



THE CENTER FOR FOOD SAFETY

Docket No. APHIS–2012–0019
Regulatory Analysis and Development
PPD, APHIS
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Comments to USDA APHIS on Draft Environmental Assessment for the
Determination of Nonregulated Status of Herbicide-Tolerant DAS-68416-4 Soybean,
Event DAS-68416-4

September 11, 2012

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Dow AgroSciences (Dow) has petitioned the United States Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service (APHIS) for a determination of non-regulated status for Event DAS-68416-4 soybean (2,4-D resistant soy). DAS-68416-4 soybean has been genetically engineered (GE) to survive direct application of 2,4-dichlorophenoxyacetic acid (2,4-D) and glufosinate, herbicides that are otherwise highly toxic to soybeans. The introduced genetic material (DNA) results in the production in plant tissues of an aryloxyalkanoate dioxygenase (AAD-12) enzyme and a phosphinothricin acetyltransferase (PAT) enzyme that render 2,4-D and glufosinate, respectively, non-toxic to plants. GE glufosinate-tolerant soy has been deregulated and sold for several years, resulting in a substantial increase in glufosinate use on soybeans. Dow's 2,4-D resistant soy is the first crop that would tolerate 2,4-D in addition to glufosinate.

The Center for Food Safety (CFS) submits the following comments concerning the agency's Draft Environmental Assessment (DEA) accompanying the petition for deregulation pursuant to the National Environmental Policy Act (NEPA), the Plant Protection Act (PPA), and the Endangered Species Act (ESA).

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

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and by promoting organic and other forms of sustainable agriculture.¹ CFS represents more than 200,000 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. In addition to these comments, CFS is filing 31,880 comments from CFS members.

SUMMARY

APHIS's draft proposal violates NEPA, the ESA, the PPA and the Administrative Procedure Act (APA).

The DEA is arbitrarily and capriciously flawed in structure, process, and substance. It is flawed in structure because it is overly narrow in scope, failing to give meaningful consideration to any alternative besides full deregulation. It is procedurally flawed and unlawful because, rather than informing APHIS's deregulation decision, the DEA's analysis is predicated on a pre-determined, separate conclusion that APHIS can only fully deregulate, making the entire NEPA analysis an empty paper exercise. The DEA is flawed in substance because its review of numerous impacts is inadequate, entirely failing to address several significant issues, and its conclusions that 2,4-D resistant soy is not likely to cause significant impacts to the environment, agriculture, or public health are contrary to record evidence. Rather, deregulation of 2,4-D resistant soy would have numerous significant impacts on agriculture and the environment that must be analyzed. The DEA's discussion of cumulative impacts is also legally deficient, in particular for its failure to consider the reasonably foreseeable issues including the potential deregulation of 2,4-D resistant corn, herbicide-resistance weeds, the stacking of multiple herbicide-resistance traits with 2,4-D resistant soy, and the injury to non-target crops from herbicide drift of 2,4-D application.

APHIS also failed to comply with the procedural mandates of the Endangered Species Act (ESA), including failing to consult with the Fish and Wildlife Service (FWS) pursuant to ESA Section 7 regarding whether listed species or critical habitat may be adversely affected by the proposed action.

APHIS's proposal to deregulate 2,4-D resistant soy is also contrary to the mandates of the Plant Protection Act (PPA). The decision is not based on sound science, and the 2,4-D resistant soy crop system promotes the proliferation of plant disease agents and other plant pest harms; noxious weeds, including herbicide-resistant weeds; and economic impacts that will harm the agricultural economy.

For these reasons, as well as those submitted in CFS's separately submitted comments and incorporated by reference here, the proposed deregulation should not be permitted unless APHIS prepares an EIS to comprehensively and meaningfully review

¹ *See generally* The Center for Food Safety, Protecting Human Health and the Environment, <http://www.centerforfoodsafety.org>.

the significant environmental effects of this deregulation, complies with the ESA by consulting with the expert wildlife agencies on likely harm to protected species and habitats, and considers denying or restricting the approval based on its likely agronomic, environmental and economic harms pursuant to the PPA.

COMMENTS

The National Environmental Policy Act

NEPA requires federal agencies, including APHIS, to prepare an EIS for all “major Federal actions significantly affecting the quality of the human environment.”² If the action may significantly affect the environment, APHIS must prepare an EIS.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 If an agency decides not to prepare an EIS, it must supply a “convincing statement of reasons” to explain why a project’s impacts are insignificant.⁵ NEPA regulations require the analysis of direct, indirect, and cumulative effects.⁶ The assessment must be a “hard look” at the potential environmental impacts of its action.⁷

NEPA also established the Council on Environmental Quality (CEQ).⁸ 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.”⁹ CEQ’s regulations are applicable to and binding on all federal agencies.¹⁰ Among other requirements, CEQ’s regulations mandate that federal agencies address all “reasonably foreseeable” environmental impacts of their proposed programs, projects, and regulations.¹¹

Plant Protection Act

APHIS regulates transgenic crops pursuant to the PPA, which consolidated several previous statutes and enhanced APHIS’s authority to prevent both “plant pest”

² 42 U.S.C. § 4332(2)(C).

³ *Steamboaters v. FERC*, 759 F.2d 1382, 1392 (9th Cir. 1985); *Idaho Sporting Cong. v. Thomas*, 137 F.3d 1146, 1150 (9th Cir. 1998) (citation omitted).

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

⁵ *Save the Yaak v. Block*, 840 F.2d 714, 717 (9th Cir. 1988).

⁶ *See* 40 C.F.R. §§ 1508.8, .9, .13, .18.

⁷ *Blue Mountains Biodiversity v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998). *Nat’l Parks & Conservation Ass’n v. Babbitt*, 241 F.3d 722, 731 (9th Cir. 2001) (quoting 40 C.F.R. § 1508.27).

⁸ *See* 42 U.S.C. §§ 4321, 4344.

⁹ 40 C.F.R. § 1500.3.

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

¹¹ *See* 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.

and “noxious weed” harms.¹² The PPA’s overarching purpose is broad: to prevent the spread of these items for “the protection of the agriculture, environment, and economy of the United States.”¹³ All of APHIS’s decisions “shall be based on sound science.”¹⁴

Endangered Species Act

The ESA is “the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.”¹⁵ The ESA’s statutory scheme “reveals a conscious decision by Congress to give endangered species priority over the ‘primary missions’ of federal agencies.”¹⁶ ESA Section 7(a)(2) requires agencies to consult the appropriate federal fish and wildlife agency to “insure” that the agency’s actions are not likely “to jeopardize the continued existence” of any listed species or “result in the destruction or adverse modification” of critical habitat.¹⁷ Agency action includes “all activities or programs of any kind authorized, funded or carried out...by federal agencies,” including the granting of permits and “actions directly or indirectly causing modifications to the land, water or air.”¹⁸

I. The Scope of APHIS’s Proposal Is Arbitrary and Capricious, In Violation of the PPA, NEPA and the APA.

APHIS has broad authority to “prohibit or restrict ... movement in interstate commerce any plant” as “necessary to prevent” either “plant pest” risks or “noxious weed” harms.¹⁹ The PPA’s overarching purpose is broad: to prevent the spread of these items for “the protection of the agriculture, environment, and economy of the United States.”²⁰ The DEA recognized the multi-faceted purpose of the PPA. *See* DEA at 1 (APHIS’s role is “[p]rotecting American agriculture” and “ensuring the health and care of plant and animals.”); *id.* (APHIS aims to improve “agricultural productivity and competitiveness, and contributes to the national economy and public health.”); DEA at 2 (APHIS biotechnology office’s “mission is to protect America’s agriculture and environment.”).

APHIS premised its assessment on the mistaken assumption that the agency is cabined by its admittedly outdated regulations at 7 C.F.R. Part 340, declaring that it must grant the petition in full when it “determines that it is unlikely to pose a plant pest risk.” DEA at 2. Yet APHIS’s claim that Part 340 limits the scope of its authority is incorrect. *See* DEA at 2. That the Part 340 regulations were promulgated pursuant to the previous, narrower Federal Plant Pest Act does not restrict APHIS’s the overall scope of PPA’s

¹² *See, e.g., id.* § 7712(a).

¹³ 7 U.S.C. § 7701(1).

¹⁴ *Id.* §§ 7701(4), 7711(b), 7712(b).

¹⁵ *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 180 (1978).

¹⁶ *Id.* at 185.

¹⁷ 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).

¹⁸ 50 C.F.R. § 402.02.

¹⁹ 7 USC § 7712(a); *see also* 7 C.F.R. §§ 2.22(a), 2.80(a)(36) (delegating authority to APHIS).

²⁰ 7 U.S.C. § 7701(1).

oversight over GE crops, nor its NEPA review duties. APHIS itself has admitted, in its proposed amended regulations in 2008, pursuant to the PPA, the agency has the ability to consider both “plant pest and noxious weed risks.”²¹ The PPA significantly expanded APHIS’s authority over noxious weeds, providing the agency new tools with which to carry out its mandate.²²

The statutory definition of “noxious weed” is very broad and requires that APHIS examine “any plant or plant product that can directly or indirectly injure or cause damage” not only to “crops,” but also to “livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.”²³ Yet APHIS fails to analyze the direct and indirect noxious weed risks 2,4-D resistant soy presents. Rather APHIS excluded from its assessment the significant harms to the “interests of agriculture” and “natural resources of the United States” associated with the inevitable development of herbicide resistant superweeds due to the cultivation of 2,4-D resistant soy and stacked hybrids.²⁴ These harms plainly meet the definition of noxious weed harms.

APHIS’s arbitrary limitation of what can constitute “plant pest risks” also undercuts the agency’s analysis, making its review of the crop’s actual impacts illusory. APHIS concluded that 2,4-D resistant soy is highly unlikely to pose a plant pest risk after examining the plant pest risks by considering only “the new genetic material inserted,” the transgenic crop’s “weedy characteristics” and responses to “disease or plant pests in the field,” the crop’s effects on other organisms, and perceived unlikelihood of horizontal gene transfer. PPRA at 09–10. Yet, “plant pest risks” properly defined by statute covers a broad range of potential adverse impacts of GE plants, including the crop’s likelihood to “directly or indirectly injure or cause disease or damage in or to any plants, or parts thereof, or any processed, manufactured, or other products of plants.”²⁵ APHIS may consider information on “agricultural or cultivation practices,” “indirect plant pest effects on other agricultural products,” as well as “any other information which the Administrator believes to be relevant to a determination.”²⁶ As discussed in detail below, and in the separately-submitted CFS Comments, 2,4-D resistant soy presents numerous environmental, economic, and health injuries, including, *inter alia*, transgenic contamination, increased herbicide use, and herbicide-resistant weeds. Further, the applications of 2,4-D resistant soy’s associated herbicides changes use patterns and increase use of 2,4-D as applied on 2,4-D resistant soy, and can cause a wide range of injuries that result in increased risk of disease and death in crops. For example, drift or contact from runoff with these substances will make conventional plants susceptible to bacteria, fungi, and viruses that normally attack them. All of these plant pest harms

²¹ 73 Fed. Reg. 60,008, 60,011-013 (Oct. 9, 2008).

²² See APHIS, *The Plant Protection Act*,

http://www.aphis.usda.gov/lpa/pubs/fsheet_faqs_notice/fs_phproact.html (noting the PPA “grants significant new regulatory authority for noxious weeds”).

²³ 7 U.S.C. § 7702(10) (emphases added); see also *ICTA*, 473 F. Supp. 2d at 25 & n.15.

²⁴ 7 U.S.C. § 7702(10); 7 U.S.C. § 7712(a).

²⁵ 7 U.S.C. § 7702(10); 7 U.S.C. § 7712(a).

²⁶ 7 C.F.R. § 340.6(c)(4).

“directly or indirectly injure” organic and GE soy production and threaten cultivation of soy and other crops in the United States.

APHIS cannot ignore the PPA’s expansive statutory mandates. The agency’s failure to consider plant pest and noxious weed risks associated with 2,4-D resistant soy is arbitrary and capricious. APHIS should prepare new assessments that adequately considers 2,4-D resistant soybean’s plant pest risks and noxious weed risks.

II. APHIS’s Analysis Is Unlawfully Narrow and Predetermined.

APHIS’s failure to acknowledge its authority under the PPA to prevent noxious weed harms, and consider a variety of plant pest risks including but not limited to prevent transgenic contamination, herbicide drift, and increased herbicide use, also caused APHIS to conduct a fundamentally flawed NEPA review. While NEPA does not mandate any particular results, its main purpose is to foster better decision-making by agencies.²⁷ An agency’s decision is arbitrary and capricious if the agency “entirely failed to consider an important aspect of the problem.”²⁸ Nor can agencies define a project so narrowly that it forecloses a reasonable consideration of alternatives, or “define [their] purpose and need so as to winnow down the alternatives until only the desired one survives.”²⁹

APHIS begins its discussion of alternatives in the DEA by stating that “APHIS has concluded that [2,4-D resistant soy] is unlikely to pose a plant pest risk. Therefore, APHIS must determine that [2,4-D resistant soy] is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.” DEA at 68. As explained above, this is legally incorrect, and undermines the structure and scope of the DEA’s analysis of potentially significant impacts. APHIS’s proposal violates NEPA because APHIS limited its assessment to only a select few potential types of impacts, *see supra*, and not other impacts of the crop system which also meet the statutory definitions of plant pest risks and noxious weed risks, such as transgenic contamination and superweeds.

