions of [NEPA] and [CEQ] regulations must be read together as a whole in order to comply with the spirit and letter of the law.”¹² CEQ’s regulations are applicable to and binding on all federal agencies.¹³ Among other requirements, CEQ’s regulations mandate that federal agencies address all “reasonably foreseeable” environmental impacts of their proposed programs, projects, and regulations.¹⁴

CEQ’s regulations clearly lay out the purpose of an EIS. “The primary purpose of an environmental impact statement is to serve as action-forcing devices to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government.”¹⁵ An EIS shall provide “full and fair discussion of significant environmental impacts and shall inform decisionmakers of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment.”¹⁶ Agencies are to focus on “significant environmental issues and alternatives.”¹⁷

I. The Scope of APHIS’ DEIS Is Improperly Narrow And The Result Pre-Determined.

APHIS’s NEPA analysis is improperly narrow and its result improperly pre-determined.

APHIS begins from the faulty proposition that the scope of its NEPA review is limited to plant pests. (7 CFR Part 340). APHIS concludes repeatedly that because it concluded in its “Plant Pest Determination” (Appendix W) that “GT alfalfa is unlikely to pose a plant pest risk” its NEPA analysis is at an end.¹⁸ *See, e.g.*, DEIS at xv, 1, 11, 13-15, 161, 164. This is a legally improper and impermissibly constrains the issues APHIS must analyze under NEPA. APHIS’ authority and mandate is quite broad: as the DEIS itself notes, it includes “protecting American agriculture,” and “ensuring plant and animal health.” By doing so, the agency aims to “improve agricultural production and competitiveness, and contributes to the national economy and public health.” (DEIS, at xiii.) APHIS authority under the Plant Protection Act, 7 USC 7701 *et seq.* is also quite broad. The fundamental purpose of the PPA is the “protection of the agriculture, environment, and economy of the United States.”¹⁹ With this purpose in mind, APHIS promulgated regulations to

¹¹ See 42 U.S.C. §§ 4321, 4344.

¹² 40 C.F.R. § 1500.3.

¹³ 40 C.F.R. §§ 1500.3, 1507.1; see, e.g., *Hodges v. Abraham*, 300 F.3d 432, 438 (4th Cir. 2002).

¹⁴ See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.

¹⁵ 40 C.F.R. § 1502.1.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ We also disagree that GT alfalfa is not likely to pose plant pest risks. *See infra* and other CFS comments submitted by Bill Freese.

¹⁹ 7 U.S.C. § 7701(1).

specifically implement the PPA to protect American agriculture from the recognized potential for GE crops to injure or damage agriculture, environment, and the economy.²⁰ The structure and scope of the DEIS is flawed to the extent it does not undertake its analysis of potentially significant impacts from this starting point.

APHIS's NEPA analysis is also improperly predetermined.

While NEPA does not mandate any particular results, its main purpose is to foster better decision-making by agencies. *See* 42 USC 4321; 40 CFR 1501.1(c). Here, the decision to deregulate GT alfalfa, which this DEIS is supposed to inform and foster, has already been determined. APHIS has already concluded, based on its 11-page Plant Pest Determination (Appendix W) that it must deregulate GT alfalfa. *See, e.g.*, DEIS, at 164 (“If APHIS determines that GT alfalfa does not pose a plant pest risk, then APHIS has no regulatory authority to deny the deregulation of GT alfalfa events J101 and J163”). The Court's required NEPA analysis then becomes nothing more than a meaningless paper exercise. It does not matter what its analysis is of risks because according to APHIS, it cannot or will not do anything different anyway. *See* DEIS, p.164 (discussing risks such as “increased prevalence of the gene product in the environment” and “potential increase in glyphosate use”). If the Plant Pest Determination is the agency action that determines whether or not GT alfalfa will be deregulated, then the agency's NEPA assessment should inform that decision. APHIS's process here turns that on its head, using the already finished Plant Pest Determination to short-circuit and prejudge the NEPA analysis.

II. APHIS' Alternatives Analysis Is Inadequate.

The DEIS' Alternatives Section is legally deficient. Federal courts have consistently held that “[i]n addition to the proposed agency action, every EIS must ‘[r]igorously explore and objectively evaluate all reasonable alternatives’ to that action.”²¹ The analysis of alternatives to the proposed action is “the heart of the environmental impact statement.”²² “The existence of reasonable but unexamined alternatives renders an EIS inadequate.”²³

The consideration of alternatives furthers NEPA's goal by guaranteeing that agency decisionmakers “[have] before [them] and take [] into proper account all possible approaches to a particular project (including total abandonment of the project) which would alter the environmental impact and the cost-benefit balance.”²⁴ An alternatives analysis must foster both informed decisionmaking and informed public participation.²⁵

²⁰ 7 C.F.R. § 340 et seq.

²¹ *Center for Biological Diversity v. U.S. Dept. of Interior*, 1071 (9th Cir. 2009) (citing 40 C.F.R. § 1502.14(a)).

²² *Or. Natural Desert Ass'n v. Bureau of Land Mgmt.*, 531 F.3d 1114, 1121 (9th Cir.2008) (quoting 40 C.F.R. § 1502.14).

²³ *Friends of Southeast's Future v. Morrison*, 153 F.3d 1059, 1065 (9th Cir.1998).

²⁴ *Calvert Cliffs' Coordinating Committee, Inc. v. United States Atomic Energy Commission*, 449 F.2d 1109, 1114 (D.C. Cir.1971).

²⁵ *Westlands Water District v. U.S. Dept. of Interior*, 376 F.3d 853, 872 (9th Cir. 2004).

NEPA's requirement that alternatives be studied, developed, and described both guides the substance of environmental decisionmaking and provides evidence that the mandated decisionmaking process has actually taken place.²⁶ Informed and meaningful consideration of alternatives is thus an integral part of the statutory scheme.²⁷

APHIS acknowledges that it has authority to “approve the petition in whole or in part.” (DEIS at 11). Yet, despite the significant risks involved in deregulating GT alfalfa, APHIS claims that no partial deregulation needs to be analyzed in this case, that no analysis of any other alternative need be included. According to APHIS only two alternatives need be considered in the DEIS: no-action and unconditional deregulation.

First of all, the Court certainly believed, in complying with its order APHIS would analyze partial deregulation alternatives such as isolation distances or geographic restrictions. Indeed, APHIS previously conceded that “one option that APHIS has is to approve Monsanto’s ‘petition with a geographic limitation stipulating that the Roundup Ready could only be grown without APHIS authorization in certain geographic areas.’”²⁸ APHIS does not adequately explain why its position has changed in the DEIS.

APHIS has a brief discussion of “considered but rejected” alternatives list. The paucity of discussion on these rejected alternatives is insufficient to comply with NEPA. In order to comply with NEPA, APHIS must “[r]igorously explore and objectively evaluate all reasonable alternatives.”²⁹ Such cursory (1 ½ pages) rejection is not “rigorous” analysis. The DEIS flatly rejects all partial deregulation reasonable alternatives, such as isolation distances or geographic restrictions in a few sentences analysis, relying on the exact same pro forma language. *See* DEIS, pp. 14-15.

The no action alternative, i.e., prohibiting deregulation: “APHIS determined this alternative is not appropriate in that GT alfalfa [] have been determined in APHIS’ Plant Pest Risk Assessment not to be plant pests (USDA-APHIS, 2009).”

Isolation distances: “Because GT alfalfa is unlikely to pose plant pest risk (USDA-APHIS, 2009), APHIS will have no regulatory authority over GT alfalfa and will be unable to require regulatory restrictions or management practices for these GE alfalfa varieties once it is granted nonregulated status.”

Geographic restrictions: “State-level or county-level restrictions on GT alfalfa, as well as the establishment of GE-free alfalfa production zones, were rejected because GT alfalfa is unlikely to pose a plant pest risk. (USDA-APHIS, 2009).

²⁶ *Id.*

²⁷ *See Bob Marshall Alliance v. Hodel*, 852 F.2d 1223, 1228 (9th Cir. 1988).

²⁸ Geertson Seed, 2007 WL 518624 at *6.

²⁹ 40 C.F.R. § 1502.14(a).

Testing: “[B]ecause GT alfalfa is unlikely to pose a plant pest (USDA-APHIS, 2009), APHIS will have no regulatory authority over GT alfalfa, and will be unable to impose regulatory restrictions on these GE alfalfa varieties.”

Such out of hand rejection of these alternatives does not comply with NEPA. Agencies cannot define the project so narrowly that it foreclosed a reasonable consideration of alternatives;” they “cannot define its purpose and need so as to winnow down the alternatives until only the desired one survives.”³⁰ “NEPA’s legislative history reflects Congress’s concern that agencies might *attempt to avoid any compliance with NEPA by narrowly construing other statutory directives* to create a conflict with NEPA. Section 102(2) of NEPA therefore requires government agencies to comply ‘to the fullest extent possible.’³¹

Further, the structure of the alternatives analysis gets to the crux of APHIS’s misconception of NEPA, impermissible frame of this DEIS, and mischaracterization of its authority under the Plant Protection Act. APHIS claims it need not analyze any partial deregulation alternatives such as isolation distances or geographic restrictions, or even meaningful consider the no-action alternative, not because other alternatives like isolation distances would not work or because such measures are not be needed, but because the agency has (erroneously) determined that GT alfalfa does not pose a plant pest risk in a separate document. Based on this faulty reasoning, APHIS rejects reasonable alternatives such as isolation distances, geographic restrictions and testing requirements without any discussion of the potential benefits of these alternatives. (DEIS at 14-15).