Similarly, the DEA’s conclusions are pre-determined by APHIS’s plant pest risk assessment (PPRA) (which is itself deficient, *see supra* Section I; *infra* Section IX). The major mission of NEPA is that it should inform the agency’s decision-making process. Yet, rather than preparing the DEA to inform the agency action, the decision to deregulate has already been determined by the outcome of APHIS’s 10-page PPRA. DEA at 4. However the PPRA is not a lawful substitute for APHIS’s independent duty to prepare an EA or EIS under NEPA. Moreover, the history of APHIS’s oversight of GE crops also contradicts APHIS’s current position that the PPRA dictates the outcome of the agency’s decision, because the agency’s draft EAs assessing impacts of deregulation of previous GE crops did not make any reference to “PPRAs” of the same GE crops until

²⁷ *See* 42 USC 4321; 40 CFR 1501.1(c).

²⁸ *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

²⁹ *Klamath-Siskiyou Wildlands Ctr v. U.S. Forest Serv.*, 373 F. Supp. 2d 1069 (E.D. Cal. 2004).

2007.³⁰ APHIS's reasoning turns the NEPA process on its head, relying on its PPRA determination (in which it also impermissibly confines the agency's PPA authority) to preclude any meaningful alternatives analysis. The DEA therefore is arbitrary and capricious.

III. The DEA's Alternatives Analysis Is Inadequate.

The DEA's alternatives analysis is legally deficient. "NEPA requires that alternatives ... be given full and meaningful consideration, whether the agency prepares an EA or EIS."³¹ The alternatives analysis should ensure that the agency has before it, and takes into account, all possible approaches to a particular project.³² "It should present the environmental impacts of the proposal and the alternatives in comparative form, thus sharply defining the issues and providing a clear basis for choice among options by the decisionmaker and the public."³³ NEPA's requirement that alternatives be studied, developed, and described both guides the substance of environmental decision-making and provides evidence that the mandated decision-making process has actually taken place.³⁴ Meaningful consideration of alternatives "furthers the goals of NEPA by guaranteeing that "informed decision-making and informed public participation."³⁵

Here, the DEA listed only two alternatives: (1) the No Action Alternative – deny the petition request for unconditional deregulation; and (2) Preferred Alternative: unconditional deregulation of 2,4-D soy. DEA at 68–69. APHIS failed to meaningfully consider any alternative other than the Preferred Alternative because, as explained above, the agency erroneously concluded that its separate PPRA for 2,4-D resistant corn dictates unconditional approval. *See supra* Section I. NEPA requires that the agency must rigorously explore and objectively evaluate all reasonable alternatives, including the no action alternative.³⁶ Yet rather than assessing the impacts of continuing 2,4-D resistant soy's status as a regulated article, APHIS improperly dismissed the No Action Alternative "because APHIS has concluded through [its Plant Pest Risk Assessment] that [2,4-D soy] is unlikely to pose a plant pest risk." DEA at 68.

APHIS also rejected out of hand several reasonable alternatives. *See* DEA at 69–71. APHIS mentioned, but rejected from further consideration: (1) an alternative that would prohibit the release of 2,4-D resistant soy entirely; (2) an alternative that would approve the petition in part, only allowing some strains applied-for to be released; (3) an alternative that would partially deregulate 2,4-D resistant soy by imposing isolation distances and/or geographical restrictions to keep the crops away from conventional crops and mitigate contamination; and (4) an alternative that would require mandatory

³⁰ *See* http://www.aphis.usda.gov/biotechnology/not_reg.html (last visited Sept. 11, 2012).

³¹ *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1217-18 (9th Cir. 2008) (alternation in original; internal quotation marks and citation omitted).

³² *Calvert Cliffs' Coordinating Comm. v. U.S. Atomic Energy Commission*, 449 F.2d 1109, 1114 (D.C. Cir. 1971).

³³ 40 C.F.R. § 1502.14.

³⁴ *Westlands Water District v. U.S. Dep't of Interior*, 376 F.3d 853, 872 (9th Cir. 2004).

³⁵ *Westlands Water District v. U.S. Dep't of Interior*, 376 F.3d 853, 872 (9th Cir. 2004).

³⁶ 40 C.F.R. § 1502.14.

testing for transgenic contamination. DEA at 69–71. APHIS rejected these alternatives without “studying, developing, and describing” them, once again improperly relying on the agency’s erroneous conclusion that the separate PPRA precluded the agency from considering any of the alternatives. *See* DEA at 70–71.

APHIS also failed to even mention several other reasonable alternatives, including:

- A partial deregulation alternative with requirements to reduce the development of weed resistance (including resistance to 2,4-D, glufosinate, or glyphosate, or a combination of these pesticides).
- A partial deregulation alternative with mandatory restrictions to prevent or mitigate substantial harms to agriculture through crop injury from herbicide drift to neighboring farms that is a reasonably foreseeable consequence of unrestricted deregulation of 2,4-D resistant soy.
- A partial deregulation containing comprehensive measures to prevent contamination of organic and non-GE seed or feed and food products, including but not limited to provisions on seed cleaning, mixing, transportation, and other protections.

With regards to resistant weed harms, the DEA elsewhere repeatedly acknowledged (and in fact identified as the main reason for considering the deregulation of 2,4-D resistant soy) the epidemic of superweeds resistant to glyphosate resulting from the commercialization of GE, glyphosate-resistant crops. DEA at 3, 25, 47, 48, 63, 64. The DEA further admitted that 2,4-D resistant soy, already resistant to phenoxy auxin herbicides and glufosinate, once deregulated will be “stacked” with other herbicide-resistance traits—beginning with glyphosate resistance—to create a GE soy variety that will be resistant to multiple herbicide modes of action. *See, e.g.*, DEA at 68–69. The demonstrated trend of glyphosate-resistant weeds emerging and spreading after the deregulation of glyphosate-resistant GE crop system makes the development of rapid evolution of weeds resistant to the synthetic auxin herbicides (including 2,4-D) a “reasonably foreseeable” consequence that must be analyzed in the DEA.³⁷ Nonetheless, APHIS failed to even consider a deregulation alternative that would impose methods to reduce the development of herbicide-resistant weeds (including weeds resistant to 2,4-D, glufosinate, or glyphosate).

Similarly, the DEA recognized that herbicide drift is “a concern for non-target susceptible plants growing adjacent to fields when herbicides are used in the production of” 2,4-D resistant soy. DEA at 49. Nonetheless, APHIS did not consider the imposition of isolation distances, buffer zones, or other limitations that may reduce or eliminate the risk of harm to other crops from the drift of herbicide sprayed on 2,4-D resistant soy.

APHIS’s failure to consider reasonable alternatives is contrary to law and inconsistent with the agency’s approach to regulating other GE, herbicide-resistant crops.

³⁷ 40 C.F.R. § 1508.7.

In the DEA, APHIS acknowledges that it has the authority to “approve the petition in whole or in part.” DEA at 70. Nonetheless, APHIS seems to believe it can only approve a petition “in part” if there is a plant pest risk associated with some but not all GE lines reviewed in the petition. DEA at 70. There is no basis in the statute or regulations for this interpretation of the agency’s authority. On the contrary, the U.S. Supreme Court has recognized that APHIS has the discretion and authority to partially deregulate a GE crop, by imposing geographic restriction and isolation distances, in order to eliminate harms from transgenic contamination and weed resistance.³⁸ Indeed, APHIS itself has exercised such partial deregulation authority in its 2011 decision to issue a partial deregulation with geographic restrictions and isolation distance requirements of glyphosate-resistant Roundup Ready sugar beets.³⁹

“An agency’s consideration of alternatives ‘must be more than a pro forma [] ritual. Considering environmental costs means seriously considering alternative actions to avoid them.’”⁴⁰ The unconditional deregulation of 2,4-D resistant soy poses significant risks to the quality of the human 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. In light of the significant harms the deregulation of 2,4-D resistant soy poses to agriculture, finalizing the current draft without fully analyzing reasonable alternatives would be arbitrary and capricious and contrary to the law’s required procedure.

IV. The DEA Fails to Adequately Analyze Transgenic Contamination.

The DEA fails to adequately analyze the likelihood of harm from transgenic contamination. The term “transgenic contamination” refers to the unintended comingling of GE crops with non-GE crops. Transgenic contamination “can occur through pollination of non-genetically engineered plants by genetically engineered plants or by the mixing of genetically engineered seed with natural or non-genetically engineered seed.”⁴¹ Where transgenic contamination of a non-GE crop is made possible by the deregulation of its GE counterpart, APHIS must prepare an EIS to disclose and analyze the contamination and its interrelated adverse economic effects.⁴² These effects include impacts to conventional and organic farmers, exports, and consumers’ fundamental right to choose to sow the crop of their choice; and the potential elimination of non-GE,

³⁸ *Monsanto v. Geertson Seed Farms*, 130 S. Ct. 2743, 2759-60 (2010).

³⁹ APHIS, USDA, *Monsanto Company and KWS SAAT AG Supplemental Request for Partial Deregulation of Sugar Beet Genetically Engineered to be Tolerant to the Herbicide Glyphosate Final Environmental Assessment* (Feb. 2011), available at http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_fea.pdf; Finding of No Significant Impact, available at http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_fonsi_rtc.pdf.

⁴⁰ *Humane Soc. of U.S. v. Department of Commerce*, 432 F. Supp. 2d 4, 23 n.13 (D.D.C. 2006) (quoting *Southern Utah Wilderness Alliance v. Norton*, 237 F. Supp. 2d 48, 52 (D.D.C. 2002)).

⁴¹ *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007), at *5, *aff’d*, 541 F.3d 938 (9th Cir. 2008).

⁴² *Geertson*, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007) *aff’d*, 541 F.3d 938 (9th Cir. 2008); *Ctr. for Food Safety v. Vilsack*, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009) (“*Sugar Beets I*”).

conventional varieties.⁴³ APHIS should properly assess the risks of gene flow from 2,4-D resistant soy to non-GE varieties of soy, and any and all environmental and intertwined socio-economic impacts of such contamination, by preparing an EIS.

The DEA admits that that contamination of non-GE soy varieties by 2,4-D resistant soy is possible. DEA at 50 (“cross-pollination of soybean plants to adjacent plants of other soybean varieties occurs at a very low frequency (0 to 6.3%)”); DEA at 120 (“cross-pollination can occur between adjacent plants and adjacent rows”). Even Dow, in its petition, acknowledges the potential for 2,4-D resistant soy to cross-pollinate or be cross-pollinated by other [herbicide-resistant] soybean varieties, with adverse consequences for management of the resultant soybean volunteers resistant to multiple herbicides. However, the DEA only considers windborne pollen, assuming that soy is only pollinated by adjacent plants. DEA at 50, 120. This ignores recent science, as discussed in separately-submitted CFS Comments, that shows pollinators regularly visit soy and spread their pollen. *See* separately-submitted CFS Comments. Honeybees, one such pollinator, can travel many miles and thus spread pollen much further than is considered or even mentioned in the DEA.

The DEA also recognized that contamination may occur through a variety of other pathways, including: volunteer growth, seed spread by wind/water/animals, mixing in the grain-handling system, weather events, and simple human error. DEA at 30, 50. Nonetheless, APHIS failed to analyze contamination from such other pathways in the DEA, assuming that they were simply not likely for soybeans. *See* DEA at 50 (“Soybean seeds do not possess the characteristics for efficient seed-mediated gene flow.”). This erroneous assumption has been disproven by independent scientific research which is lacking from the DEA’s analysis.

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.⁴⁴ *Gone to Seed* demonstrated 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 plants’ flowers very often), therefore, the contamination of soybean seed is likely to be significant from seed-mediated gene flow. Such causes could include seed mixing or human error, and the contamination suggests that these sources may be at least as important as cross-pollination, and must also be analyzed fully.

In 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

⁴³ *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007), *aff’d*, 541 F.3d 938 (9th Cir. 2008); *Ctr. for Food Safety v. Vilsack*, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009) (“*Sugar Beets I*”).

⁴⁴ M. MELLON AND J. RISSLER, UNION OF CONCERNED SCIENTISTS, *GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY* (2004).

pharmaceutical crops that would be grown on small acreage and under stringent confinement. 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.⁴⁵

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.⁴⁶ Thus, transgenic contamination through human error and human behavior, such as composting, exchanging seeds, or mislabeling seeds, must be addressed in an EIS.

Past GE crops contamination episodes, particularly the past contamination incident with LibertyLink rice, further illustrates why contamination is an impact that must be adequately considered in an EIS. Transgenic contamination is widespread and has been documented around the world.⁴⁷ A report from an environmental organization documented 39 cases in 2007 and more than 200 in the last decade.⁴⁸ Contamination incidents have not been limited to a single crop or region; corn, rice, canola and other crops have all been contaminated by transgenes.

Of particular interest is the recent contamination of rice by the unapproved GE LL601 “LibertyLink” 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 requirements. It had not been grown at all for several years

⁴⁵ DAVID ANDOW ET AL., UNION OF CONCERNED SCIENTISTS, A GROWING CONCERN: PROTECTING THE FOOD SUPPLY IN AN ERA OF PHARMACEUTICAL AND INDUSTRIAL CROPS (Dec. 2004).

⁴⁶ M. Marvier and R. Van Acker, *Can Crop Transgenes be Kept on a Leash?*, 3 FRONTIERS IN ECOLOGY AND THE ENV'T. 95-100 (2005).

⁴⁷ *See, e.g., New Study Finds GM Genes in Wild Mexican Maize*, NEW SCIENTIST, Feb. 21, 2009; Rex Dalto *Modified Genes Spread to Local Maize: Findings Reignite Debate over Genetically Modified Crops*, 456 NATURE 7219, 149 (2008); Inst. for Nutrition and Food Tech. (INTA), *Chile Enters the List of Countries Contaminated with GMOs: A Report from INTA Has Detected Transgenic Contamination of Maize in the Fields of Central Chile* (Oct. 22, 2008), available at <http://www.nwrage.org/content/chile-enters-list-countries-contaminated-gmos-0>; Graeme Smith, *Illegal GM Crops Found in Scotland*, HERALD, Sept. 13, 2008; Elizabeth Rosenthal, *Questions on Biotech Crops with No Clear Answers*, N.Y. TIMES, June 6, 2006; *Gene Flow Underscores Growing Concern over Biotech Crops*, ASSOCIATED PRESS, Sept. 22, 2004; Andrew Pollack, *Can Biotech Crops Be Good Neighbors?*, N.Y. TIMES, Sept. 26, 2004; Lyle F. Friesen et al., *Evidence of Contamination of Pedigreed canola (Brassica napus) Seedlots in Western Canada with Genetically Engineered Herbicide Resistance Traits*, 95 AGRON. J. 1342-1347 (2003); Simon Jeffery, *Rogue genes: An Unauthorised Strain of GM Crops Has Been Found Across England and Scotland.*, GUARDIAN, Aug. 16, 2002; Alex Roslin, *Modified Pollen Hits Organic Farms: Genetically Altered Strains Spread by Wind*, TORONTO STAR, Sept. 30, 2002; Fred Pearce, *The Great Mexican Maize Scandal*, NEW SCIENTIST 2347, June 15, 2002.

⁴⁸ GREENPEACE INT'L. *GM CONTAMINATION REGISTER REPORT 2007* (Feb. 28, 2008), available at <http://www.greenpeace.org/international/press/reports/gm-contamination-register-2007>; *see also* Carey Gillam, U.S. Organic Food Industry Fears GMO Contamination, REUTERS NEWS SERV., Mar. 12, 2008, available at <http://www.reuters.com/article/idUSN1216250820080312>.

when contamination of the US rice supply was detected at low levels that have nonetheless caused great economic harm to the U.S. rice industry. At least one identified source of contamination by LL601 occurred at Louisiana State University (LSU), where one of the scientists in charge has claimed that they exceeded APHIS confinement recommendation considerably, but still experienced contamination.⁴⁹ Despite an extensive investigation, USDA was unable to determine exactly how the contamination occurred.⁵⁰

The StarLink corn contamination also 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.⁵¹ 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. 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 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.⁵² 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).⁵³ Despite the limited acreage planted in 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.⁵⁴

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 abundant evidence that popcorn,

⁴⁹ G. Vogel, *Tracing the transatlantic spread of GM rice*, 313 SCIENCE 1714 (2006).

⁵⁰ USDA, REPORT OF LIBERTY LINK RICE INCIDENTS 1 (2007), *available at* www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf.

⁵¹ For background to the discussion of StarLink that follows see Bill Freese, Friends of the Earth, *The StarLink Affair* (July 2001), *available at* <http://www.foodallergyangel.com/documents/GMO/StarlinkReport.pdf>.

⁵² EPA Cry9C Fact Sheet, *Biopesticide Fact Sheet: Bacillus thuringiensis subspecies tolworthi Cry9C Protein and the Genetic Material Necessary for Its Production in Corn (006466)* (Nov. 2000).

⁵³ SAP StarLink, FIFRA Scientific Advisory Panel to the EPA, *Assessment of Additional Scientific Information Concerning StarLink Corn*, SAP Report No. 2001-09 (from meeting on July 17/18, 2001).

⁵⁴ A. Shadid, *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.

sweet corn, white corn and seed corn stocks were also contaminated with StarLink.⁵⁵ These latter findings strongly suggest that StarLink pollen blown by the wind fertilized conventional corn, despite the 660-foot border strip requirement. In fact, 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 2001.⁵⁶ The estimated overall cost of this major contamination debacle to Aventis CropScience, StarLink's developer, as well as farmers and the food industry, has been estimated at \$1 billion.⁵⁷

Further examples abound. In late 2010, contamination stemming from a 2005 field trial of Roundup Ready Bentgrass was discovered in Ontario, Oregon, four miles from the field trial location in Idaho.⁵⁸ The U.S. Fish and Wildlife Service (FWS) also documented another contamination incident: the escape of GE Roundup Ready Sugar Beets into potting soil being sold to the public. FWS noted, the “[r]ecent escape of G[enetically] M[odified] 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.”⁵⁹ Courts have unquestionably found “it significant that there have been instances in which genetically engineered corn, cotton, soybean and rice have mixed with and contaminated the conventional crops.”⁶⁰ The “significance” of these events is further evidence that 2,4-D resistant soy can cause significant impacts through contamination, whether via gene flow or other pathways. These impacts must be analyzed in an EIS.

The Interrelated Economic Impacts of Transgenic Contamination Are Not Considered

APHIS's conclusion that the deregulation will not have significant interrelated economic impacts also is wrong. *See* DEA at 72, 108–09. Economic effects are relevant under NEPA, and must be examined “when they are interrelated with natural or physical environmental effects.”⁶¹ Here, contamination of non-GE conventional and organic soy,

⁵⁵ Press Release, USDA, *USDA purchases Cry9C affected corn seed from seed companies*, (June 15, 2001), formerly accessible at: www.usda.gov/news/releases/2001/06/0101.htm; A. Hovey, *StarLink protein found in other crops*, *Lincoln Star Journal*, Mar. 29, 2001.

⁵⁶ Bill Freese, Friends of the Earth, *The StarLink Affair* (July 2001), available at <http://www.foodallergyangel.com/documents/GMO/StarlinkReport.pdf>.

⁵⁷ *Tests to Detect Allergens in Altered Foods Fall Short*, ST. LOUIS POST-DISPATCH, June 12, 2002.

⁵⁸ Mitch Lies, *GMO bentgrass found in Eastern Oregon*, CAPITAL PRESS, Nov. 9, 2010, available at <http://www.capitalpress.com/oregon/ml-gmo-bentgrass-111210>.

⁵⁹ FWS, *Draft Biological Opinion, Roundup Ready Bentgrass* (2010) (included in references submitted with comments).

⁶⁰ *See Sugar Beets I*, 2010 WL 964017, at *2.

⁶¹ *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 944 (9th Cir. 2005) (quoting 40 C.F.R. §1508.14).

and products that rely on non-GE soy, will in fact cause significant economic harm that must be addressed under NEPA. “The economic effects on the organic and conventional farmers of the government’s deregulation decision are interrelated with, and a direct result of, the effect on the physical environment; namely, the alteration of a plant specie’s [*sic*] DNA through the transmission of the genetically engineered gene to organic and conventional [crops].”⁶² As in past cases, “APHIS was required to consider those effects in assessing whether the impact of its proposed action is ‘significant.’”⁶³

Market Rejection of Contaminated Organic and Conventional GE-Sensitive Products

APHIS failed to adequately assess the potential impact on organic farming from contamination by 2,4-D resistant soy. APHIS admits in the DEA that organic soy farming is worth more than its market share would indicate as compared to the overall soy crop, and this despite the agency’s assertion that organic farmers pay more per acre and “generally harvest lower yields,” *see* DEA at 33, these facts demonstrate the high value of organic soy to the market—price premiums for the crop exceed all of the obstacles that APHIS sees before organic farmers, or else there wouldn’t be a steady organic soy market for the foreseeable future. Yet, APHIS entirely ignores socioeconomic impacts to organic farmers if transgenic contamination occurs. *See* DEA at 107–09 (discussing socioeconomic effects on the domestic and international markets for soy without mentioning contamination’s potential to harm both markets).

Further, APHIS unfairly places the burden of preventing contamination entirely on organic farmers and producers, and grossly mischaracterizes consumers’ expectations of organic products. APHIS based this conclusion on the assumption that organic farmers will “use multiple methods to prevent unwanted [genetic] material from entering their fields . . .” DEA at 81. APHIS once again dismissed any impacts to organic farming by summarily stating that the presence of a detectable GE residue does not constitute a violation of the National Organic Standards. DEA at 31–32. This argument completely misses the mark. APHIS is aware that, for the public, there is no question that “organic” means GE free: the USDA’s proposal to allow GE crops in organic agriculture was met with an outpouring of opposition:

275,603 commenters on the first proposal nearly universally opposed the use of this technology in organic production systems. Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods even though there is no current scientific evidence that use of excluded methods presents unacceptable risks to the environment or human health. While these methods have been approved for use in general agricultural production and may offer certain benefits for the environment and human health, consumers have made clear their strong opposition to their use in organically grown food. Since the use of

⁶² *Geertson*, 2007 WL 518624 at *8.

⁶³ *Id.*

excluded methods in the production of organic foods runs counter to consumer expectations, foods produced with these methods will not be permitted to carry the organic label.⁶⁴

Furthermore, USDA has acknowledged that organic is more than simply a labeling process, but a standard that satisfies consumer expectation that organic food will not contain GE material. During the implementation of the Organic Food Production Act (OFPA), USDA 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.”⁶⁵ Yet APHIS here capriciously ignores that when consumers become aware of the likelihood of contamination, consumers may reject organic foods as not truly “organic.” This is not a merely hypothetical risk. In the mid to late 1990s, following Canada’s approval of Bayer’s LibertyLink and Monsanto’s Roundup Ready canola varieties,⁶⁶ the speed and extent of cross-pollination among these GE canola plants surpassed even the most conservative predictions.⁶⁷ The economic consequences of this contamination were swift and severe, for seed sales as well as for Canadian organic and GE-free canola markets, as organic canola from western Canada disappeared virtually overnight.⁶⁸ Today, canola crops and oil from western Canada cannot be marketed as organic or non-GE because of the risk of contamination.⁶⁹

Impacts on Export and Domestic GE-Sensitive Markets

Conventional, GE-sensitive markets are also at significant risk and APHIS is similarly required to consider the economic effects on such markets of deregulating 2,4-D resistant soy, yet has failed to adequately do so in the DEA. According to APHIS, the U.S. exports about 44% of the world’s total soybean production; the majority of which is exported to China, Mexico, the European Union, Japan, Taiwan, Indonesia, Egypt, Turkey, South Korea, and Syria. DEA at 108 & 67; *see id.* at 64 (noting soy exports are “a major share of the total agricultural exports for the U.S., representing 20.1% of the total value of U.S. exports”). None of these countries have currently approved 2,4-D resistant soy for importation. DEA at 109. One significant contamination event similar to

⁶⁴ 65 Fed. Reg. 13,512, 13513-13514 (March 13, 2000).

⁶⁵ *Id.* at 13534-35 (Mar. 13, 2000).

⁶⁶ JOSH BRANDON AND LOUISE SALES, GREENPEACE GE CANOLA OUT OF CONTROL IN CANADA 3 (2007), *available at* <http://gefreesbc.files.wordpress.com/2011/01/ge-canola-out-of-control-in.pdf>.

⁶⁷ M. Marvier and R. Van Acker, *Can Crop Transgenes be Kept on a Leash?*, 3 FRONTIERS IN ECOLOGY AND THE ENV’T. 95-100 (2005).

⁶⁸ Stuart Smyth, et al., *Liabilities and Economics of Transgenic Crops*, 20 NATURE BIOTECH. 6 (June 2002).

⁶⁹ WORLD AGRICULTURE: TOWARD 2015/2030, AN FAO PERSPECTIVE 314 (Jelle Bruinsma ed. 2003), *available at*

<ftp://ftp.fao.org/docrep/fao/005/y4252E/y4252e.pdf>; *The U.S. Department of Agriculture Accounting for the Costs to Farmers from Contamination Caused by Genetically Engineered (GE) Plants: Hearing Before the Subcomm. on Domestic Policy of the H. Comm. on Oversight and Gov’t Reform*, 110th Cong. 3 (Mar. 13, 2008) (statement of Frederick Kirschenmann, Director, Leopold Center at Iowa State University).

LL601 LibertyLink Rice, or Starlink Corn, could impact the soy exports to these countries and economically devastate American farmers and producers of soy products.

The DEA is silent on how the deregulation of 2,4-D resistant soy may affect U.S. export markets for soy, despite the fact that APHIS acknowledges a worldwide sensitivity to this type of food and that the majority of the export markets have not approved the importation of 2,4-D resistant soy. DEA at 109 (noting that regulatory “[a]pproval in these export countries is intended to mitigate global sensitivities to GE productions ...” but then assuming no significant difference in trade from the no action alternative). Instead, APHIS assumes that “producers who sell their products to markets sensitive to GE traits ... use practices ... to protect their crop from unwanted substances.” DEA at 81. Market rejection of soy contaminated by 2,4-D resistant soy, like what occurred in the recent LL601 case, discussed below, and the resulting adverse economic effects of such rejection, must be considered in an EIS.

The example of rice farmers’ huge financial loss due to market rejection of LL601-contaminated rice is illustrative.⁷⁰ 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.⁷¹ 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.⁷² As a result, rice farmers in the South experienced a severe shortage of seed rice for the 2007 season.⁷³ APHIS conducted an investigation into the contamination episodes, but was unable to determine precisely how they occurred.⁷⁴ Courts have subsequently found Bayer negligent in every bellwether case, with total damages estimated at a billion dollars.⁷⁵ The litigation was eventually settled in part for \$750 million dollars.⁷⁶

⁷⁰ R. Weiss, *Gene-altered profit-killer*, *Washington Post*, Sept. 21, 2006.

⁷¹ R. Weiss, *Firm Blames Farmers, ‘Act of God’ for Rice Contamination*, *Washington Post*, Nov. 22, 2006.

⁷² USDA APHIS. *Statement by Dr. Ron DeHaven regarding APHIS hold on Clearfield CL131 long-grain rice seed*, Mar. 5, 2007, available at

http://www.aphis.usda.gov/newsroom/content/2007/03/ge_riceseed_statement.shtml (last accessed Sept. 11, 2012).

⁷³ D. Bennett, *Arkansas’ emergency session on CL 131 rice*, Delta Farm Press, March 1, 2007.

⁷⁴ USDA, *Report of LibertyLink Rice Incidents*, Oct. 2007, available at

<http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf>.

⁷⁵ See, e.g., *In re Genetically Modified Rice Litigation*, 666 F.Supp.2d 1004 (E.D. Mo. Oct. 9, 2009); *In re Genetically Modified Rice Litigation*, 2009 WL 4801399 (E.D. Mo. Dec. 9, 2009).