First, beyond its plant pest determination, APHIS has broad authority to protect and further U.S. agriculture and therefore violated NEPA by failing to perform an adequate alternatives analysis. Second, again, APHIS has the analysis process precisely backwards: the EA *should inform the agency’s decision-making process*, not the other way around (i.e., have the agency’s forgone conclusion limit and prejudge the NEPA analysis). The policy behind NEPA is “to ensure that an agency has at its disposal all relevant information about environmental impacts *before* the agency embarks on the project.”³²

APHIS also claims it can only approve a petition “in part” if there is a plant pest risk associated with some but not all lines requested in the petition. (DEIS at 12). There is no basis in the statute or regulations for this extremely limited interpretation.

The agency also argues it could consider a deregulation with geographic restrictions, if there is a “geographic variation” in risk, but then removed from consideration the concept of approving partial deregulation with geographic restrictions because the DEIS states that there are no geographical variations in risk.

³⁰ *Klamath-Siskiyou Wildlands Center v. U.S. Forest Service*, 373 F. Supp. 2d 1069 (E.D. Cal. 2004).

³¹ *Center for Biological Diversity v. National Highway Traffic Safety Admin*, 538 F.3d 1172, 1213 - 1214 (9th Cir. 2008).

³² *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1356 (9th Cir.1994).

This reasoning is arbitrary and capricious and not take the hard look NEPA requires. There are significant geographical variations in risks. As APHIS points out, alfalfa hay production occurs across the country, “in almost all the States, with farming conditions varying considerably depending on climate rainfall, soil fertility, weed and disease prevalence, whether it is seeded in the fall or the spring...” (DEIS at 34). In contrast, “[u]nlike alfalfa hay production, alfalfa seed production is largely concentrated both geographically and in number of producers.” (DEIS at 43). In fact, 60% of seed production occurs in California, Washington, and Idaho. Id.

There are of course a variety of differences between hay and seed production. The presence of weeds can have a greater impact on the costs in alfalfa seed production than alfalfa forage production because the separation of weeds seeds from alfalfa after harvest is costly. (DEIS at 44). Transgenic contamination can occur in different ways in seed and hay fields. While hay fields can and often do go to seed and pollination does occur, farmers purposefully stock bees in seed fields for pollination. (DEIS at 94).

Additionally, the type of managed bees used for pollination depending on geographic location. Leafcutter bees are used primarily in the Pacific Northwest while honey bees are typically used in the irrigated valleys of the Desert Southwest. The honey bee is known to travel six miles or more, while the leafcutter bee travels far less. (DEIS at 95). Different wild pollinators are located in different regions. Different weather patterns affect the timing of harvest and the ability to harvest forage hay before bloom in different parts of the country.

In short, the environmental risks differ for cultivation of hay and seed, and differ between different regions of the country. Reasonable alternatives may exist for mitigating these risks, such as isolation distances and geographic restrictions, which APHIS arbitrarily and capriciously refused to even consider.

Further, APHIS claims it has no authority to mandate isolation distances and so it does not have to analyze an alternative with isolation distances, but the 2008 Farm Bill, Section 10204(b)(7), requires the Secretary to take actions that enhance “the use of the latest scientific techniques for isolation and confinement distances.” Farm Bill Section 10204(c)(1)(C) requires the Secretary to consider establishing “standards for isolation and containment distances.” Congress clearly understands APHIS’s existing oversight to include the power to establish isolation distances, else the agency could not comply with this particular directive in the Farm Bill.

The unconditional deregulation of GT alfalfa poses significant risks to the quality of the human environment. For example, the significant likelihood of gene flow from GT alfalfa to non-GT alfalfa poses risks to the livelihood of organic and conventional farmers as well as the environment. The potential for APHIS to reduce these significant impacts by adopting one or more of these “rejected” alternatives must be fully analyzed as an alternative. Finalizing the current draft without fully analyzing reasonable alternatives would be arbitrary and capricious agency action.

III. Transgenic Contamination Is Not Adequately Analyzed And Is A Significant Impact.

The DEIS inadequately addresses the risk for transgenic contamination of non-GT Alfalfa and erroneously concludes that this harm is not significant.

Contamination Is Likely

As the outpouring of comments to this docket will show, transgenic contamination is likely and will happen by a variety of means if APHIS deregulates GT alfalfa.

Transgenic contamination occurs through a variety of pathways. Pollination of non-genetically engineered plants by genetically engineered plants, mixing of genetically engineered seed with non-genetically engineered seed, improper seed cleaning, weather events and human error all lead to biological contamination. For example, widespread practices of land leasing, and contract hay farming routinely result in the harvest and transport of significantly overripe hay crops. Table 4-3 also acknowledges that gene transfer between feral populations is likely.

Evidence submitted during the *Geertson* lawsuit demonstrated that not only is contamination through gene transfer possible, but that even after the alfalfa industry had only converted 1% of the industry to GE, contamination had already begun. Foundation Seed fields of Dairyland in Idaho, Montana, and Wyoming were found to be contaminated, and Cal/West seed fields in California were similarly found to be contaminated. Recent evidence submitted in this docket demonstrates that over two years later, the contamination is getting worse. For example, in Cal/West Seeds Winter 2010 newsletter, Dr. Jonathan Reich, Cal/West Executive Director for R &D published the following data:

- 12% of over 200 lots of non-GE alfalfa seed tested positive for RR alfalfa gene, compared to 3% in 2008
- During 2008, 100% of 6 research seed stock lots produced at Cal/West's Woodland, CA research farm tested positive for GE contamination - attributed to hay-to-seed gene transmission
- Preliminary 2009 has revealed 30% of 10 seed stock lots have tested positive for GE contamination.
- Conclusion: "It is becoming clear that this gene or any gene can easily spread and that we are going to have to take extraordinary measures when producing foundation seed and commercial seed for GMO sensitive markets."

While APHIS disregards the potential for contamination of seed stocks as unlikely and inconsequential, industry data such as that from Cal/West seed demonstrates that this is simply false. Therefore such conclusions are arbitrary and capricious.

APHIS analysis offers no discussion of the possibility of shatter/scatter from transport of overripe hay, non-intentional seed production, and the potential for this to create feral or unintentional populations, which then pose unidentified sinks of cross-pollination risks not subject to farmers' intentions to comply with "best practices." This exact scenario has unfolded with alarming frequency in GE canola cultivation. No data is presented as to the frequency with which viable alfalfa seed might escape in this manner or the potential distribution and gene flow that might result from such a scenario.

If GT alfalfa is deregulated there would be no restrictions or permits required to grow GT alfalfa. Instead, APHIS relies on farmers' perfect adherence to Monsanto MTA and FGI's Best Practices to keep gene flow at bay. APHIS lists several conditions that increase the possibility of gene flow such as seed field proximity, pest management strategy, feral alfalfa gene flow corridors, movement of honey bees and overstocking pollinators. In addition to unenforceable best practices, farmers must also "take these factors and employ methods to counter these factors" to help reduce or prevent gene flow between neighboring alfalfa crops. (DEIS at 105). Yet, despite best practices and additional methods to reduce gene flow, contamination can and will occur. Furthermore, APHIS cannot delegate its statutory duties to third parties in this way and to do so completely in this manner is arbitrary and capricious.

In any event, the sufficiency of mitigation measures has been stated as whether they constitute "an adequate buffer against the negative impacts that may result from the authorized activity."³³ As a practical matter, the job of preventing gene flow falls to the people least likely to actually take those precautions, namely those who don't care if contamination occurs and a full analysis of the likelihood that such practices will actually be used is lacking. Moreover here it is clear the business as usual practices given APHIS' imprimatur will not prevent contamination. The DEIS documents that wild and farmed pollinators can travel and cross-pollinate well beyond any distances of seed contracts and best practices. APHIS' conclusion that transgenic contamination will not occur despite this fact is flatly contrary to the record evidence.

The U.S. Fish and Wildlife Service, in a recent draft of a Biological Opinion on the effects of Roundup Ready creeping bentgrass, prepared pursuant to the Endangered Species Act, noted: "Recent escape of GM sugar beets into compost sold to homeowners illustrates the potential for products to move outside of their intended market. Sugar beets are . . . wind pollinated and were thought to be well controlled by the growers using the product. Despite best management practices, escape of the transgenes occurred."³⁴

In the Union of Concerned Scientist ("UCS") report, "Gone to Seed," UCS found that about 50% or more of the certified non-GE corn, canola, and soybean seed has been contaminated with transgenes.³⁵ The level of contamination was typically 0.05%-1.0%, far greater than the minimum levels that can be detected. "Gone to Seed" demonstrated

³³ National Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722 (9th Cir. 2001).

³⁴ FWS Draft Biological Opinion, Roundup Ready Bentgrass, July 2009.

³⁵ M. Mellon and J. Rissler, *Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply*, Union of Concerned Scientists, 2004.

that the frequency and levels of contamination of soybean seed was found to be about as high as for corn. Soybeans are largely self-pollinating (do not pollinate other soybean flowers very often), while corn is highly out-crossing. Therefore, the contamination of soybean seed is likely to be largely from causes other than cross-pollination. Such causes could include seed mixing or human error, and suggests that these sources may be at least as important as cross-pollination.

Another report, “A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops,” UCS enlisted the assistance of several academic experts in agricultural sciences to determine whether GE pharmaceutical-producing crops could be kept out of food. This report demonstrates how difficult this is, even for pharmaceutical crops that would be grown on small acreage and under stringent confinement, to avoid contaminating food. The authors of this report examined confinement methods, such as field separation, cleaning of farm equipment, segregation of seed, and others, and found that it would still be difficult to ensure the absence of contamination.³⁶ The experts felt that contamination might be prevented by taking heroic means, such as geographical isolation from food crops. Union of Concerned Scientists concluded that even though it may be theoretically possible to prevent contamination, it would not be economically feasible.