⁷⁶ Andrew Harris and David Beasley, *Bayer Agrees to Pay \$750 Million to End Lawsuits Over Gene-Modified Rice*, Bloomberg News, July 1, 2011, available at <http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html>.

Farmers and producers of other GE crops have suffered similar export market losses. The genetic engineering of papaya in Hawaii (no other country in the world grows it) has also resulted in widespread contamination⁷⁷ and huge losses in export income to papaya growers there, and reduced prices, due to rejection of the GE papaya overseas.⁷⁸ U.S. corn exporters lose about \$300 million per year in exports due to European Union rejection of engineered corn.⁷⁹ Similarly, the potential approval in the U.S. of genetic engineered wheat would cause major disruptions in the global wheat economy, because foreign markets in Japan, Italy, France, Norway, South Korea, Taiwan, Egypt, the Philippines, Algeria, China, Indonesia, Malaysia and Thailand would reject contaminated wheat.⁸⁰ An assessment by an agricultural economist from Iowa State University revealed that if transgenic wheat were to be commercialized, U.S. wheat growers would lose between 43% and 52% of their total exports, resulting in a net loss in the price paid to farmers of between 32% and 35%.⁸¹ Additionally, the recent approval of Roundup Ready alfalfa is likely to significantly damage the U.S.'s approximately \$200 million a year alfalfa hay and seed export market; many foreign importers will shift to other sources due to the high risk of contamination in the U.S.⁸²

Yet, despite these cautionary tales, APHIS once again completely failed to analyze the economic losses that may stem from an import ban from the top importing countries of U.S. soy. APHIS's discussion on the export of soy to Turkey is a telling example of the poor analysis of foreseeable trade response to U.S. exports of 2,4-D resistant soy. The DEA lists Turkey as one of the ten top export markets for U.S. soy. DEA at 67. Failing to mention or analyze that country's new law that will severely restrict GE soy shipments,⁸³ the DEA makes no mention of losing this major trade partner due to U.S. reliance on new engineered crops like 2,4-D resistant soy. Considering that Turkey is not likely to allow imports in the coming years to match the high historic numbers listed in the DEA, the agency has presented that data in a misleading manner.

⁷⁷ MELANIE BONDERA & MARK QUERY, HAWAII SEED, HAWAII PAPAYA: GMO CONTAMINATED 11-13, (2006) (finding that after the 1998 deregulation of PRSV resistant papaya, within six years contamination rates as high as 50% were found on the island of Hawaii); HAWAII SEED, FACING HAWAII'S FUTURE, HARVESTING ESSENTIAL INFORMATION ABOUT GMOS 44 (2006).

⁷⁸ GREENPEACE INT'L, THE FAILURE OF GE PAPAYA IN HAWAII (May 2006), *available at* <http://www.greenpeace.org/international/Global/international/planet-2/report/2006/5/FailureGEPapayainHawaii.pdf>.

⁷⁹ Pew Initiative on Food and Biotechnology, US v. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food (2005) at 3-4.

⁸⁰ *Cost of Genetically Engineered Plants: Hearing before the Subcomm. on Domestic Policy of the H. Comm. on Oversight and Gov't Reform*, 110th Cong. 7 (Mar. 13, 2008) (Statement of Todd Leake, Conventional and GE grain grower).

⁸¹ *Id.*

⁸² *See Roundup Ready Alfalfa FEIS*, at 58-59, 169-170, App. R at R-3, R-14 to R-15 (2011).

⁸³ Under the 2011 law only three events in GE soy have been approved for animal feed for import, no events have been approved for food. *See* U.S. DEPARTMENT OF AGRICULTURE, GAIN REPORT: TURKEY AGRICULTURAL BIOTECHNOLOGY ANNUAL 2 (2012), *available at* http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Ankara_Turkey_7-13-2012.pdf.

APHIS's failure to discuss the impact of deregulating GE 2,4-D resistant soy on a large section of U.S. trade is arbitrary and capricious.

Burden on Organic & Specialty Soy Production

Organic and specialty soy growers bear completely the onerous burden of reducing the risk of contamination under the Preferred Alternative. DEA at 81 (“Organic production plans prepared pursuant to the NOP include practical methods to prevent the unintended presence of GE materials.”); DEA at 31 (“Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management.”). APHIS concludes that organic farmers wishing to avoid transgenic contamination should isolate their farms, create physical barriers and buffer zones, and coordinating with neighbors to delay or stagger planting. DEA at 31. APHIS failed to analyze the potential efficacy of these measures. Even assuming *arguendo* that these methods were sufficient to prevent contamination, this theory places zero responsibility on those producing the GE crops. For example, the practice of staggering plantings with neighbors often forces organic corn farmers to miss the optimum time for planting, reducing crop yield. DEA at 31. This is contrary to the mandates of the PPA, that APHIS protect all agriculture, not just transgenic farming.

APHIS cannot gloss over the potential harms posed to organic farmers from contamination, as doing so is simply arbitrary, capricious, and unsupported by any evidence. APHIS must disclose and analyze the impact of deregulating 2,4-D resistant soy on both organic and conventional non-GE soy in an EIS prior to adopting a deregulation decision.

Harm to Organic Industry

APHIS also entirely failed to assess the socioeconomic impacts of transgenic contamination on the entire organic industry, especially in light of the importance of soy as animal feed. The National Organic Program excludes the use of GE materials in food production.⁸⁴ Organic products require 100% organic feed; there is no *de minimus* exception.⁸⁵ The DEA acknowledged that “[n]early 98% of soybean meal produced in the U.S. is used as animal feed,” yet is silent on any potential impacts on the organic industry should organic soy feed be contaminated by 2,4-D resistant soy. DEA at 56; *see also* DEA at 59. Contamination of organic feed soy with the transgene will render the soy ineligible for organic certification and will eliminate it as a permissible feed for organic livestock.

The DEA also does not address how the risk of transgenic contamination places pressure on growing and sourcing organic feed. A 2007 article on the dramatic increase in demand for organic dairy products found that demand for organic grain feeds such as

⁸⁴ 7 C.F.R. § 205.105; 7 C.F.R. § 205.2.

⁸⁵ *Id.* § 205.237(a).

organic soy is growing as much as 20 percent each year.⁸⁶ Soy farmers have been forced by low supply to order organic soy from as far away as China when supplies dwindle. APHIS recognized that the production of soy seeds of all types requires isolation intervals, border rows and pollen barriers, and field monitoring “to preserve varietal identity” from pollen contamination. *See* DEA at 80. Yet, the DEA baldly assumes that organic farmers can avoid all contamination with unspecified “practices” that are somehow going to effectively make contamination impossible. DEA at 81. However if APHIS deregulates the crop without restrictions and post-market limitations, there will be no federally enforced mandatory measures to protect farmers. Current contamination levels across all the GE crops planted in the U.S. show that industry voluntary measures are wholly inadequate. Regardless, the EIS threshold is a low bar: if the addition of 2,4-D resistant soy might increase contamination, the agency must prepare an EIS.

The agency failed to analyze the potential impacts of deregulating 2,4-D resistant soy on the supply of organic soy feed. APHIS’s omission of the impact on the organic industry from potential contamination of organic soy feed is arbitrary and capricious. An EIS is required.

Cost of GE Testing & Certification

The DEA’s silence on the cost of testing for GE presence and certifying products as free of contamination also is arbitrary and capricious. As previously stated, APHIS rejected out of hand a deregulation alternative that would impose testing for GE presence. *See supra*; DEA at 70–71. APHIS’s failure to account for such testing costs in its discussion of the socioeconomic impacts of deregulating 2,4-D resistant soy is arbitrary.

Impacts on the Public’s and Farmers Fundamental Right to Choose

APHIS also violated NEPA when it did not consider the impact that deregulating 2,4-D resistant soy will have on the public’s right to choose non-GE soy. NEPA and its implementing regulations provide that where a social or economic effect is tied to a physical impact, those effects must be discussed.⁸⁷ NEPA aims to “maintain, wherever possible, an environment which supports diversity and a variety of individual choice.”⁸⁸ Elimination of grower and consumer choice are “interrelated with, and are a direct result of, the effect on the physical environment, namely, the alteration of a plant specie’s [sic] DNA though the transmission of the genetically engineered gene to organic and conventional [crops].”⁸⁹ Accordingly, “[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.”⁹⁰ “An action which

⁸⁶ Dininny S., “Organic Dairies Test Supply of Feed,” ASSOCIATED PRESS, Dec. 20, 2007.

⁸⁷ 40 C.F.R. § 1508.14.

⁸⁸ *Id.*

⁸⁹ *Geertson*, 2007 WL 518624 at *8.

⁹⁰ *Id.*

potentially eliminates or at least greatly reduces the availability of a particular plant...has a significant effect on the environment.”⁹¹

The DEA noted that there are organic and other markets that are “GE-sensitive [due to] public concerns regarding possible gene movement between GE and non-GE plants,” DEA at 70, yet skips over any discussion of the impacts of deregulating 2,4-D resistant soy by stating that that farmers selling to such markets are assumed to be using practices to avoid contamination although APHIS admits that this assumption is false: “AHIS recognizes that not all farmers follow these best management practices for soybean.” DEA at 73–74. This is not the hard look that NEPA requires; basing an Environmental Assessment on a false premise is exactly the opposite of APHIS’s duty under the law. As discussed above, for the public organic means GE-free. If organic foods are contaminated they lose their integrity, and the public will lose a standard that currently provides them a choice. APHIS must analyze the impacts on the public’s right to choose in an EIS.

APHIS also completely ignores the potential socio-economic, cultural, and agricultural impacts faced by farmers in Mexico and other parts of the world where transgenic contamination will quickly undercut an agricultural economy that is already reeling from uncontrollable GE traits in the production chain. In particular, farmers in Mexico are already suffering the effects of transgenic contamination from other GE crops, which harm beneficial insects, soil fertility, and impair the availability of natural pesticides.⁹² APHIS did not consider the possible impacts that yet another genetic trait can have on farmers in Mexico, whose exports of honey have been severely constrained by the effects of GE pollen contamination of honey.⁹³ This came only two months after the first government commercialization approval for a GE soybean⁹⁴ – and the contamination potential explained above (and more thoroughly in the separately-submitted CFS Comments) will further advance the destruction of this market because of foreseeable GE sensitivities. If the DEA recognizes the likelihood of contamination up to 6.3% within soybeans it must take this as a cue to better analyze what this GE pollen will predictably do to contaminate honey, organic products, and conventional non-GE soybeans.

⁹¹ *Id.* at *9.

⁹² See Greenpeace International, *Maize Under Threat: GE Maize Contamination in Mexico* (Aug. 2003), available at <http://www.greenpeace.org/international/Global/international/planet-2/report/2003/8/maize-under-threat-ge-maize.pdf>.

⁹³ *Monsanto Loses to Beekeepers of Yucatan Peninsula*, THE YUCATAN TIMES, Aug. 6, 2012, available at <http://www.theyucantimes.com/2012/08/monsanto-loses-to-beekeepers-of-yucatan-peninsula/> (“European businesses have suspended the purchase of honey from Yucatan and Quintana Roo until they have evidence that the product is free of transgenic organisms.”)

⁹⁴ See U.S. Department of Agriculture, GAIN Report: Mexico Cautiously Moves Forward with Biotechnology (2012) (describing the approval of GM soy and the proposed large-scale planting bans in Mexico that demonstrate the difficulties this country face due to potential contamination), available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Mexico%20City_Mexico_7-19-2012.pdf.

Seed Market Concentration

The DEA failed to discuss seed market concentration. Seed companies have aggressively undermined independent researchers' ability to fully investigate their patented crops' performance.⁹⁵ Research and development suffer from seed market concentration. Seed companies often want the right to approve all publications, which researchers find unreasonable. This chills research on GE crops.

Further, “[i]t is estimated that the top ten seed corporations around the globe hold 49-51% of the commercial seed market, and the top ten agro-chemical[companies] 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 the GM food market.”⁹⁶ As the practical options become limited to transgenic, patented varieties, there are effects on the price of seed, and in this case the price of the various commodities that the DEA acknowledges are made with soy as well as the cost of groceries.

The increased seed market concentration has already made it hard for farmers to purchase conventional corn and soy seeds.⁹⁷ As a result, farmers are forced to purchase GE seed and with that pay high technology fees. The DEA acknowledged that GE seeds can only be purchased by farmers with a hefty technology fee and that “GE seeds are traditionally more expensive than conventional seed.” DEA at 107. Nonetheless, APHIS summarily disregards the economic impact of the elevated cost of 2,4-D resistant soy to farmers because “APHIS has no control over the establishment of these technology fees.” DEA at 107.

The Department of Justice has noticed the effects. In August of 2009, it announced that it would investigate anticompetitive conduct in the seed industry. Major seed companies set out to acquire ownership of, or control over, smaller firms, leading to the number of corn seed producers dropping from over 300 to merely a handful of large firms able to muster the capital for genetic manipulation through laboratory operations. The commercialization of 2,4-D resistant soy will influence Dow's control over seed production and increase market consolidation. The general public is adversely affected by this, as increased seed prices are reflected in the cost of food. Concentration of the seed industry “affects virtually every farmer in the country and in a very vital way,” and has drawn large crowds at unprecedented hearings scheduled by the antitrust division of the Department of Justice and USDA.⁹⁸

⁹⁵ *Sugar Beets I*, Huber Decl., ¶¶ 17-18 (April 13, 2010); Emily Waltz, *Under Wraps*, 27 *Nature Biotechnology* 880, 882 (2009).

⁹⁶ Yamuna Ghale and Bishnu Raj Upreti, *Concentration and Monopolisation of Seed Market: Impact on Food Security and Farmer's Rights in Mountains*.

⁹⁷ *CFS, Monsanto v. US Farmers*, Jan. 13, 2005, *available at* <http://truefoodnow.files.wordpress.com/2009/12/cfsmontantovsfarmerreport1-13-05.pdf>; Farmer Campaign on Genetic Engineering, *Out of Hand* (2009), *available at* <http://farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf>.

⁹⁸ *Rapid Rise in Seed Prices Draws U.S. Scrutiny*, N.Y. TIMES, Mar. 12, 2010, at B1.

For these and other reasons, the DEA does not adequately address the cumulative impact of seed market concentration. To the extent that APHIS does not have the expertise to analyze the significant anticompetitive and illegal effects of such concentration, APHIS has a duty to consult with agencies who have such expertise:⁹⁹ in this case the Department of Justice and the Federal Trade Commission. The seed market concentration impacts of a deregulation of 2,4-D resistant soy constitute a significant intertwined socioeconomic impact that is reasonably foreseeable. Until expert agencies are consulted on this important topic area, APHIS's failure to adequately address the issue of seed market concentration is arbitrary and capricious.

In sum, there is overwhelming evidence that the deregulation of 2,4-D resistant soy will result in the contamination of non-GE soy and have a significant adverse economic impact on farmers, producers, consumers and the public. Potentially significant impacts include cumulative impacts, which include impacts from "past, present and future foreseeable actions."¹⁰⁰ APHIS's failure to analyze and disclose the interrelated economic impacts of deregulating 2,4-D resistant soy violated NEPA and is arbitrary, capricious and an abuse of its discretion.

V. **The DEA's Cumulative Impacts Analysis Is Inadequate.**

NEPA requires agencies to consider possible cumulative impacts of deregulation.¹⁰¹ The CEQ regulations define 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."¹⁰² Consideration of cumulative impacts requires "some quantified or detailed information; ... [g]eneral statements about 'possible' effects and 'some risk' do not constitute a 'hard look' absent a justification regarding why more definitive information could not be provided."¹⁰³ Although APHIS recognizes its duty to quantify results where possible, DEA at 73, 110, it fails to quantify information that researchers and other agencies readily find ways to estimate. This retreat to generality is inadequate compliance with NEPA.

a. Increased Herbicide Use

APHIS's conclusion that deregulating 2,4-D resistant soy will not increase overall herbicide use on soy is based on mistaken baseline, flawed assumptions, and directly defies numerous admissions regarding herbicide use on herbicide-resistant GE crop

⁹⁹ See 40 CFR 1501.6.

¹⁰⁰ 40 CFR § 1502.8.

¹⁰¹ 40 CFR 1508.27(b)(7); *Oregon Natural Resources Council v. U.S. Bureau of Land Management*, 470 F.3d 818, 822 (9th Cir. 2006); *Geertson Seed Farms v. Johanns*, 2007 WL 518624, at *10 (N.D. Cal. 2007).

¹⁰² 40 CFR 1508.7.

¹⁰³ *Kern v. Bureau of Land Mgmt.*, 284 F.3d 1062, 1075 (9th Cir. 2002).

systems elsewhere in the DEA. For detailed comments see separately-submitted CFS Comments.

First, APHIS uses an inaccurate baseline to compare the changes in herbicide use due to the adoption of 2,4-D resistant soy. APHIS wrongly assumes that 2,4-D resistant soy will simply displace existing herbicide-resistant GE soy acreage, *see, e.g.*, DEA at 76, despite the agency's concurrent assertion in the DEA that U.S. soy production (figured in terms of increased exports) will continue to rise. DEA at 66. Further, APHIS acknowledges that Dow plans to stack the 2,4-D resistant trait while asserting that 2,4-D resistant soy will *displace* the same crop traits with which it will be combined. *See* DEA at 110 & 112. This is an arbitrary and capricious standard contrary to the CEQ language requiring consideration of the impact of the action when added to other past, present, or reasonably foreseeable future actions. APHIS cannot disregard the effects of potential increases in acres planted, or increased acres of added-herbicide resistant crops that result from stacked traits.¹⁰⁴ This sort of fundamental baseline error renders the entire analysis arbitrary and capricious.

APHIS admits there will be an increase in the use of 2,4-D on soy. *See, e.g.*, DEA at 98. In light of that admission, APHIS was required to, but completely failed to, estimate how much of an increase will likely occur. APHIS relies heavily on the assumption that permitted maximum rates of usage of 2,4-D on 2,4-D resistant soy will be identical to the current maximum allowance of 2,4-D on conventional corn. *See, e.g.*, DEA at 59 (“The proposed maximum 2,4-D application rate for soybean is the same as that currently approved for use on field corn and popcorn which is typically grown in the same areas as soybeans and often in the same fields in rotation with soybean.”). Yet, as discussed in detail in CFS separately-submitted Comments, the present average use of 2,4-D on conventional corn is just over 1/10 of the maximum permitted. Moreover, mentioning that 2,4-D maximums for other crops will be similar to that of 2,4-D resistant soy does nothing to fulfill APHIS's duty to quantify expected actual use of the pesticide on this new crop.¹⁰⁵ In reality, 2,4-D resistant soy will allow a totally new application to soy acres post-emergence. The DEA readily admits that such spraying on soy acres without this GE trait would predictably damage 60-93% of the crop, making it self-destructive as a farming practice. DEA at 4. By contrast, this new trait allows post-emergent application of this highly destructive herbicide without any crop losses, the addition of this extra opportunity later in the season to apply 2,4-D over the whole crop

¹⁰⁴ Industry analysts often speak of acres of GE coverage by acres-per-trait, so where the agency ignores that stacking effectively increases the numbers of acres covered by multiplying the environmental effect on each acre by the number of traits APHIS ignores both logic and the practice of the industry scientists it otherwise overwhelmingly relies upon.

¹⁰⁵ Comparisons found throughout the DEA between allowable amounts of 2,4-D on other crops and the proposed maximum for 2,4-D resistant soy is worse than comparing apples and oranges. The comparison of GE soy to unmodified corn makes about as much sense as a hypothetical EA where the Department of Transportation asserts that speed limits in Colorado are set at 75 miles per hour and therefore all motorists in New Jersey will always drive 65 miles per hour on highways, none slower and certainly none speeding. That is to say, basing assumptions on actual use on totally unrelated maximums in other crop types, which have not been engineered for herbicide tolerance, is arbitrary and the opposite of thoughtful analysis.

plainly is significant enough to require APHIS to quantify and assess it rather than making vague statements that do not satisfy NEPA.

Separately-submitted CFS Comments do what the DEA improperly does not attempt to do: estimates the projected increased overall national pesticide use due to 2,4-D resistant soy's release. *See* separately-submitted CFS Comments.¹⁰⁶ In brief, the maximum amount of 2,4-D that can be used on soybeans at present is 1 lb./acre/year. The proposed label for 2,4-D resistant soy would increase maximum permissible applications three-fold, to 3 lbs./acre/year. At present, 2,4-D is applied to only 10% of soybean acres, at an average seasonal rate of 0.5 lb./acre, all applied pre-emergence. CFS bases its estimate of 2,4-D use on 2,4-D soybeans on a projection by Penn State weed scientists in a peer-reviewed publication in the journal *Bioscience*. Based on this projection, CFS estimates that 2,4-D resistant soy would lead to vastly increased use of 2,4-D in U.S. soybean production, from 3.7 million lbs. at present to a conservatively estimated 67 million lbs. That the use of 2,4-D on soy genetically engineered to withstand its application will be much greater is a reasonably foreseeable consequence that APHIS has entirely failed to identify, let alone assess.

The DEA fails to quantify the increased use of 2,4-D and glufosinate, as well as the continued expansion of glyphosate use that will come of this deregulation. APHIS's oversight is particularly egregious in light of the DEA's open admission that as of 2006, glufosinate use on soybeans was 10,000 lbs. annually in the U.S. while only two years after commercialization of the glufosinate-tolerant LibertyLink soybean usage on soybeans had risen to 550,000 lbs. annually. DEA at 28. This is a 55-fold increase in the course of three planting seasons, and the potential for more explosive growth in glufosinate use is easily identified as the increase came with only a 1.3% adoption rate by U.S. farmers. DEA at 28.

APHIS's conclusion that the use of glufosinate on 2,4-D resistant soy would reduce the use of 2,4-D or glyphosate is also arbitrary and capricious. DEA at 80. The DEA acknowledged that Dow plans to stack 2,4-D soy with other herbicide resistant traits. As these herbicide tolerance traits are stacked, allowing for increased use of more and more herbicides on the same field, the idea that herbicides will be "replace[d]" by new ones and therefore not increase overall runs counter to all available evidence. DEA at 79. The thought that overall pesticide use will not increase is even more untenable when the DEA lists "[u]se of full labeled application rates"¹⁰⁷ as one method of dealing with herbicide-resistant superweeds, see DEA at 25, stacking new pesticide tolerances in

¹⁰⁶ For an earlier estimate on increased 2,4-D use due to Dow's similar corn crop see <http://www.centerforfoodsafety.org/projected-increase-in-24-d-use-with-introduction-of-24-d-resistant-corn-through-2019-benbrook2012/>.

¹⁰⁷ The application rate of 2,4-D allowable on 2,4-D resistant soy is three times that of the amount currently allowed on soy, DEA at 77, so at minimum the tripling of allowable pesticide along with the DEA's assertion that the maximum should be used to control superweeds seemingly gives APHIS a starting point for even the simplest of quantification – which the agency fails to perform anywhere in the document. *See also* DEA at 91 (suggesting that 2,4-D be applied at this new maximum rate year after year in rotation with corn, which has the same maximum rate allowed).

soy crops and then using the maximum allowable amount of every pesticide available could not lead to a leveling-off of overall pesticide used.

APHIS's analysis of the predictable increase in use of other herbicides on soy is similarly deficient. The DEA stated that 2,4-D resistant soy "has varying levels of demonstrated tolerance to the herbicides 2,4-DB, MCPA, triclopyr, and fluroxypyr, because these herbicides are not approved for use on soybean and DAS intends to only allow use of their herbicide formulation containing 2,4-D. . . impacts of these other herbicides are not considered. . . ." DEA at 74. This misconstrues APHIS's duty to address all foreseeable impacts under NEPA. If APHIS deregulates this crop and then these other pesticides are approved for use on the crop—as would follow the pattern of ever-increasing herbicide use in response to superweeds—the agency would have failed to address a plainly foreseeable impact at the one NEPA analysis where this information would aid decision-making. APHIS's failure to analyze the potential impacts of foreseeable herbicide use on this resistant crop is arbitrary and capricious.

Finally, APHIS's assumptions that 2,4-D will simply replace existing herbicide use on soy crops is directly contradicted by the existing data on herbicide usage on GE, glyphosate-resistant crops. To the contrary, GE crops have dramatically increased overall pesticide and herbicide use in the past sixteen years.¹⁰⁸ The DEA itself recognizes this fallacy, admitting that that "wide adoption of glyphosate herbicide-tolerant crops in the U.S. has been accompanied by a greater use of glyphosate" which lead to the development of glyphosate-tolerant weeds that this new crop is meant to tackle, with more herbicides. DEA at 3. APHIS attributed the massive increase in glyphosate use to the adoption of glyphosate-resistant crop systems, but recognized that during the same period, 2,4-D was still applied on soy acres in significant amounts. DEA at 20–22. Thus, glyphosate has not eliminated nor replaced the use of more toxic herbicides. *See* DEA at 20–21. These errors are discussed in further detail in separately submitted CFS Comments.

b. Resistant Weeds

The DEA's discussion of the issue of weed resistance is inconsistent and contradictory. On the one hand, APHIS states the purpose of 2,4-D resistant soy is to enable growers to use 2,4-D and glufosinate to manage glyphosate-resistant weeds that have developed due to APHIS's previous deregulations of glyphosate-resistant crops; on the other hand, the agency dismisses the likelihood that a similar epidemic of superweeds resistant to synthetic auxin herbicides—as well as glyphosate, after development of stacked varieties—will follow the deregulation of 2,4-D resistant crop systems. *Compare* DEA at 3 ("This new soybean offers an additional option for growers that provides for greater flexibility in the choice of herbicides to control economically important weeds by broadening the application window, and providing an additional mode of action to

¹⁰⁸ *See* Charles Benbrook, the Organic Center, *Impacts of Genetically Engineered Crops on Pesticide Use: The First Thirteen Years* (Nov. 2009), at i (Since the introduction of GE crops, pesticide use has increased by 383 million pounds in the US).

minimize the development of glyphosate herbicide-resistant weeds”), DEA at 78 (“An increase in diversity of weed control tactics is necessary to mitigate selection pressures for more glyphosate-resistant broadleaf weeds”), *and* DEA at 25 (“To combat this trend and to avoid decreased crop yields resulting from weed competition, growers continually adapt weed management strategies, including the use of herbicides with alternative modes of action”), *with* DEA at 77, 83 (“As [2,4-D resistant soy] is essentially equivalent to other GE herbicide-tolerant and non-GE soybeans, no changes in agronomic practices (such as crop rotation), cultivation . . . are expected to occur”).

APHIS is aware of the existence of at least twenty-eight weeds that are already resistant to synthetic auxin herbicides, of which 2,4-D is the most prominent member; and two that are resistant to glufosinate. *See* DEA at 48; *see also* DEA at 45 (“The first reports of weed resistance to herbicides were in the 1950s . . . which included 2,4-D-resistant spreading dayflower (*Commelina diffusa*) in a sugarcane field in Hawaii in 1957”). APHIS’s failure to analyze the likelihood and impacts of reasonably foreseeable weed resistance to 2,4-D and glufosinate is arbitrary and capricious.