Another route of contamination that is unpredictable, but likely over time, is human error. Two academic ecologists address this in a peer-reviewed paper, and conclude that contamination by GE crops due to human error or other means has occurred numerous times, and is likely to continue to occur. This paper documents many instances where GE crops are known to have contaminated non-GE crops or food.³⁷ Thus, biological contamination through human error and human behavior, such as composting and exchanging seeds, must be addressed in an EIS.

Past Contamination Episodes

Past contamination episodes from GE crops provide cautionary tales for why contamination is an impact that must be considered here. For example, the Star Link corn contamination showed how much damage a GE-crop can do to the agricultural economy. StarLink is a variety of corn genetically engineered to produce the Cry9C insecticidal toxin to kill certain corn pests.³⁸ Due to the concerns of leading allergists advising the EPA that this toxin might cause food allergies, the EPA approved StarLink in 1998 only for animal feed and industrial uses such as ethanol production, but not for human consumption. The EPA had a binding agreement with the developer of StarLink, Aventis CropScience. According to this agreement, all Aventis-affiliated seed dealers would sell StarLink corn seed to farmers only if the farmers would agree to the following

³⁶ David Andow, et al., A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops Union of Concerned Scientists, December 2004.

³⁷ M. Marvier and R. Van Acker, “Can crop transgenes be kept on a leash?” *Front. Ecol. Environ.*, 2005, vol.3, p.95-100.

³⁸ For the following discussion of StarLink, see Freese, B. (2001). “The StarLink Affair,” *Friends of the Earth*, July 2001. www.foe.org/safefood/starlink.pdf.

conditions: 1) Plant a buffer strip 660 feet wide around StarLink corn plots to mitigate cross-fertilization of neighboring corn fields; and 2) Segregate StarLink corn and buffer strip corn for distribution only to non-food channels.³⁹ Aventis CropScience assured the EPA that with these measures it could keep StarLink out of the human food supply.

StarLink corn was grown for only three years, from 1998 to 2000, on at most 341,000 acres, or 0.43% of total U.S. corn acreage (year 2000).⁴⁰ Despite the limited acreage planted to StarLink, and the conditions attaching to its cultivation, testing initiated by public interest groups and subsequently conducted by the U.S. Food and Drug Administration (FDA) found that over 300 corn products in grocery stores around the country were contaminated with StarLink. The USDA found StarLink contaminating 9-22% of grain samples.⁴¹

The extent of the contamination is startling when one considers that StarLink never represented more than 0.43% of U.S. corn acreage. While post-harvest mixing was responsible for much of the contamination, there is also abundant evidence that popcorn, sweet corn, white corn and seed corn stocks were also contaminated with StarLink.⁴² These latter findings strongly suggest that StarLink pollen blown by the wind fertilized conventional corn, despite the 660-foot border strip requirement. In fact, the a USDA-sponsored testing program for seed companies that had never been licensed to grow StarLink found that nearly one-fourth of these seed firms (71 of 288) had some corn lines that tested positive for StarLink. USDA had to buy back nearly 450,000 units of StarLink-contaminated seed corn at a cost of several million dollars to prevent further spread of StarLink in future years. Tainted seed dated anywhere from production year 1997 to 2001.⁴³

Recent contamination events in other crops illustrate how difficult it is to prevent contamination at detectable and economically important levels. Of particular interest is the recent contamination of rice by the unapproved GE LL601 “Liberty Link” rice. This type of GE rice was grown only in limited-acreage field tests, rather than on a commercial scale, and under the regulatory auspices of APHIS, which includes confinement recommendations. It had not been grown at all for several years, but contamination of the US rice supply was detected several years later at low levels that have nonetheless caused economic harm to the US rice industry. At least one identified source of contamination by LL601 occurred at Louisiana State University (LSU), where

³⁹ EPA Cry9C Fact Sheet (2000). “Biopesticide Fact Sheet: *Bacillus thuringiensis* subspecies *tolworthi* Cry9C Protein and the Genetic Material Necessary for Its Production in Corn (006466),” Issued November 2000.

⁴⁰ SAP StarLink (2001). “Assessment of Additional Scientific Information Concerning StarLink Corn,” FIFRA Scientific Advisory Panel to the EPA, SAP Report No. 2001-09, from meeting on July 17/18, 2001.

⁴¹ Shadid, A. “Genetically engineered corn appears in one-tenth of grain tests,” Boston Globe, May 3, 2001. Shadid, A. “Testing shows unapproved, altered corn more prevalent than thought,” Boston Globe, May 17, 2001.

⁴² USDA News Release (2001). “USDA purchases Cry9C affected corn seed from seed companies,” June 15, 2001. Formerly accessible at: www.usda.gov/news/releases/2001/06/0101.htm; Hovey, A (2001). “StarLink protein found in other crops,” Lincoln Star Journal, March 29, 2001.

⁴³ Freese, B. (2001). “The StarLink Affair,” Friends of the Earth, July 2001, p. 12.

one of the scientists in charge has claimed that they exceeded APHIS confinement recommendation considerably, but still experienced contamination.⁴⁴

By one estimate, rice farmers lost \$150 million due to rejection of LL601-contaminated rice shipments by countries in Europe and elsewhere, and the consequent sharp drops in rice prices.⁴⁵ Affected rice farmers were forced to sue Bayer CropScience, the developer of LL601, in an effort to recover their losses. In response to a petition from Bayer CropScience, APHIS subsequently deregulated LL601, but did nothing to redress the economic harms to rice farmers. Rather than accept responsibility for the episode, Bayer CropScience blamed farmers and an “Act of God” for the contamination episode.⁴⁶ At least one identified source of contamination by LL601 occurred at Louisiana State University (LSU), where LL601 had been grown in small-scale field trials. One of the scientists in charge of the field-testing stated that LSU had grown LL601 under conditions that met and exceeded APHIS confinement recommendations considerably, but still experienced contamination.⁴⁷ Just months later, still another unapproved GE rice variety developed by Bayer CropScience, LL604, was found contaminating a popular variety of conventional rice sold to farmers as seed rice (Clearfield 131). APHIS responded by issuing several emergency action notifications to distributors of Clearfield 131 to halt sales of the contaminated seed rice.⁴⁸ As a result, rice farmers in the South experienced a severe shortage of seed rice for the 2007 season.⁴⁹ APHIS conducted an investigation into the contamination episodes, but was unable to determine precisely how they occurred.⁵⁰

Furthermore, there is substantial variation in the results from different experiments when measuring biological contamination through pollen transfer. This has been seen for virtually every crop studied. Many factors affect gene flow frequencies, including weather conditions (precipitation, wind, temperature, humidity), which will affect bee behavior, pollination levels, and the duration of pollen viability. The relative size of the pollen recipient and pollen production fields also has a very big impact on the distances and frequencies of gene flow. As one example, a field trial of creeping bentgrass containing 286 plants revealed contamination at up to about 1400 feet, while one of 400 acres had cross-pollination at 13 miles.⁵¹ Small canola field trials (a bee pollinated crop) often have significant cross pollination at several hundred to several thousand feet, while

⁴⁴ G. Vogel, “Tracing the transatlantic spread of GM rice,” *Science*, 2006, vol. 313, p. 1714.

⁴⁵ Weiss, R. (2006). “Gene-altered profit-killer,” *Washington Post*, Sept. 21, 2006.

⁴⁶ Weiss, R. (2006). “Firm Blames Farmers, ‘Act of God’ for Rice Contamination,” *Washington Post*, Nov. 22, 2006.

⁴⁷ Vogel, G. (2006). “Tracing the transatlantic spread of GM rice,” *Science*, 2006, vol. 313, p. 1714.

⁴⁸ USDA APHIS (2007). “Statement by Dr. Ron DeHaven regarding APHIS hold on Clearfield CL131 long-grain rice seed,” March 5, 2007.

http://www.aphis.usda.gov/newsroom/content/2007/03/content/printable/gericeseed_statement.doc

⁴⁹ Bennett, D. (2007). “Arkansas’ emergency session on CL 131 rice,” *Delta Farm Press*, March 1, 2007.

⁵⁰ USDA (2007). “Report of LibertyLink Rice Incidents,” October 2007.

⁵¹ (JK. Wipff and C. Fricker, “Gene flow from transgenic creeping bentgrass (*Agrostis stolonifera* L.) in the Willamette Valley, Oregon,” *International Turfgrass Society Research Journal*, 2001, vol. 9, p. 224;LS Watrud et al., “Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker,” 2004, *PNAS*.

a study in Australia at the commercial scale observed contamination at up to about 3 kilometers.⁵²

Contamination is a Significant Impact

As the *Geertson* Court noted: “Once the gene transmission occurs and a farmer’s seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread.”⁵³ Despite documented incidents of Alfalfa contamination, APHIS nevertheless concludes that granting nonregulated status to GT Alfalfa will not have significant impact on the human environment. This conclusion is contrary to NEPA.

Contamination will cost farmers their right to sow the crops of their choice and consumers the right to feed their families non-GE food. The court expressly found that this was cognizable harm pursuant to NEPA in his underlying order. “A federal action that eliminates a farmer’s choice to grow non-genetically engineered crops, or a consumer’s choice to eat non-genetically engineered food, is an undesirable consequence: another NEPA goal is to “maintain, wherever possible, an environment which supports diversity and variety of individual choice.” 42 U.S.C. § 4331(b)(4).”