APHIS’s assumption that growers are engaged in weed management practices to stall the reasonably foreseeable development of weed resistance is unsupported; in fact, it defies the DEA’s account of farming practices and the development of glyphosate-resistant weeds. Throughout the DEA, APHIS repeatedly stresses the importance of weed management strategies to prevent weed resistance. *See, e.g.*, DEA at 25, 47, 48. APHIS’s assumption that growers will utilize proper weed management practices to avoid weed resistance to 2,4-D and glufosinate directly contradicts the DEA’s admission that weed management strategies such as alternating different herbicide modes of actions and crop rotations have not been followed. Indeed, the DEA stated that “adoption of glyphosate-tolerant crops, including soybean, resulted in growers changing historical weed management strategies and relying on a single herbicide, glyphosate, to control weeds in the field.”) DEA at 47.

APHIS also recognized, but failed to analyze, the fact that farmers are increasingly planting consecutive rotations of corn, that would be planted in rotation with 2,4-D resistant soy, resulting in further increase in herbicide use. DEA at 15 (“With the recent high corn prices, many producers are turning to a corn-corn-soybean rotation”). The DEA not only admits that Dow will be selling a 2,4-D-glyphosate premix for this new soy crop, but also says it will be the exact same formulation used on Dow’s 2,4-D resistant corn crop. DEA at 74–75; *id.* at 74 (“DAS has indicated that a premix of the 2,4-D choline salt and glyphosate would be marketed for use with [2,4-D resistant soy]. . . . the premix application directions will be the same as those for [2,4-D resistant] corn.”). Acknowledging that Dow’s plan for this crop system is to force all growers¹⁰⁹ to use both 2,4-D and glyphosate, the premix it is going to sell, and that the exact same formulation will be applied year after year proves that the agency’s assertions about overall herbicide usage and development of superweeds are not based on any reasoned analysis. APHIS’s

¹⁰⁹ “DAS has indicated that only DAS-approved herbicides would be allowed to be used on [2,4-D resistant soy].” DEA at 74

blind reliance on unproven weed management practices, Dow’s proposed “stewardship program,” to mitigate the threat of weed resistance does not comply with NEPA, runs contrary to the evidence and is arbitrary and capricious.¹¹⁰ *See* DEA at 78.

The DEA is also flawed because APHIS failed to consider that the value of crop rotation for suppressing weeds is undermined when rotated crops are resistant to the same herbicides. In the case of 2,4-D resistant soy, all growers will be compelled by Dow to use their new formulation of the pesticides, DEA at 78, which will also be used on other 2,4-D resistant crops the company is promoting for delisting – making the year-on-year use of the exact same formulation of 2,4-D on both soy and corn highly likely. *See* DEA at 74, 77 (“The proposed maximum 2,4-D application rate for soybean is the same as that currently approved for use on field corn and popcorn . . . which is typically grown in the same areas as soybeans and often in the same fields in rotation with soybean.”). The DEA’s silence on this issue is arbitrary and capricious, because the development and potential deregulation of 2,4-D resistant corn, another crop within the 2,4-D resistant crop system, is reasonably foreseeable.¹¹¹ The DEA recognized that, excluding the increasing practice of consecutive corn cultivation, a “corn-soybean rotation” is the most common practice with soy production. DEA at 15. The rotation of glyphosate-resistant, Roundup Ready soybean and Roundup Ready corn in the same fields have fostered the proliferation of glyphosate-resistant weeds in the Midwest.¹¹² The DEA admitted that “[w]hen only one herbicide is used year after year as the primary means of weed control, the number of weeds resistant to that herbicide compared to those susceptible to the herbicide may change. . . . in time, the weed population may be composed of more and more resistant weeds.” DEA at 47. APHIS must take into account the reasonably foreseeable impact of future 2,4-D resistant crop deregulations in analyzing the development of superweeds that are resistant to 2,4-D and other herbicides.

Finally, weed resistance is an increasingly expensive and environmentally harmful problem faced by US farmers. However, APHIS’s discussion of this increased cost to farmers is inconclusive. The DEA recognized that many growers combatting glyphosate-resistant weeds have returned “to tillage and other cultivation techniques to

¹¹⁰ *See High Sierra Hikers Ass’n v. Weingardt*, 521 F. Supp. 2d 1065, 1087 (N.D. Cal. 2007) (“Relying on the packstock operators to monitor their stock to exclude them from breeding habitat despite the reality that even close management will not prevent drift of stock into that sensitive habitat does not constitute an adequate discussion of mitigation measures or the requisite hard look at this issue.”); *Neighbors of Cuddy Mountain v. U.S. Forest Serv.*, 137 F.3d 1372, 1380-81 (9th Cir. 1998) (“Nor has the Forest Service provided an estimate of how effective the mitigation measures would be if adopted, or given a reasoned explanation as to why such an estimate is not possible.”).

¹¹¹ APHIS, USDA, Petitions for Nonregulated Status Granted or Pending by APHIS as of August 29, 2012, http://www.aphis.usda.gov/biotechnology/not_reg.html (last visited Sept. 11, 2012); Dow AgroScience LLC; Availability of Petition, Plant Pest Risk Assessment, and Environmental Assessment for Determination of Nonregulated Status of Corn Genetically Engineered for Herbicide Tolerance 76 Fed. Reg. 80872 (Dec. 27, 2011), *available at* http://www.aphis.usda.gov/brs/fedregister/BRS_20111227a.pdf; *see More Herbicide-Resistant Crops in Pipeline*, AGPROFESSIONAL, Mar. 25, 2010, *available at* http://www.agprofessional.com/agprofessional-magazine/more_herbicide-resistant_crops_in_pipeline_120033049.html.

¹¹² *See* separately-submitted CFS Comments.

physically control these species when herbicide proves ineffective.” DEA at 48. Yet, the DEA failed to include any meaningful discussions of increasing costs and labor to combat resistant weeds that persist and spread in their fields. Given the DEA’s open admission of the threat posed by glyphosate-resistant weeds, the DEA’s cursory treatment on the issue of weed resistance is arbitrary and capricious. APHIS must prepare an EIS.

c. Stacking

The DEA fails to assess foreseeable stacking, which will lead to significant impacts worthy of a full EIS. Under NEPA, APHIS must assess the “incremental impact of the [proposed action] when added to other past, present, and reasonably foreseeable future actions regardless of what agency ... or person undertakes such other actions.”¹¹³

2,4-D resistant soy is already “stacked” with both glufosinate and 2,4-D, and Dow plans to add yet another trait to the mix. As APHIS acknowledged, “DAS has indicated that it will likely develop a ‘stacked’ hybrid with [2,4-D resistant soy] and other commercially available traits, expected initially to be GE glyphosate tolerance.” DEA at 110. Further, DAS asserted that stacked varieties might also include insect resistance or other traits. *Id.* at 75. Nevertheless, APHIS gave almost no consideration to how stacking herbicide tolerance or pesticide producing traits into 2,4-D resistant soy might affect the environment, or what the cumulative impact of these pesticides might be in drought regions.

Stacking of GE crops may create significant environmental effects that have not been analyzed. For example, stacking with glyphosate resistance will enable increased use of this chemical (sprayed over tens of millions of acres of American farmland, and growing, every year) in an attempt to keep ahead of the rapid evolution of glyphosate resistance in various weed species. The result is a vicious circle of rising glyphosate use to control resistant weeds, followed by increased weed resistance, which in turn drives still more chemical use. 2,4-D, which already has its group of resistant weeds as discussed *supra*, will predictably join glyphosate in this pesticide treadmill under Dow’s plan to stack tolerances and force growers to use its bundled chemical formulations.

Contrary to APHIS’s assumptions, studies show that stacking of GE crops may create significant environmental impacts that have not before been analyzed anywhere, such as “super-herbicide tolerance.”¹¹⁴ As Dr. David Mortensen has explained, mutated weeds with resistance to different herbicide actions, such as glyphosate and synthetic auxin herbicides like 2,4-D “would be able to spread and multiply rapidly” after the combined applications of multiple herbicide actions kill off susceptible weeds (i.e. weeds that have yet to develop multiple resistance).¹¹⁵ This will result in more frequent applications of different toxic herbicides, perhaps over the entire growing season of the

¹¹³ 40 CFR 1508.7.

¹¹⁴ *Mortensen et al.*, Navigating a Critical Juncture for Sustainable Weed Management, 62(1) *BioScience* 75-84 (2012).

¹¹⁵ *Id.*

crop. Since the DEA admitted that stacking 2,4-D resistant soy is reasonably foreseeable, the impacts of stacking is a cumulative impact that APHIS must address in an EIS.

Despite a demonstrable need for more analysis of the combined impacts from stacked varieties and the potential for serious environmental harm, APHIS barely touched on the issue in the DEA. However, even the agency's passing consideration uncovered the fact that:

[2,4-D resistant soy] stacked with other herbicide-tolerant traits may exacerbate management of volunteer soybeans in regions in which they are prone, especially in crops with herbicide tolerance to the same mode(s) of action. Management of these soybeans may require the use of more narrow-spectrum herbicides (such as atrazine in maize), or more aggressive mechanical control methods.

Id. at 120. Methods of mechanical control include tillage. As APHIS asserts, more aggressive tillage may lead to a reduction in crop residue and soil organic matter, a decrease in soil stability, structure, and water holding capacity, and also increased wind and water erosion. *Id.* at 114. Nevertheless, APHIS dismissed its concern about the effects of stacked varieties by simply wagering that increased management of volunteers is “not expected to be anything beyond common agronomic practices.” *Id.* at 120.

Although initially stating that it intended to consider the cumulative effects of stacking, DEA at 110, APHIS otherwise gave no substantive consideration to the issue. Since stacking is inevitable with 2,4-D resistant soy, the agency erred in failing to address cumulative impacts in any detail, which it must undertake in an EIS.

d. Volunteers

As explained further in CFS Comments submitted separately, glyphosate-tolerant soy has become a problematic volunteer because its herbicide tolerance makes it difficult to control through customary conventional spraying methods. In several parts of the DEA, APHIS claims that volunteer soy is not concerning because “herbicides usually used for weed control in corn are also effective at controlling volunteer soybean.” *See* DEA at 49. Yet this statement ignores soybeans that have been created to tolerate the exact same herbicides that are so “effective at controlling” non-tolerant soy, demonstrating the DEA's failure to address the foreseeable future environmental impacts of deregulation of 2,4-D soy – instead it seems the DEA only analyzes volunteer soybeans as they exist now, prior to the added tolerances of this new crop.

The DEA itself highlights volunteer soy as an environmental impact, worthy of an EIS analysis, when it casually admits: 2,4-D resistant soy “stacked with other herbicide-tolerant traits may exacerbate management of volunteer soybeans.” DEA at 120. The DEA also acknowledges that there are regions of the U.S. where volunteer soybeans that have not been stacked with these multiple herbicide tolerances are already known to sprout as disruptive volunteers. DEA at 120. This deregulation will make an immediate

problem impacting farmers worse. Acknowledging this fact and pursuing deregulation without first performing a full NEPA analysis and creating an EIS is arbitrary and capricious.

APHIS acknowledged that control of herbicide-resistant volunteered corn “create[s] problems for growers in the Midwest.” DEA at 49. This problem is exacerbated by the fact that the corn has been bred to be herbicide tolerant, so it can only be controlled with practices that soy farmers would normally have to resort to on superweeds. *See id.* Yet APHIS’s analysis of the volunteer corn problem stops there. This is troubling, because the argument for deregulating soy – the purported Purpose and Need for this action – is the similar herbicide-tolerance to glyphosate in other weeds. *See* DEA at 3 (“This new soybean offers an additional option for growers . . . to minimize the development of glyphosate herbicide-resistant weeds”). Since other 2,4-D resistant crops, namely Dow’s 2,4-D resistant corn (currently under review for deregulation by APHIS), will be rotated with 2,4-D resistant soy, such a dismissive attitude towards a man-made herbicide-tolerant volunteer in the same field (a foreseeable environmental impact that will lead to even more pesticide use in soy fields due to shared tolerance of 2,4-D) is arbitrary and capricious. The regular conventional chemical control for weedy grasses – glyphosate – will be useless in stopping stacked herbicide-tolerant volunteer corn, and so herbicides will increase both in quantity and variety due to this foreseeable consequence.

e. Conservation Tillage

APHIS repeatedly touts the promotion of conservation tillage associated with the deregulation of 2,4-D resistant soy as an environmental benefit relative to conventional corn production. *See, e.g.*, DEA at 89, 90, 92, 114, 116, 117, 118, 121. However, the DEA itself shows that APHIS’s assumption that 2,4-D resistant soy will promote conservation tillage is inconsistent and erroneous. The DEA assumes in certain places that 2,4-D resistant soy will promote the continuation of conservation tillage practices, but in other places asserts that 2,4-D resistant soy would have no impact on cultivation practices of corn, including tillage. *See, e.g.*, DEA at 120 (“A determination of nonregulated status for [2,4-D resistant soy] is not expected to change any agronomic practices for the commercial production of soybean other than the application of certain herbicides.”).

USDA itself has called into question whether herbicide-resistant crop systems such as 2,4-D resistant soy is the direct cause of increased conservation tillage practices.¹¹⁶ Based on a study of glyphosate-resistant soybeans and different tillage practices, USDA concluded that: “Farmers using no-till were found to have a higher probability of adopting herbicide-tolerant seed, but using herbicide-tolerant seed did not significantly affect no-till adoption. The result seems to suggest that farmers already

¹¹⁶ FERNANDEZ-CORNEJO, J. AND W.D. MCBRIDE, U.S. DEPT. OF AGRICULTURE, ECONOMIC RESEARCH SERVICE, ADOPTION OF BIOENGINEERED CROPS, AGRICULTURAL ECONOMIC REPORT NO. 810, (May 2002), *available at* <http://www.ers.usda.gov/publications/aer810/aer810.pdf>.

using no-till found herbicide-tolerant seeds to be an effective weed control mechanism that could be easily incorporated into their weed management systems. Alternatively, the commercialization of herbicide-tolerant soybeans did not seem to encourage the adoption of no-till, at least at the time of the survey in 1997.”¹¹⁷ *See also* separately-submitted CFS Comments.

f. Harm from 2,4-D and glufosinate

The DEA entirely fails to independently analyze the potential harm to plants, wildlife, and humans from 2,4-D and glufosinate. 2,4-D resistant soy is specifically designed to be used with such herbicides.¹¹⁸ The DEA acknowledged that 2,4-D resistant soy “was developed to provide growers with alternative herbicides to use in soybean.” DEA at 25. Just as the DEA refers to the “glyphosate-tolerant cropping system,” DEA at 126, 2,4-D resistant soy is part of the 2,4-D resistant crop system. The use of the synthetic auxin herbicides and the commercialization of 2,4-D resistant soy will come hand in hand, especially since 2,4-D is only used on less than 10% of current conventional soy acreage, DEA at 20, and the use of 2,4-DB, MCPA, triclopyr, and fluroxypyr on soy is not yet approved. DEA at 74. Glufosinate is already being applied to resistant soy crops, recently deregulated, and the DEA concedes that the trend is for glufosinate usage to continue increasing rapidly. *See* DEA at 77. Therefore, the impacts from all of these pesticides’ use on 2,4-D resistant soy are “reasonably foreseeable” risks that must be analyzed by the agency.

Instead, the DEA improperly sidesteps the discussion entirely by relying on EPA’s authority to regulate herbicide use under FIFRA. However, Courts have repeatedly held that an agency is not exempted from analyzing the effects of herbicides under NEPA just because the EPA had registered the same herbicides under FIFRA.¹¹⁹ Hence, APHIS’s reliance on EPA’s FIFRA registration of 2,4-D is unlawful. Further, as the DEA recognized, 2,4-D resistant soy will provide growers with “new uses” of 2,4-D and glufosinate. In terms of 2,4-D, this crop will allow the unprecedented application of the herbicide post-emergence, something that was unheard of in modern agriculture before APHIS proposed this deregulation. EPA’s registration could not consider either the quantity or timing owing to this new use when it registered the herbicide. EPA’s prior reregistration of 2,4-D was seven years ago, in 2005, before the petition for deregulation of 2,4-D resistant soy was submitted to APHIS. Thus, EPA’s FIFRA analysis never accounted for the potential adoption of 2,4-D resistant soy and the increased use of 2,4-D on soy. 2,4-D is also up for registration review in 2014. Until

¹¹⁷ *Id.* at 59.

¹¹⁸ As discussed *supra*, the DEA also fails to discuss to any degree the case of herbicides 2,4-DB, MCPA, triclopyr, and fluroxypyr, despite the foreseeable use of these pesticides upon further EPA action after APHIS deregulates this crop.

¹¹⁹ *See Or. Env'tl. Council v. Kunzman*, 714 F.2d 901 (9th Cir. 1983); *S. Or. Citizens Against Toxic Sprays, Inc. v. Clark*, 720 F.2d 1475 (9th Cir. 1983); *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984) (reiterating that reliance on EPA registration to circumvent environmental laws was “clearly improper”). *See also Wash. Toxics Coal.*, 413 F.3d at 1032 (“[C]ompliance with FIFRA requirements does not overcome an agency’s obligation to comply with environmental statutes with different purposes.”).

EPA completes a review of the herbicide in light of all the new uses proposed for it, it cannot be relied upon. If APHIS seeks to use FIFRA registration in NEPA documents for this deregulation, it must begin by halting this process until EPA finishes reregistration, so that the agency can review the informed EPA analysis.

Similarly, APHIS cannot rely on EPA's FIFRA registration of glufosinate to substitute the agency's independent duty under NEPA. Glufosinate's prior registration is similarly outdated. DEA at 44. Relying on EPA's outdated analyses of 2,4-D and glufosinate falls below the standards of NEPA; it also fails to satisfy APHIS's independent duty to analyze all reasonably foreseeable impacts of its own action pursuant to NEPA, and to consider "indirect risks" to plants and the environment under the PPA.¹²⁰ At a minimum, APHIS should wait for EPA to complete its process of registering glufosinate and 2,4-D for the new uses on 2,4-D resistant soy so that the agency may independently assess and incorporate EPA's analyses into its own NEPA process and PPA risk assessment.

Herbicide Drift

As explained in detail in separately-submitted CFS Comments, the DEA failed to adequately analyze reasonably foreseeable harm from drift of 2,4-D and glufosinate to non-target plants near to 2,4-D resistant soy fields. The potential crop damage resulting from herbicide drift is a significant impact that must be addressed in an EIS. A highly volatile herbicide, 2,4-D is prone to drift beyond the field of application and damage neighboring crops and wild plants.¹²¹ Drift from 2,4-D will injure most broadleaf plants, such as grapes, tomatoes, cottons, soybeans, sunflower and lettuce, at extremely low levels.¹²² In fact, surveys conducted at the state level have shown that 2,4-D is already responsible for more episodes of crop injury from herbicide drift than any other pesticide.¹²³ Tellingly, APHIS admitted that "[s]pray drift is a concern for non-target susceptible plants growing adjacent to fields when herbicides are used in the production of [2,4-D resistant soy]." DEA at 49.

APHIS tries to dismiss the significant harms and crop injury stemming from drift of 2,4-D and glufosinate applications by relying, once again, on the EPA's regulatory oversight under FIFRA and the crop vendor's domination of any grower through use agreements. *See* DEA at 95. However, as discussed above, EPA's FIFRA registration does not obviate APHIS's independent statutory duties to consider the reasonably

¹²⁰ *See* 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.7 U.S.C. § 7702(10) (emphasis added); 7 U.S.C. § 7712(a).

¹²¹ *See* separately-submitted CFS Comments; Breeze, V.G. & West, C.J. (1987). "Effects of 2,4-D butyl vapor on the growth of six crop species," *Ann. Appl. Biol.* 111: 185-91.

¹²² *See, e.g.*, Walker, T. (2011). "Avoiding 2,4-D Injury to Grapevines," Colorado State University Extension, July 2011; Bennett, D (2006). "2,4-D herbicide drift damage stuns east Arkansas cotton," *Delta Farm Press*, 8/11/06. <http://deltafarmpress.com/24-d-herbicide-drift-damage-stuns-east-arkansas-cotton>.

¹²³ AAPCO (1999 & 2005). "1999/2005 Pesticide Drift Enforcement Survey," Association of American Pesticide Control Officials, *available at* <http://www.aapco.org/documents/surveys/DriftEnforce05Rpt.html>. Survey periods 1996-1998 and 2002-2004, respectively.

foreseeable impacts of herbicide drift under NEPA, and to assess the potential of 2,4-D and glufosinate use on 2,4-D resistant soy to “damage ... any plants” under the PPA.¹²⁴ APHIS’s reliance on the fact that Dow has applied for a new formulation of 2,4-D with supposedly lower volatility is also arbitrary and capricious: the “lower volatility, improved stability, and lower odors” of the new 2,4-D formulation is insufficient to satisfy the rigorous analysis that NEPA demands.¹²⁵ DEA at 112. APHIS’s own admissions in the DEA indicate that 2,4-D’s “low volatility” formulations volatilize when the temperature climbs above 90° Fahrenheit, DEA at 40, and as 2,4-D resistant soy now makes it possible for this highly drift-prone herbicide to be applied even later in a growing season it seems almost guaranteed that increasingly warmer Spring weather will lead to the very drift that the DEA assumes is impossible. This reliance on others’ assertions about drift control against clear evidence of the imminent danger is arbitrary and capricious; in order to remediate this failure in the DEA the agency must prepare an EIS.

In addition, 2,4-D choline has not been registered for use on 2,4-D resistant soy. The application for such use is still pending with EPA. And in any case, it is highly likely that growers will use other, more drift-prone formulations of 2,4-D. Neither Dow nor EPA will be able to prevent use of these cheaper 2,4-D formulations.

The harm and damage to neighboring crops, such as tomatoes, grapes, cotton, soybeans, sunflower and lettuce from 2,4-D drift is a significant cumulative impact that warrants preparation of an EIS. The pending releases of other 2,4-D resistant crops (such as 2,4-D resistant corn and 2,4-D resistant cotton) are imminently foreseeable actions whose impacts must be considered along with the impacts of deregulating 2,4-D resistant soy.

Harm to Human Health and Farm Workers

APHIS’s cursory review of the potential harm to humans and farm workers is also severely flawed. Once again, APHIS improperly relies on the EPA’s registration of 2,4-D and glufosinate herbicides to conclude that 2,4-D and glufosinate use on 2,4-D resistant soy would not endanger the health and safety of farm workers. *See* DEA at 103–04. However, EPA’s FIFRA registration does not obviate APHIS’s own independent NEPA duties.¹²⁶

APHIS’s conclusion that there would be no additional impacts on worker safety is also inconsistent with the DEA’s other findings. APHIS completely misses the fact that 2,4-D resistant soy would allow more frequent, post-emergence applications of 2,4-D, increasing workers’ exposure to the toxic herbicide. DEA at 4. APHIS also failed to

¹²⁴ 7 U.S.C. § 7702(10); 7 U.S.C. § 7712(a).

¹²⁵ Insofar as APHIS attempts to rely on Dow’s application to mitigate the danger of 2,4-D volatilization, it is subject to the high standards for mitigation highlighted in these comments, *supra*.

¹²⁶ *See Or. Env’tl. Council v. Kunzman*, 714 F.2d 901 (9th Cir. 1983); *S. Or. Citizens Against Toxic Sprays, Inc. v. Clark*, 720 F.2d 1475 (9th Cir. 1983); *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984).

consider how the introduction of glufosinate, an herbicide that is not currently used on more than 98% of U.S. soy acreage, would increase workers' overall exposure to toxic chemicals. DEA at 28 (acknowledging pre-adoption of GE LibertyLink application of glyphosate was limited to less than 1% of soy acres, but that after adoption that crop took 1.3% of acreage and significantly increased glufosinate used on soy). The above discussion of EPA's lack of consideration of these GE herbicide-resistant traits in approving these pesticides applies equally to worker safety, and APHIS's failure to account for higher potential for frequent larger dosings, increasing the danger to workers, is arbitrary and capricious.

More generally, APHIS failed to assess the harms to human health stemming from the massive increase in 2,4-D use that will accompany the deregulation of 2,4-D resistant soy. As discussed in detail in the separately-submitted CFS Comments, numerous studies have linked exposure to 2,4-D to major health risks such as cancer, lowered sperm counts, liver disease and Parkinson's disease.¹²⁷ Exposures to 2,4-D have also been shown to have negative effects on hormonal, developmental, neurological, and immune systems. Furthermore, 2,4-D remains contaminated with dioxins, highly toxic chemical compounds that have detrimental effects on human health. EPA has reported that 2,4-D is the seventh largest source of dioxin in the U.S.¹²⁸

APHIS must address the potential harms to human health in its NEPA analysis. Public health effects may be significant effects requiring an EIS. The CEQ regulations articulate the factors that may be significant effects on the human environment and therefore require EISs. One such factor is "[t]he degree to which the proposed action affects public health or safety."¹²⁹ Thus, the EA must address any potential human health or safety risks and determine whether they may be significant. If those impacts are found not to be significant, there must be a convincing statement of reasons. APHIS failed to do so here and an EIS is required.

Global Warming

APHIS's discussion of the cumulative impacts of the new generation of 2,4-D crop systems on global warming relies on unsupported presumptions and unsound science. The analysis APHIS provided on this issue falls short both of the CEQ draft guidance¹³⁰ and contemporaneous agency practice.

¹²⁷ Tanner, C.M., *et al.*, *Occupation and Risk of Parkinsonism*, 66 Archives of Neurology 1160-1113 (2009); Leonard, C., *et al.*, *Golf Ball Liver: Agent Orange Hepatitis*, 40 Gut 687-88 (1997); Johnston *et al.*, *Golf Ball Liver: A Cause of Chronic Hepatitis?*, 42 Gut 143 (1998).

¹²⁸ EPA, *Reregistration Eligibility Decision (RED) for 2,4-D* (June 2005).

¹²⁹ 40 C.F.R. § 1508.27(b)(2); *see, e.g., Stauber v. Shalala*, 895 F.Supp. 1178, 1195 (W.D. Wis. 1995).

¹³⁰ *See* Council on Environmental Quality, Draft NEPA Guidance on Consideration of the Effects of Climate Change and Greenhouse Gas Emissions (Feb. 18, 2010), *available at* http://ceq.hss.doe.gov/nepa/regs/Consideration_of_Effects_of_GHG_Draft_NEPA_Guidance_FINAL_02182010.pdf.

APHIS's assertion that 2,4-D resistant soy will reduce global warming impacts is predicated upon the DEA's erroneous conclusion that 2,4-D resistant crop will increase the use of conservation tillage. *See* DEA at 116. As discussed *supra* and separately by additional CFS Comments, the adoption of the herbicide-resistant crop system is not the cause of the increased utilization of conservation tillage practices in farming. Even assuming that herbicide-resistant crop systems have promoted conservation tillage practices such as no-till, recent studies have called into question whether no-till methods reduces global warming impacts. Recent scientific literature casts doubt on the claim that no-till method results in more carbon sequestration than tillage. Conversely, studies have found that greenhouse gases that contribute to global warming are generated at higher levels in no-till fields.¹³¹ APHIS's repeatedly touts conservation tillage as the main benefit of the 2,4-D resistant crop system without reviewing the best science available, instead relying on industry-sponsored studies and reviews.