IV. Deregulation Will Cause Significant Interrelated Economics Impacts.

APHIS concludes that the deregulation will not have significant interrelated economic impacts on alfalfa farmers and alfalfa end users. However overwhelming evidence belies this conclusion, demonstrating that biological contamination of non-GE conventional and organic alfalfa seed, hay, and end products that rely on non-GE alfalfa will in fact cause significant economic harm that must be addressed under NEPA. Failure to acknowledge this interrelated economic harm, and failure to find that this economic harm is a significant impact under NEPA is arbitrary, capricious, and an abuse of discretion.

The rule under NEPA is that economic effects are relevant and must be examined “when they are interrelated with natural or physical environmental effects.”⁵⁴ The court explained in *Geertson*: “The economic effects on the organic and conventional farmers of the government’s deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment; namely, the alteration of a plant species’ DNA through the transmission of the genetically engineered gene to organic and conventional [sugar beets].”⁵⁵

Moreover, “one of Congress’s express goals in adopting NEPA was to attain ‘the widest range of beneficial uses of the environment without degradation, risk to health and safety,

⁵² MA Rieger et al., “Pollen-mediated movement of herbicide resistance between commercial canola fields,” *Science*, 2002, vol. 296, p. 2386-2388.

⁵³ 2007 WL 518624 *5.

⁵⁴ *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 944 (9th Cir. 2005) (quoting 40 C.F.R. §1508.14).

⁵⁵ 2007 WL 518624 *8.

or other undesirable and unintended consequences.”⁵⁶ Accordingly, “[a] federal action that eliminates a farmer’s choice to grow non-genetically engineered crops, of a consumer’s choice to eat non-genetically engineered food, is an undesirable consequence: another NEPA goal is to ‘maintain, whenever possible, an environment which supports diversity and variety of individual choice.’”⁵⁷

APHIS’ claim that there will be no impacts on organic farmers or organic consumers because the presence of a detectable GE residue does not constitute a violation of the National Organic Standards, are equally arbitrary and capricious. (DEIS at 60). During the implementation of the Organic Food Production Act, the Department of Agriculture indicated that the presence of GE contaminants would render a product unmarketable as organic. The Department explained:

[C]onsumers have made clear their opposition to the use of [GE] 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 food runs counter to consumer expectations, [GE foods] will not be permitted to carry the organic label.⁵⁸

Thus, as the *Geertson* court found:

[E]ven APHIS is uncertain whether farmers can still label their products organic under the federal government’s organic standards. Second, many farmers and consumers have higher standards than what the federal government currently permits; to these farmers and consumers organic means not genetically engineered, even if the farmer did not intend for his crop to be so engineered. . . . Third, and most importantly, APHIS’s comment simply ignores that these farmers do not want to grow . . . genetically engineered alfalfa, regardless of how such alfalfa can be marketed.⁵⁹

Like in *Geertson*, “APHIS reasoning that farmers will ‘not necessarily’ be prohibited from labeling their products as organic is wholly inadequate.”⁶⁰ And here, contrary to APHIS’s brazen conclusion that “most U.S. consumers are unaware of the prevalence of GE material in the U.S. food supply,” (DEIS at 58), as the evidence in the record will demonstrate, consumers are in fact extremely concerned about avoiding GE content in organic food. For example, during the *Geertson Seed Farm* litigation, organic dairy companies including CROPP Cooperative (aka Organic Valley), Straus Family Creamery, and dairies across Wisconsin that rely on organic alfalfa forage for their organic dairy production, indicated that contamination of organic alfalfa from GE alfalfa

⁵⁶ Id. (emphasis in original) (quoting 42 U.S.C. § 4331(b)(3)).

⁵⁷ Id. (quoting 42 U.S.C. § 4331(b)(4)).

⁵⁸ 65 Fed. Reg. 13534-35 (Mar. 13, 2000) (emphasis added). Like in this record where over 200,000 members of the public expressed concern that release of GE alfalfa will contaminate organic alfalfa, during the rule-making for organic 275,000 members of the public expressed concern that GE be prohibited in organic production.)

⁵⁹ 2007 WL 518624 at *7.

⁶⁰ Id. at *7.

could cost millions. Straus Family Creamery indicated that loss of organic alfalfa in 2007 could jeopardize their entire \$15 million dairy operation. Organic Valley's \$287 of 2006 sales, projected to be \$450 million in 2007 and significantly more by 2010, could lose significant portions of its business. At a minimum, contamination of organic alfalfa would eliminate the loss of organic premiums, which can be over 40% more than conventional premiums. For a \$450 million dairy industry, biological contamination could account for hundreds of millions of dollars in losses, never mind the potential loss of markets and market credibility in the specific organic sector.

Beyond organic dairy losses that could result from deregulation of GE alfalfa, there will be significant losses in the seed markets themselves. In 2007, alfalfa seed was grown on over 120,000 acres to produce over 60 million tons of seed, including over 2 million pounds of organic seed. Contamination of this seed will result in losses exceeding well over \$3 million. Similarly, non-GE conventional seed export markets are in jeopardy because critical foreign markets, including Japan, Saudi Arabia, and the EU are GE-sensitive markets or reject GE seed stocks outright. Conservatively, U.S. seed exports exceed \$3.5 million, and are in grave risk due to broad contamination once GE alfalfa is deregulated.

Furthermore, there will be significant adverse economic impacts in the alfalfa hay markets. As indicated in the EIS (p. 37), over 204,000 acres of organic hay are grown in the U.S. Given an organic price premium of over \$18 for organic hay (DEIS at p. 49 (common place for organic feed stuff to sell for at 10 to 30 percent premium)), once GE alfalfa contaminates and therefore displaces organic hay production, lost organic hay premiums will exceed \$11 million.

In short, there is overwhelming evidence that the deregulation of Roundup Ready alfalfa will result in the contamination of non-GE alfalfa and have a significant adverse economic impact on farmers, producers and ultimately on consumers. APHIS' failure to analyze and disclose this impact in the DEIS violated NEPA and is arbitrary, capricious and an abuse of its discretion.

V. The DEIS' Analysis of Cumulative Impacts Is Inadequate.

The DEIS must fully consider the cumulative impacts from past, present and future foreseeable actions by APHIS or other agencies, including but not limited to future market introductions of GE crops. This is required by the Council on Environmental Quality (CEQ) regulations (40 CFR 1500 to 1508) as part of the EIS process. CFR 1508.7 defines cumulative impacts as:

[T]he impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

The cumulative impacts analysis presented in the DEIS is lacking in several ways. First, it inaccurately assumes that glyphosate will replace more toxic herbicides in alfalfa when in fact, alfalfa farming is not dependant on herbicides and herbicides are rarely used. The dramatic increase in glyphosate use from a deregulation of GT alfalfa must be analyzed. Second, the cumulative impacts of stacking are not addressed. Third, the impacts of seed market concentration are minimized. Finally, APHIS underestimates the impacts of increase glyphosate-tolerant crop systems will have on global climate change.

Herbicide Use

APHIS recognizes that several GT crops are available on the commercial market, including GT corn, GT cotton, GT soy and GT sugarbeets. (EIS at 169). In fact, in 2009, approximately 115,000,000 acres of herbicide-tolerant crops were planted, mostly glyphosate- or glufosinate-tolerant corn, cotton or soybean. These crops are part of binary weed control technology that comprises the glyphosate-tolerant crop and direct application of glyphosate-based herbicide. In fact, glyphosate use increased more than six-fold between 1992 and 2002, to become the most used herbicide in the United States. (DEIS at 170).

If even half of all alfalfa acres are planted with GT alfalfa, 10.5 million acres of alfalfa will be converted to GT, comprising nearly 10% of the total GT acreage. (DEIS at 169). This conversion to GT alfalfa will exacerbate the known problems with the glyphosate-tolerant or Roundup Ready crop system. Alfalfa is a perennial crop that covers the ground uninterruptedly for the life of the stand, leaving little or no room for weeds to survive. Alfalfa also is a vigorous, dense plant, generally out competing weeds. Alfalfa's conversion to an herbicide-dependant crop system will promote glyphosate-resistant noxious weeds and alter the environmentally friendly farming and nutrient building qualities alfalfa is know for.

APHIS claims that as GT alfalfa is adopted, glyphosate herbicide will replace other, more toxic forms of weed control currently used in alfalfa. (DEIS at 171). APHIS assumes that current forms of weed control are more toxic than glyphosate and that all conventional alfalfa growers regularly use large quantities of herbicides. However, as the agency's own studies show, the great majority of alfalfa is currently grown without the use of any herbicides at all.⁶¹ In fact, only 7 percent of alfalfa hay farmers apply pesticides to their crops.⁶² Therefore, in contrast to APHIS' bald assumptions, GT alfalfa will dramatically increase Roundup use without significantly displacing other herbicides.⁶³ The impact of this dramatic increase of the Roundup Ready crop system on the environment is a significant environmental impact.

⁶¹ See USDA Agricultural Chemical Usage, 1998 Field Crop Summary, 1999).

⁶² Id. at 3.

⁶³ For more information on pesticide usage in alfalfa, see Center for Food Safety's Science Comments submitted by Bill Freese.

Resistant Weeds

Increasing glyphosate-tolerant crops systems can and will increase the instances of glyphosate-tolerant weeds, causing farmers to use more toxic herbicides than the glyphosate that is currently available to them. As discussed in separately submitted CFS comments, weed resistance to glyphosate is well documented. Weed resistance is an increasingly expensive and environmentally harmful problem faced by US farmers. However, APHIS' discussion of this increased cost to farmers is also inconclusive.

USDA admits that GT alfalfa will require more toxic herbicides like 2,4-D and dicamba for taking out old stands. (DEIS at 66). Yet, the DEIS is silent on the cumulative effects of the increased use of more toxic pesticides in response to weed resistance to glyphosate. As more weeds become resistant to glyphosate, this so called "environmentally friendly" herbicide will no longer be available for farmers and landscapers. They will be forced to use more toxic herbicides and destroy many of the benefits of alfalfa growing.

Monsanto and weed scientists are well aware of the problem of weed resistance caused by these glyphosate-tolerant crop systems and are advising farmers to employ non-glyphosate herbicides (preemergence, residual herbicides; tank mixes) to control and forestall the further spread of glyphosate-resistant weeds. For instance, paraquat and 2,4-D are recommended in addition to glyphosate to control GR horseweed and Pigweed.⁶⁴ And, glyphosate-tolerant crop systems promote the creation of new herbicides. Monsanto recently announced the approval of a new herbicide for use on resistant weeds. Monsanto representative Kerry Overton stated that "[f]armers face a number of weed control challenges in cotton and soybean production."⁶⁵ On both crops, glyphosate based herbicides are heavily used. (See DEIS 171). This new herbicide formulation will provide improved control over the famed palmer amaranth, the dominant pigweed in the south. (DEIS at G-28). The glyphosate-resistant palmer amaranth is "the most competitive and rapidly growing species of pigweeds and can reach a height of six feet."⁶⁶ In sum, the cumulative impacts of increased herbicide use in GT alfalfa were not properly analyzed.

The creation and further increase of glyphosate-resistant weeds is a significant impact on the environment.

⁶⁴ Laws, F. (2006). "Glyphosate-resistant weeds more burden to growers' pocketbooks," *Delta Farm Press*, November 27, 2006, <http://deltafarmpress.com/news/061127-glyphosate-weeds/>. For an overview of recommendations by weed scientists and Monsanto for controlling and/or forestalling GR weeds, see: FoEI-CFS (2008). "Who Benefits from GM Crops? The Rise in Pesticide Use," Friends of the Earth International-Center for Food Safety, January 2008, Section 2.3. <http://www.centerforfoodsafety.org/pubs/FoE%201%20Who%20Benefits%202008%20-%20Exec%20Sum%20FINAL.pdf>.

⁶⁵ Agriculture Online, Monsanto Targets Resistant Weeds with New Herbicide, Feb. 2, 2010, *available at* <http://www.agriculture.com/ag/story.jhtml?storyid=/templatedata/ag/story/data/1265129824811.xml>

⁶⁶ For a detailed discussion of the significant impacts of glyphosate-resistant weeds, see the CFS Comments.

Stacking

While Monsanto and FGIs GT Alfalfa is currently the only existing GE alfalfa, it is possible that in the future, additional lines of GE alfalfa will be created with traits that can be “stacked.” Stacking of GE crops may create significant environmental impacts that have not before been analyzed anywhere, such as “super-glyphosate tolerance.” For instance, in other GT crops, GE crop producers intend on stacking up to three mechanisms of glyphosate-tolerance in a single plant. This will allow more frequent applications of higher doses of glyphosate, perhaps over the entire growing season of the crop. Such super-tolerance will enable vastly increased use of glyphosate (over already exorbitant and growing levels) in an attempt to keep up with the rapidly growing level of glyphosate-resistance found in various weed species. The end result is a vicious circle of rising glyphosate use to control resistant weeds, followed by increased weed resistance, which in turns drives still more chemical use. New GT crop varieties have also begun to stack glyphosate-resistance with resistance to older, more toxic pesticides like 2,4-D, demonstrating that the proliferation of glyphosate-resistant weeds is driving the creation of new stacked crops, which will in turn drive the return to using of more toxic herbicides. While Monsanto and FGI have yet to propose such stacking in alfalfa, it is a potential future impact that APHIS must address.

Seed Market Concentration

The DEIS briefly discusses seed market concentration and concludes that the even the scant evidence discussed suggests “a possible negative impact of market concentration on future research and development.” (DEIS at 178). Yet, research and development is not the only area that suffers from seed market concentration. The privatization and concentration of the worlds seed supply is a serious and continuously evolving problem, compounded with each new GE crop deregulation. “It is estimated that the top ten seed corporations around the globe hold 49-51% of the commercial seed market, and top ten agro-chemicals control 84% of the agrochemicals market. Likewise, all genetically modified (GM) seeds are bio-patented by multinational corporations and 13 commercial corporations own 80% of GM food market.”⁶⁷

With increased seed market concentration, the once diverse selection of conventional seed is disappearing. Farmers are finding it increasingly difficult to find conventional soy and corn seeds.⁶⁸ Farmers are forced to purchase GE seed and with that pay hefty technology fees and adhere to strict regulations stripping them of the age old practice of saving seed. For these and other reasons, the DEIS does not adequately address the cumulative impact of seed market concentration. The seed market concentration impacts of a deregulation of GT alfalfa is a significant cumulative impact.

⁶⁷ Yamuna Ghale and Bishnu Raj Upreti, Concentration and Monopolisation of Seed Market: Impact on Food Security and Farmer’s Rights in Mountains, *available at* http://docs.google.com/viewer?a=v&q=cache%3A3CPrhC0TuVIJ%3Awww.mtnforum.org%2Frs%2Fol%2Fcounter_docdown.cfm%3FfID%3D2056.pdf+seed+market+concentration&hl=en&gl=us&sig=AHIEtbTwpX0MzR5HZZ8CUBA8qoWofinQvw&pli=1.

⁶⁸ CFS, Monsanto v. US Farmers, Jan. 13, 2005, *available at* <http://truefoodnow.files.wordpress.com/2009/12/cfsmonsantovsfarmerreport1-13-05.pdf>.

Global Warming

APHIS' discussion on the cumulative impact of glyphosate-tolerant crop systems on global warming relies on unsupported presumptions. First, APHIS again inaccurately presumes that glyphosate use on GT alfalfa will replace more toxic herbicides: “[G]lyphosate is less toxic than other herbicides, and would be used instead of more environmentally harmful herbicides in GT alfalfa, it is likely that the increased use of glyphosate in GT alfalfa would have little cumulative effect on amphibians” and that the “cumulative effect of glyphosate use [will] likely be minimal.” (DEIS at 181). APHIS' continued reliance on erroneous information undermines and negates the analysis on global climate change. If the agency begins with this inaccurate presumption, as it has several times in the DEIS, the arguments that stem from this presumption are also flawed.

Additionally, APHIS assumes that farmers and producers will follow label restrictions for glyphosate use and that this adherence to application guidelines will somehow protect fish populations from the toxic effects of herbicides in snowmelt. (DEIS at 181-82). APHIS provides no support for the contention that the label restrictions will prevent environmental damage from the ever increasing use of glyphosate on glyphosate-tolerant crop systems. APHIS must properly examine the risks of increased glyphosate use on global warming.

VI. The DEIS Fails to Analyze Significant Impacts to Public Health.

Public health issues may be significant environmental impacts. The CEQ regulations explain what factors may be significant effects on the human environment and one such factor is “[t]he degree to which the proposed action affects public health or safety.”⁶⁹ Moreover in the APHIS draft programmatic EIS, issued July 7, 2007, APHIS listed impacts on human health as a category of impacts of its NEPA assessment.⁷⁰ Accordingly, APHIS's DEIS must address any potential human health or safety risks and determine whether those human health and safety impacts are significant.

If those impacts are to be found not to be significant, there must be a convincing statement of reasons. Here there is no meaningful analysis by the agency of potential human health impacts or a convincing statement of reasons why such impacts may not be significant. APHIS has not complied with NEPA. APHIS cannot solely rely on another agency's evaluation of effects under a separate statute to adequately fulfill its own NEPA obligations. Health impacts are cognizable impacts pursuant to NEPA that require an EIS if they may significantly impact the “human environment.” These impacts are interrelated to the environment because they would stem from the biological contamination of natural alfalfa (through cross-pollination and other means) and cause unknown and unwilling human exposures. Accordingly, APHIS has its own duty to comply with NEPA, including assessment of potential significant impacts to public health and safety.

⁶⁹ 40 C.F.R. § 1508.27(b)(2).

⁷⁰ DEIS at 67-90.

APHIS must not merely defer in toto to FDA: FDA's voluntary consultation process is extraordinarily weak. It is based on a statement of policy, not a binding regulation. GE crop developers may choose to consult with FDA, but this process is vitiated by its voluntary nature and a lack of any established testing standards; in particular, GE crop developers seldom if ever conduct animal feeding trials with GE crops for the purpose of detecting potential toxicity. The manufacturer merely sends FDA a summary of its findings. FDA makes no findings. FDA did not prepare any NEPA documentation (no EA nor EIS) on its policy nor provide notice and comment. In any event, APHIS cannot solely rely on another agency's evaluation of environmental effects under a separate statute to adequately fulfill its own NEPA obligations.⁷¹

It is well accepted that genetic engineering has a greater likelihood of producing unintended effects than traditional breeding, some of them hazardous or detrimental.⁷² Unintended effects are rarely well-understood, but can result from extensive mutations to the organism's genes caused by the genetic engineering process,⁷³ or unexpected metabolic alterations. Such disruptions are sometimes evident in the form of non-viable or debilitated organisms. Others may have subtler effects that go undetected in the development process. Potential adverse effects include the unintended amplification of naturally occurring toxins that are normally present at low, unobjectionable, levels; the unintended creation of novel toxins; or reduced levels of nutrients.

The impacts of the Glyphosate-Tolerant Crop System on health must also be analyzed. Roundup use has been associated with increased risk of non-Hodgkin's lymphoma and hairy cell leukemia in pesticide applicators,⁷⁴ and increased risk of neurobehavioral disorders in children of Roundup applicators.⁷⁵ Roundup/glyphosate has been shown to inhibit steroidogenesis.⁷⁶ Both Roundup and glyphosate have been found to inhibit the aromatase enzyme involved in estrogen production, though Roundup was more potent.⁷⁷

⁷¹ Save Our Ecosystems v. Clark, 747 F.2d 1240, 1248 (9th Cir. 1983); Oregon Envtl. Council v. Kunzman, 714 F.2d 901, 905 (9th Cir. 1983).

⁷² NAS (2004). *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects, Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health*, Institute of Medicine & National Research Council, National Academy of Sciences.

⁷³ Wilson, AK, Latham, JR and RA Steinbrecher (2006). "Transformation-induced mutations in transgenic plants: Analysis and biosafety implications," *Biotechnology and Genetic Engineering Reviews*, Vol 23, Dec. 2006, 209-234.

⁷⁴ Hardell et al (2002). "Exposure to pesticides as risk factor for non-Hodgkin's lymphoma and hairy cell leukemia: pooled analysis of two Swedish case-control studies," *Leuk. Lymphoma*, 43(5):1043-9.

⁷⁵ Garry et al (2002). "Birth Defects, Season of Conception, and Sex of Children Born to Pesticide Applicators Living in the Red River Valley of Minnesota, USA," *Environmental Health Perspectives*, 110, Suppl. 3, 441-449.

⁷⁶ Walsh et al (2000). "Roundup inhibits steroidogenesis by disrupting steroidogenic acute regulatory (StAR) protein expression," *Environmental Health Perspectives*, 108(8):769-76.

⁷⁷ Richard et al (2005). "Differential Effects of Glyphosate and Roundup on Human Placental Cells and Aromatase," *Environmental Health Perspectives*, 113: 716-720; for a comprehensive review of the adverse human and environmental impacts of glyphosate, see: FoE UK (2001). "Health and Environmental Impacts of Glyphosate," Friends of the Earth UK, July 2001.

http://www.foe.co.uk/resource/reports/impacts_glyphosate.pdf.

Finally, APHIS' conclusions regarding the lack of expression of transgenes from GE alfalfa feed in the resulting organic milk or meat are questionable and require further analysis. *See* separately submitted CFS comments.

VII. APHIS' Failed To Comply with the ESA and Consult on Impacts to Threatened and Endangered Species.

Failure to Consult

In preparation of the DEIS, APHIS failed to consult with the FWS as is required under Section 7 of the Endangered Species Act (ESA) on the potential effects on threatened and endangered species and their critical habitats.

The ESA requires APHIS to consult with FWS and/or NMFS to determine “whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action.”⁷⁸ If APHIS learns from FWS and/or NMFS that threatened or endangered species may be present, a biological assessment must be prepared to identify any endangered species or threatened species which are likely to be affected by such action.⁷⁹ The initial request for information from FWS and/or NMFS is a predicate to further agency action and cannot be ignored.⁸⁰

Accordingly, prior to a completion of the deregulation, APHIS must demonstrate that at the very least, it has consulted with the United States Fish and Wildlife Service (“FWS”) and/or the National Marine Fisheries Service (“NMFS”) and taken the first step in considering the impacts of an APHIS deregulation of GT alfalfa on threatened or endangered species. As has become APHIS' pattern, it once again failed to take even the first step by doing any consultation with any other agency regarding endangered species.⁸¹ APHIS has already once been previously found to have violated the ESA when it skipped this initial, mandatory step of obtaining information about listed species and critical habitats from FWS and/or NMFS.⁸² The court emphasized that regardless of whether there is any evidence that species or habitat may be harmed in any way, “an agency violates the ESA when it fails to follow the procedures mandated by Congress, and an agency will not escape scrutiny based on the fortunate outcome that no listed plant, animal, or habitat was harmed.”⁸³

APHIS claims it analyzed the direct effects of GT alfalfa to determine whether an impact was expected on any listed or proposed T&E species or any designated critical habitat. (DEIS at 114). Yet, there is no evidence it consulted with FWS. Instead, APHIS concludes that it has “not identified any stressor that could affect the reproduction, numbers, or distribution of a T&E species or species proposed for leasing.” (DEIS at

⁷⁸ 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12(c) (requiring federal agencies to request information regarding listed species and critical habitat from the Department of the Interior).

⁷⁹ *Id.*

⁸⁰ *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).

⁸¹ *Center for Food Safety v. Johanns*, 451 F.Supp.2d 1165, 1182 (D. Hawaii 2006).

⁸² *Center for Food Safety v. Johanns*, 451 F.Supp.2d 1165, 1182 (D. Hawaii 2006).

⁸³ *Id.*

116). Further, APHIS considered the effect of the production of GT alfalfa on critical habitat or habitat proposed for designation and could identify no difference from impacts that would occur from the production of other alfalfa varieties (non-GT or organic varieties.” Id. APHIS concludes that following a determination of nonregulated status, GT alfalfa “would have no effect on federally listed threatened or endangered species or species proposed for listing, nor is it expected to adversely modify designated critical habitat proposed for designation, compared to current agricultural practices.” Id. Based on these conclusions, APHIS finds that “a written concurrence or formal consultation with the United States Fish and Wildlife Service or the National Marine Fisheries Service is not required.” Id.

Here, there is no evidence in the DEIS that APHIS took the first steps of consultation with FWS and/or NMFS to determine whether the deregulation of GT alfalfa may harm listed species or habitat.⁸⁴ Instead, APHIS relies on a report conducted by petitioner Monsanto along with independent review to support the conclusion that “terrestrial and aquatic T&E animals are expected to be at low risk from exposure to glyphosate used in agriculture.” (DEIS at 118). Thus, prior to deregulation, APHIS must at the very least consult with FWS and/or NMFS prior to approving this deregulation.

Glyphosate

The analysis of glyphosate toxicity is also lacking. The impacts of glyphosate are part and parcel of the glyphosate-tolerant crop system. As discussed in other CFS comments, any deregulation will dramatically increase amount and acreage of glyphosate use and impacts on the environment.

APHIS acknowledges that deregulation will “result in a potential increase in the use of glyphosate-based herbicide formulations.” Yet again, APHIS relies on the unfounded and blatantly incorrect assumption that this increase in glyphosate-based herbicide formulations will reduce/eliminate other, more toxic herbicides. As discussed *supra* and detailed in other CFS comments, the vast majority of alfalfa farmers do not currently use herbicides so glyphosate will not be reducing or eliminating any herbicide use. Not only will more glyphosate be used, but it will be applied throughout the planting, not just before the planting to wipe out stands as is currently common with glyphosate. The DEIS also fails to consider impacts from commercial glyphosate formulations (e.g. those containing polyethoxylated tallowamine), shown to have greater toxicity than glyphosate alone to amphibians and other organisms. For instance, certain formulations of Roundup have been found to be highly toxic to amphibians at field-relevant usage rates.⁸⁵

⁸⁴ CFS sent a Freedom of Information Act request to FWS asking for documents relating to Endangered Species Act issues and GT alfalfa. FWS was “unable to locate any records responsive to [CFS’] request.” See FOIA Request # 2010-00030 and Response to FOIA Request # 2010-00030 on file with FWS and CFS.

⁸⁵ Relyea, R.A. (2005). “The lethal impact of Roundup on aquatic and terrestrial amphibians,” *Ecological Applications* 15(4): 1118-1124; Relyea, R.A., N.M Schoeppner & J.T. Hoverman (2005). “Pesticides and amphibians: the importance of community context,” *Ecological Applications* 15(4): 1125-1134.

APHIS relies on its own analysis of Priester et al., 2007 and Priester et al., 2008 to determine that there are 31 counties with 78 T&E species potentially at risk from glyphosate use but concludes that negative impacts are unlikely to occur. APHIS determines this without any additional analysis of the individual sensitivity of these 78 T&S species or consultation with FWS. APHIS then admits that aerial applications at label rates could result in glyphosate drift capable of harming T&E species. “[N]egative impacts may occur in situation of aerial applications, which may be applied at a rate of 1.55 pounds glyphosate a.e. per acre and have a higher probability of drifting into neighboring fields.” (DEIS at 119). APHIS attempts to minimize this risk by stating that currently, only 2% of glyphosate is applied aerially in the US. *Id.* APHIS does not consider a possible increase in aerial applications with the adoption of GT alfalfa. Instead, APHIS claims this risk could be “mitigated by following label use restrictions that maintain application rates below critical levels in the counties where listed species would be within 250 feet of GT alfalfa fields.” Yet, APHIS fails to consider such options for mitigation based on its purported lack of regulatory authority to mandate label use restrictions for glyphosate used on GT alfalfa fields. *Id.* Nor did APHIS consult with FWS on this risk to protected species.

Contrary to APHIS’ assertions, aerial applications of glyphosate do not pose the only risk to plants. APHIS fails to consider the well-known sub-lethal effects of glyphosate on plants that impact reproduction therefore jeopardizing species survival. Reproductive problems and other impacts can occur at low doses of glyphosate, often lower than the EPA’s application rates. The use of glyphosate-tolerant crop systems raises concerns about increased use of glyphosate and impacts on non target plants, many of which are T&E species.

The risks of glyphosate herbicides to endangered plant and some animal species are documented in numerous studies. In 1996, The U.S. Fish and Wildlife service identified 74 endangered plant species believed to be at risk as a result of glyphosate use. Endangered species known to be harmed or put at further risk by glyphosate specifically include the California red-legged frog⁸⁶, the Houston toad⁸⁷, Monarch butterflies and the plant they rely solely upon, Milkweed,⁸⁸ and the Valley Elderberry Longhorn beetle.⁸⁹ Glyphosate has been found harmful to a predatory beetle (Bembidion) and slightly harmful to a parasitic wasp (Trichogramma), a predatory mite (Typhlodromus pyn), a ladybird (Semiadalia) and a lacewing (Chrysoperla carnea)⁹⁰, and Lepidoptera butterflies and moths,⁹¹ the African amphibian species *X laevis*.⁹² Studies have shown glyphosate to be toxic to fish, particularly rainbow trout, sockeye salmon and coho salmon.⁹³

⁸⁶ <http://www.epa.gov/espp/litstatus/effects/redleg-frog/glyphosate/transmittal-ltr.pdf>

⁸⁷ <http://www.epa.gov/oppsrrd1/REDS/factsheets/0178fact.pdf>

⁸⁸ Nottingham, Stephen. “Genescapes.” 2002

⁸⁹ http://www.blm.gov/pgdata/etc/medialib/blm/ca/pdf/folsom/ea.Par.91728.File.dat/Amador_spurge.pdf

⁹⁰ Nottingham, Stephen referencing Hassan et al 1988.

⁹¹ Nottingham, Stephen. “Genescapes.” 2002

⁹² <http://www.earthjustice.org/library/references/AIDASprayingCritique122106.pdf>

⁹³ Nottingham, Stephen. “Genescapes.” 2002. Referencing the studies Folmar et al. 1979 Holtby and Baillie, 1987; Liong et. All 1988, Mitchell et al. 1987; Servizi et al. 1987, Wan et al 1989.

Glyphosate has also been shown to reduce midge populations, vital to aquatic processes.⁹⁴

Even Monsanto acknowledges glyphosate's potential harm to endangered species. The company has a web-based tool called "*Pre-Serve: Glyphosate Mitigation Instructions*", which shows areas in the United States where threatened or endangered plant species may exist near agriculture. This web site advises growers on appropriate pattern and application rates of glyphosate to minimize risks to rare or endangered plant species.⁹⁵

A 1986 EPA Guidance for the Reregistration of Pesticide Products Containing Glyphosate (EPA Case No. 0178), identifies three listed species that, according to EPA's consultation with the USFWS Office of Endangered Species, may be jeopardized by use of the compound (jeopardy being the highest level of effect under the Sec. 7 regulations). In particular, for use of glyphosate in a "crop cluster" in that document, the then-listed species jeopardized were *Solano grass*, the *Valley elderberry longhorn beetle*, and the *Houston toad*. (Each of those species is still listed.) EPA also stated that many endangered plants may be at risk from glyphosate. The EPA's 1993 Re-registration Eligibility Decision (RED) for Glyphosate, the most current registration for the compound, confirmed and expanded on this 1986 jeopardy opinion, stating:

*The Agency does have concerns regarding exposure of endangered plant species to glyphosate. In the June 1986 Registration Standard, the Agency discussed consultations with the US Fish and Wildlife Service (FWS) on hazards to crops, rangeland, silvicultural sites, and the Houston toad which may result from the use of glyphosate. Because a jeopardy opinion resulted from these consultations, the agency imposed endangered species labeling requirements in the Registration Standard to mitigate the risk to endangered species. Since that time, additional plant species have been added to the list of endangered species.*⁹⁶

APHIS failed to consider the 1986 Guidance and the 1993 RED with respect to the threatened and endangered plants and animals they identified as potentially jeopardized by glyphosate use in conjunction with GT alfalfa, or to update the analysis to the current, greater number of potentially affected listed species. EPA's prior registration of these herbicides does not alleviate APHIS of its duty to comply with the ESA and NEPA.⁹⁷ The FIFRA registration process is very different that review pursuant to NEPA and the ESA. Section 7 of the ESA requires every Federal agency to conserve species listed as endangered or threatened.⁹⁸ It also mandates that "in consultation with and with the assistance of the Secretary," each agency shall "insure that any action authorized, funded

⁹⁴ (Buhl and Faerber, 1989).

⁹⁵ <http://www.pre-serve.org/Pre-Serve-B02/>, <http://www.monsanto.com/responsibility/pre-serve.asp>

⁹⁶ Online at www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf, at p. 70.

⁹⁷ *Wash. Toxics Coal. v. U.S. EPA*, 413 F. 3d 1024 (9th Cir. 2005); *Or. Env'tl. Council v. Kunzman*, 714 F.2d 901 (9th Cir. 1983).

⁹⁸ 16 U.S.C. § 1536(a)(1).

or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species . . .”⁹⁹

In addition, APHIS relies on EPA’s analysis of glyphosate’s use in this new context without its own analysis even though EPA has made no determinations on the impacts on threatened and endangered species from glyphosate use in conjunction since 1993. In 1993, EPA named the *Houston toad* as jeopardized by glyphosate use in association with its use on crops, but the RED failed to even list the other two species that had been found to be in similar jeopardy as of 1986, the *Solano grass* and the *Valley elderberry longhorn beetle*. It also failed to even preliminarily list the many other potentially-affected species that were listed between 1986 and 1993, even though it acknowledged that many would be affected.¹⁰⁰ Glyphosate is currently undergoing re-registration by EPA. APHIS should consult with EPA as well.

Furthermore, changes to plant systems caused by glyphosate applications could indirectly impact threatened and endangered species by harming pollinators, limiting plant populations or otherwise impacting the food chain. APHIS disregarded such impacts based on the incorrect assumption that glyphosate is not likely to harm wild plants.

VIII. The Proposed Deregulation of GT Alfalfa Does Not Comply With the Plant Protection Act.

Sound Science

Under the Plant Protection Act, decisions affecting regulated products “shall be based on sound science.”¹⁰¹ Sound science includes objective findings, which take into account all relevant and available data, does not disregard superior data and is based on accepted scientific method, which includes peer review and methodology that is widely used and can be replicated. Instead, the DEIS is largely based on Monsanto and FGI’s own studies, which are largely not peer reviewed or objective.

“Sound science” would counsel that APHIS should properly inform its PPA decision, with its NEPA analysis, which was not done here. *See supra*. Further, even if the agency *had* informed the PPA decision with its NEPA assessment, the DEIS is chock full of unsound sciences – biology, botany, agronomy, genetics, and economics – to name a few; the result of which allows APHIS to conclude, at least preliminarily, that the deregulation will have no significant impacts. Again, as discussed *supra* the DEIS currently is predicated upon arbitrary and capricious assumptions about: contamination harms to farmers, exporters and dairies; intertwined economic risk to various sectors and geographic regions of the U.S. agricultural economy.

⁹⁹ 16 U.S.C. § 1536(a)(2).

¹⁰⁰ EPA’s September, 1993, Re-registration Eligibility Decision (“RED”) for glyphosate (No. 738-R-93-014).

¹⁰¹ 7 U.S.C. § 7701(4).

On March 9, 2009, President Obama issued a Memorandum entitled “Scientific Integrity” mandating that “[s]cience and the scientific process must inform and guide decisions of my Administration,” with the “highest level of integrity in all aspects of the executive branch’s involvement with scientific and technological issues.”¹⁰² President Obama established several core principles that indicate what constitutes scientific integrity, including:

- Having “appropriate rules and procedures to ensure the integrity of the scientific process within the agency,”
- Subjecting scientific or technological information “to well-established scientific processes, including peer review,”
- “Appropriately and accurately reflect[ing] that information in complying with and applying relevant statutory standards,”
- Making “available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions,”
- Putting “in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised,” and
- Adopting additional procedures, such as whistle blower protections, in order to “ensure the integrity of scientific and technological information and processes on which the agency relies.”¹⁰³

APHIS has frequently violated the tenants of sound science in its decision-making documents on GE crops in numerous ways, such as excessive reliance on applicants’ analysis and data; frequent citation of dubious, industry-sponsored white papers with little or no scientific merit or review; and egregious factual errors biasing decisions in favor of applicants among other unscientific practices. Here, APHIS has seemingly willfully violated basic tenets of sound science. APHIS has willfully ignored high-quality data and information crucial to the DEIS, data and information well-known to it, some of it generated by its sister agencies, the Agricultural Research Service, and the National Agricultural Statistics Service. Instead, APHIS has relied extensively on outdated information, misinformation from industry sources, and speculation. For more detailed analysis on this point, *see* separately submitted CFS comments.

In contrast, sound science requires APHIS to: undertake its own independent and holistic analysis of the impacts of GE crops; base its decision-making on peer-reviewed scientific literature whenever possible; critically examine applicant claims and analysis rather than uncritically accept them; and call on independent experts from outside the agency for external peer review. In addition, unduly narrow assessments – for example, not assessing impacts from pesticides used in conjunction with herbicide-tolerant GE crops – cannot be considered sound science.

¹⁰² Barack Obama, Memo for the Heads of Departments and Agencies, March 9, 2009, at http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/.

¹⁰³ *Id.*

In addition to physical science, sound assessments must also apply the social sciences, for instance, to analyze the economic impacts of transgenic contamination of non-GE crops. The purpose of the PPA is summarized in its first finding: “the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds is necessary for the protection of the agriculture, environment, and economy of the United States.” 7 U.S.C. § 7701(1) (emphasis added). The ultimate goal – contained in the second half of the first finding – is the protection of US agriculture and economy. *Id.* Disregarding significant adverse economic impacts on the agricultural economy, as discussed *supra*, further violates the PPA.

Plant Pest Authority

By statute, “plant pest” is defined as: “any living stage of any of the following that can directly or indirectly injure, cause damage to . . . any plant or plant product.”¹⁰⁴ APHIS’s regulations defined a “plant pest” as “[a]ny living stage (including active or dormant forms) of . . . bacteria [among other organisms] . . . or any organisms similar to or allied with any of the foregoing . . . which can directly or indirectly injure cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.”¹⁰⁵ The regulations further reference with regard to plant pest analyses: “indirect plant pest effects on other agricultural products.”¹⁰⁶

APHIS concludes that “[d]ue to the lack of plant pest risk from the inserted genetic material, the lack of weediness characteristics of alfalfa events J101 and J163 alfalfa, the lack of atypical responses to disease or plant pests in the field, the lack of deleterious effects on non-targets or beneficial organisms in the agro-ecosystem, and the lack of horizontal gene transfer, APHIS concludes that Events J101 and J163 alfalfa are unlikely to pose a plant pest risk.” (DEIS at W-11).

As a general matter, GT alfalfa and associated glyphosate use of Roundup Ready crops systems must be considered together as a system and will foster increased plant disease affecting both alfalfa and other important agricultural crops, in violation of the PPA’s plant pest provisions. APHIS has not considered the impacts of the crop system together, as they will be used in the field. Such an assessment is necessary in order for the determination to be based on sound science.

An assessment of the crop system based on sound science would necessarily include the “deleterious effects” of glyphosate from the GT alfalfa crop system on numerous “non-target” and “beneficial organisms”, *see supra*, which would change the conclusions to significant impacts.

Similarly, an assessment of the crop system based on sound science would include the “weediness potential” in light of the massive amounts of glyphosate the deregulation will

¹⁰⁴ 7 U.S.C. § 7702(14).

¹⁰⁵ 7 C.F.R. § 340.1.

¹⁰⁶ 7 C.F.R. § 340.6(c)(4).

bring about and with it, the concomitant increase/creation of glyphosate-resistant weeds. For a detailed analysis here, *see* separately submitted CFS comments.

Furthermore, the language defining plant pests in the regulation includes “any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other parts of plants.” As the record will show, gene flow and feral propagation of GT alfalfa is likely if deregulation happens. And, as the record will show, such transgenic contamination will “directly or indirectly cause [] damage in or to” conventional and organic alfalfa, resulting in massive damage to important sectors of the agricultural economy, including organic farmers and dairies and exporters of conventional alfalfa. This physical and economic harm will be directly and/or indirectly attributable to GT alfalfa’s plant pest impacts. APHIS’ current conclusion is not based on sound science.

Finally, we note that APHIS’s PPA conclusion in Appendix W is slightly different in language and specific findings than the explanation under the PPA that the agency provided with the original EA in this case, although the overall conclusion is the same. In the original determination, 70 Fed. Reg. 36918-19 (June 27, 2005), as compared to the above conclusions, *see supra*, APHIS made six findings, that GT alfalfa

- (1) Exhibits no plant pathogenic properties;
- (2) are no more likely to become weedy than the nontransgenic parental line or other cultivated alfalfa;
- (3) are unlikely to increase the weediness potential of any other cultivated or wild species with which it can interbreed;
- (4) will not cause damage to raw or agricultural commodities;
- (5) will not harm threatened or endangered species or organisms that are beneficial to agriculture; and
- (6) should not reduce the ability to control pests and weeds in alfalfa and other crops.

We request the agency to clarify: are these findings equivalent or different from the current version in Appendix W? If they are different, please explain why and on what basis, and how that difference, or lack thereof, is based on sound science.

For more information on the analysis on the Plant Pest Determination, *see* separately submitted CFS comments.

Noxious Weed Authority

Under the current regulations, no existing regulation prohibits APHIS from regulating GE crops that do not pose a plant pest risk. In fact, the PPA gives APHIS broad statutory power to prohibit or regulate not only plant pests, but “noxious weeds”:

The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to

prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.¹⁰⁷

The statutory definition of “noxious weed” is very broad:

The term “noxious weed” means any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.¹⁰⁸

Thus APHIS has much more authority over GT alfalfa than the DEIS acknowledges, which repeatedly cabins itself to the Plant Pest Determination. It clearly has the statutory authority to “prevent” and “restrict” any plant if necessary to prevent the dissemination of a plant pest or noxious weed. In fact, APHIS itself recognizes that its statutory authority is broader than it claims in this DEIS in its currently proposed revised regulations. In the new proposed regulations APHIS points out:

The PPA grants the Secretary authority to regulate ... noxious weeds.

... In order to best evaluate the risks associated with these GE organisms and regulate them when necessary, APHIS needs to exercise its authorities regarding noxious weeds and biological control organisms, in addition to its authority regarding plant pests.

...

We propose to better align the regulations with the PPA authorities in order to ensure that the environmental release, importation, or interstate movement of GE organisms does not pose a risk of introducing or disseminating plant pests or noxious weeds. ... [T]echnological advances have led to the possibility of developing GE organisms that do not fit within the plant pest definition, but may cause environmental or other types of physical harm or damage covered by the definition of noxious weed in the PPA. Therefore, we consider that it is appropriate to align the regulations with both the plant pest and noxious weed authorities of the PPA.¹⁰⁹

A noxious weed is defined to include many of the types of harms noted in these comments from biological contamination to other crops from GT alfalfa: public health risks, damage to crops, the environment, and the interests of agriculture, for example.

Given APHIS’s current rulemaking process (APHIS Docket 2008-0023), it is clear that APHIS intends to broaden the scope of how it regulates GE crops, in particular to implement its noxious weed authority, which will give APHIS broader authority to

¹⁰⁷ 7 U.S.C. § 7712(a) (emphasis added).

¹⁰⁸ 7 U.S.C. § 7702(10) (emphasis added).

¹⁰⁹ 73 Fed. Reg. 60008, 60011 (Oct. 9, 2008) (emphasis added).

address the full range of adverse agricultural, public health, and environmental impacts associated with GE crops,¹¹⁰ in order to fulfill the PPA’s purpose to “protect[] the agriculture, environment, and economy of the United States.”¹¹¹ Therefore, APHIS’s intent to more broadly construe its PPA authority in its regulations demonstrates its broad statutory authority. Its overly narrow application of that statutory authority here violates the statutory and regulatory scheme put into place to give APHIS regulatory authority over GE crops.¹¹² For APHIS to deregulate GT alfalfa without analyzing the noxious weed risks involved, would be contrary to its current rule-making process. APHIS should at a minimum delay any decision under the PPA on GT alfalfa and any other GE crop until it finalizes its new regulations

Further, the approval of Roundup Ready alfalfa and associated glyphosate use with the Roundup Ready crop system will promote the rapid evolution and spread of noxious weeds tolerant of or resistant to glyphosate herbicide, in violation of the PPA’s noxious weed provisions. RR crop systems have triggered the rapid emergence of glyphosate-tolerant and glyphosate-resistant noxious weeds by fostering near exclusive reliance on glyphosate for weed control – and by doing so on a massive and growing scale, and in ever more frequent and heavy applications. If introduced and widely adopted, GT alfalfa will have this same noxious weed-promoting effect, both independently and cumulatively with pre-existing Roundup Ready crop systems. Glyphosate-resistant weeds are noxious because of their manifold negative impacts on the interests of agriculture, human health, the environment, and farmers’ welfare. Because GT alfalfa will directly and indirectly foster and cause these significant negative noxious weed impacts, APHIS must apply its noxious weed authority to GT alfalfa.

For a thorough analysis on this argument, *see* separately submitted CFS comments.

Finally, APHIS’s statutory authority aside, as noted above it has discretion whether to grant a petition under its plant pest regulatory authority, and may exercise that discretion to grant a petition “in whole,” “in part,” or not at all.¹¹³ And partial deregulation could include isolation distances, geographic restrictions, or testing as noted *infra*. APHIS’s decision to refuse to consider such options was not based on sound science.

CONCLUSION

For the above reasons, the reasons given in our separately submitted organizational comments, and additionally based on the body of evidence submitted in this administrative record, we request USDA to comply with the legal mandates of the National Environmental Policy Act, the Endangered Species Act, the Administrative

¹¹⁰ 7 U.S.C. § 7702(10); 73 Fed. Reg. 60013 (stating that “evaluation of noxious weed risk expands what we can consider.”)

¹¹¹ 7 U.S.C. § 7701(1).

¹¹² *American Paper Institute, Inc. v. American Electric Power Service Corp. et al.*, 461 U.S. 402, 413 (1983) (failure to consider relevant factors in its decision making violates the PPA); 5 U.S.C. § 706.

¹¹³ 7 C.F.R. § 340.6(3)(i).

Procedure Act and the Plant Protection Act, as well as the Court's order requiring this agency action. In order to do so, USDA must:

Overhaul the structure, process and substance of its proposed NEPA compliance to properly analyze and disclose the impacts of potential deregulation;

Overhaul the structure and process of its proposed ESA process to properly assess the impacts of the crop system and to consult with expert agencies;

Make findings under all of its PPA statutory authority regarding the impacts of the GT alfalfa crop system on the environment and agricultural economy based on sound science; and

Comply with the APA to avoid taking action that is arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law.

Submitted by,

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