CEQ's draft guidance to agencies is ignored in the DEA. CEQ makes it clear that agencies should address both the Greenhouse Gas (GHG) emissions of the proposed action and the relationship of different alternatives and climate change "including the relationship to proposal design, environmental impacts, mitigation and adaptation measures."¹³² The DEA does none of these things. *See* DEA at 116–17. "[W]here a proposed Federal action that is analyzed in an EA or EIS would be anticipated to emit GHGs to the atmosphere in quantities that the agency finds may be meaningful, it is appropriate for the agency to quantify and disclose its estimate of the expected annual direct and indirect GHG emissions in the environmental documentation for the proposed action."¹³³ The DEA not only does not attempt to quantify the GHG emissions, it seems to assume that the extra application of pesticides "by ground spray equipment or aircraft" will be emissions free – since it did not even discuss why it did not quantify those extra emissions in the "Climate Change" sections of the DEA it must have either made this assumption or ignored the CEQ guidance to consider the meaningfulness of emissions. At the same time the DEA recognizes emissions from farm vehicles in its "Air Quality" sections, *see* DEA at 86–87, so the agency's oversight of the same emissions in the Climate Change analysis is unjustifiable within the document's own logic, as well.

Other federal agencies have quantified GHG emissions in their EAs and EISs in order to satisfy their duties under NEPA.¹³⁴ By shirking a duty that other agencies actively address in their NEPA documents APHIS demonstrates the insufficiency of its

¹³¹ *See* CFS Science Comments.

¹³² Council on Environmental Quality, Draft NEPA Guidance on Consideration of the Effects of Climate Change and Greenhouse Gas Emissions (Feb. 18, 2010) at 1.

¹³³ *Id.* at 2.

¹³⁴ *See, e.g.*, Department of Energy, Final Environmental Assessment: Next Autoworks Louisiana Manufacturing Project (2011) (quantifying emissions reductions due to the addition of electric vehicles to the market), *available at* <http://lpo.energy.gov/wp-content/uploads/2010/10/Final-Next-Autoworks-EA1.pdf>; *see also* Columbia Law School: NEPA and State NEPA EIS Resource Center, Environmental Impact Statements that Include Discussions of Climate Change-Related Impacts, <http://www.law.columbia.edu/centers/climatechange/resources/eis> (last visited Aug. 30, 2012) (providing detailed information on agencies' assessment of global warming impacts in EISs)

analysis – a national deregulation that could affect millions of acres of land in the majority of U.S. states calls for more quantification and analysis than is provided in the DEA.

APHIS minimizes the fact that the increased use of 2,4-D and glufosinate in soy production, made possible only by deregulation of 2,4-D resistant soy, promotes global warming. APHIS inaccurately assumes in this analysis that deregulation of 2,4-D resistant soy is “not expected to change the cultivation or agronomic practices or agricultural land acreage associated with growing soybean.” DEA at 89. Yet, the DEA recognized that 2,4-D resistant soy would allow 2,4-D, which was applied to around 10% of total soy acreage in the U.S. in 2006, and glufosinate, which is not even listed in the DEA as a historically-significant pesticide for soy, to be applied to the GE soy in new ways and at additional times of the year. DEA at 20–21. APHIS also readily acknowledged that, 2,4-D resistant soy will be stacked with a glyphosate-resistant variety, thus increasing the variety and use of herbicides that will be applied. DEA at 75, 110. Nowhere does the DEA discuss the GHG emissions implications of producing and applying the additional pesticides associated with this crop. APHIS’ reliance on erroneous information and assumptions undermines and negates its analysis and conclusions regarding climate change impacts.

Additionally, APHIS assumes that farmers and producers will adhere to label restrictions for herbicide use. *See, e.g.*, DEA at 75, 86, 91, 92, 103, 139. APHIS provides no support for the contention that the label restrictions will prevent environmental damage from the increasing and new uses of 2,4-D and glyphosate on the 2,4-D-Resistant crop system. Nor can the agency pass the buck on its NEPA duties to another agency, or industry submissions. APHIS must properly analyze the climate change impacts of its action in an EIS.

VI. Various Mitigation Measures In the DEA Are Insufficient.

APHIS lists mitigation measures but does not support them with any agency authority or sufficient analysis to satisfy NEPA’s requirements for mitigation. The agency seeks to rely on seed industry practices to avoid seed-based contamination. *See* DEA at 30, 120; *see also* DEA at 31 (“Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields”). Without this reliance the DEA unquestionably accepts contamination of organic and other non-GE soybeans, which would be a significant impact meriting an EIS since it would do great damage to American agriculture. APHIS also mentions that best practices will serve to minimize “potential for pesticide impacts to surface and groundwater,” DEA at 39, implying that these best practices are integral to the DEA’s overall findings of no significant impacts meriting an EIS. *See also* DEA at 40 (“Currently, EPA is evaluating new regulations for pesticide drift labeling and the identification of best management practices to control such [herbicide] drift”). APHIS makes the assumption that all farmers use best management practices a central assumption to the scope of analysis.

DEA at 73–74. However, the agency mentions these salves to the implicit harms of this action without addressing how mitigating measures will be undertaken or ensured. In the case of best management practices, the agency states that it assumes “some farmers do not follow these best management practices,” DEA at 74, but it never seeks to explain how many farmers this is or how it affects the overall stated assumption that all farmers follow such practices. Also, as discussed above the agency blindly relies on Dow’s proposed weed management system to determine that 2,4-D, a highly volatile and therefore drift-prone herbicide, will not drift and therefore will not cause large non-target plant losses across the nation.

APHIS’s lack of analysis and clarity here violates NEPA. NEPA requires that mitigation measures must be described “in detail,”¹³⁵ and an analysis explaining the effectiveness of the measures is “essential.”¹³⁶ Further, the effectiveness of mitigation measures must be supported by studies and analytical data in the record.¹³⁷ Here, APHIS failed to provide any estimates or analysis of the cost to farmers adopting anti-contamination protections, or best agricultural practices for pesticide use, weed management, and other agricultural practices, on which all of the DEA’s findings depend.

VII. APHIS Has a Duty to Prepare a Programmatic EIS to Analyze the Cumulative Effects of All 2,4-D Resistant Crops

In addition to remedying the problems outlined above by preparing an individual EIS for this 2,4-D resistant soy, APHIS also has a legal duty to consider the overall impacts of all 2,4-D crops in a Programmatic EIS. The CEQ regulations provide that a Programmatic EIS “may be prepared, and are sometimes required, for broad federal actions such as the adoption of new agency programs or regulations.”¹³⁸ The U.S. Supreme Court has held that the environmental impacts of agency actions must be considered together in a single EIS when their impacts will be “cumulative or synergistic.”¹³⁹ Indeed, “a comprehensive impact statement may be necessary in some cases for an agency to meet [its NEPA] duty.”¹⁴⁰ Similarly, Section 1508.25 of the CEQ regulations provides that the scope of an EIS should consider:

¹³⁵ *Ore. Natural Res. Council v. Marsh*, 832 F.2d 1489, 1493-94, 1493 (9th Cir. 1987), *rev’d on other grounds*, *Marsh v. Ore. Natural Res. Council*, 490 U.S. 360 (1989).

¹³⁶ *South Fork Band Council of W. Shoshone of Nev. v. U.S. Dep’t of Interior*, 588 F.3d 718, 727 (9th Cir. 2009) (rejecting the agency’s arguments that an effectiveness discussion was not required because it was “impossible to predict the precise location and extent” of impacts, and that “problems should instead be identified and addressed as they arise,” emphasizing that “NEPA requires that a hard look be taken, if possible, before the environmentally harmful actions are put into effect.”).

¹³⁷ *League To Save Lake Tahoe v. Tahoe Regional Planning Agency*, 739 F. Supp. 2d 1260, 1282 (E.D. Cal. 2009) (“the Ninth Circuit has repeatedly held that NEPA requires ‘analytical data’ describing mitigation’s effectiveness. ‘A perfunctory description or mere listing of mitigation measures, without supporting analytical data,’ is inadequate.”) (quoting *Nat’l Parks & Conservation Ass’n*, 241 F.3d at 734).

¹³⁸ 40 C.F.R. § 1502.4(b) (2010).

¹³⁹ *Kleppe v. Sierra Club*, 427 U.S. 390, 410 (1976).

¹⁴⁰ *Kleppe v. Sierra Club*, 427 U.S. 390, 409-410 (1976).

(2) Cumulative actions, which when viewed with other proposed actions have cumulatively significant impacts should therefore be discussed in the same impact statement.

(3) Similar actions, which when viewed with other reasonably foreseeable or proposed agency actions, have similarities that provide a basis for evaluating their environmental consequences together, such as common timing or geography. An agency may wish to analyze these actions in the same impact statement. It should do so when the best way to assess adequately the combined impacts of similar actions or reasonable alternatives to such actions is to treat them in a single impact statement.¹⁴¹

The decisions to deregulate 2,4-D resistant crops, including the 2,4-D resistant soy at issue and the 2,4-D resistant corn petition for deregulation that is also before the agency, constitute “similar actions” because they result in similar environmental consequences. As discussed in Sections IV & V, *supra*, the commercialization and planting of GE, HR crops have significant environmental impacts including, *inter alia*, risk of transgenic contamination, the increase in the associated herbicide use, the evolution of herbicide resistant weeds, and the harms to human beings, species and the environment from 2,4-D, glyphosate, and glufosinate. Coordinated NEPA review would serve to decrease the considerable uncertainty around the synergistic effects of deregulating multiple crops with the same resistance at the same time. As mandated by NEPA regulations, uncertainty and unknown risks are sufficient showing to demonstrate “significance” meriting an EIS.¹⁴² Since APHIS has proven unable to adequately predict the emergence of superweeds, not to mention the massive over-adoption of pesticides, by preparing individual NEPA documents, seemingly the only way to adequately address this type of uncertainty is to proceed with a Programmatic EIS on these similar, related herbicide resistant crop systems.

VIII. APHIS Failed To Comply with the ESA.

APHIS failed to consult with FWS on the potential effects on threatened and endangered species and their critical habitats, as required under Section 7 of the ESA. As previously explained, Section 7(a)(2) of the ESA requires every federal agency to consult the appropriate federal fish and wildlife agencies to “insure” that the agency’s actions are not likely “to jeopardize the continued existence” of any listed species or “result in the destruction or adverse modification” of critical habitat.¹⁴³ APHIS must prove its deregulation of 2,4-D resistant soy will neither jeopardize any species, nor harm any critical habitat, anywhere the crop system may be grown.¹⁴⁴

¹⁴¹ 40 C.F.R. § 1508.25.

¹⁴² 40 C.F.R. § 1508.27(b)(5). *See also Nat'l Parks & Conservation Ass'n*, 241 F.3d at 731 (either degree of uncertainty or controversy “may be sufficient to require preparation of an EIS in appropriate circumstances.”).

¹⁴³ 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).

¹⁴⁴ *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1035 (9th Cir. 2005).

APHIS must first make a written request to the expert agencies for a list of the protected species in the proposed action area that may be present.¹⁴⁵ There is no evidence that APHIS took this first step, even though it is a prerequisite for further agency action.¹⁴⁶ Instead, APHIS improperly relied almost exclusively on the petitioner's analysis to reach its conclusion that the deregulation of 2,4-D resistant soy will have "no effect" on listed species or their critical habitats. DEA at 135.

Congress required in Section 7 the process that all Federal agencies must follow to insure against jeopardy. Under this mandatory regime APHIS must determine whether its action "may affect" any listed species or any designated critical habitat; if so, it must consult the designated expert wildlife agencies before acting.¹⁴⁷

This proposed deregulation is unrestricted, nationwide. APHIS knows that a large number of protected species are found on or near the acreage where the crop system may be used. "APHIS is aware that there may be potential environmental impacts resulting from the use of 2,4-D and glufosinate on [2,4-D resistant soy], including potential impacts on [threatened and endangered species] and critical habitat." DEA at 136 (emphasis added). Thus, APHIS's acknowledgment that its action "may affect" endangered species and their habitat triggered the need for consultation. Nevertheless, seeing where its deregulation led, APHIS aborted compliance with the ESA, refusing to consult with the expert wildlife agency.

APHIS's excuse that it need not consult on the acknowledged potential impacts on threatened and endangered species and their critical habitats from the use of herbicides that 2,4-D resistant soy is designed to withstand is contrary to law. The ESA's implementing regulations broadly define agency action to include "all activities or programs of any kind authorized, funded or carried out...by federal agencies," including the granting of permits and "actions directly or indirectly causing modifications to the land, water or air."¹⁴⁸ APHIS's assessment under Section 7(a)(2) must also include the indirect effects, and the effects of all activities "interrelated or interdependent" with the deregulation.¹⁴⁹ "Indirect effects are 'those that are caused by the proposed action and are later in time, but still reasonably certain to occur.'"¹⁵⁰ Here, the DEA makes plain that the application of 2,4-D and glufosinate are certain to accompany the deregulation of 2,4-D resistant soy. These include effects of the herbicides it is undisputed will be used with the deregulated crop, since their use is the crop's very (and sole) purpose.

¹⁴⁵ 16 U.S.C. § 1536(c)(1).

¹⁴⁶ Pac. Rivers Council, 30 F.3d at 1054 n.8.

¹⁴⁷ 50 C.F.R. § 402.14(a).

¹⁴⁸ 50 C.F.R. § 402.02 (emphasis added).

¹⁴⁹ 50 C.F.R. § 402.02; *see Wild Fish Conservation v. Salazar*, 628 F.3d 513, 525 (9th Cir. 2010).

¹⁵⁰ *Wild Fish Conservation*, 628 F.3d at 525-26; *see also Ariz. Cattle Growers' Assoc. v. U.S. Fish and Wildlife Serv.*, 273 F.3d 1229, 1248 (9th Cir. 2001) (approving FWS restrictions based on indirect effect of cattle grazing and resulting river sedimentation on fish habitat); *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 481 F. Supp. 2d 1059, 1097 (N.D. Cal. 2007).

APHIS has broad authority under the PPA to restrict the crop system's harms in order to protect endangered species and their habitat through partial deregulation or other means. In fact, including a determination that an herbicide-resistant crop system did "not harm threatened or endangered species" was a routine APHIS prior practice in deregulations, prior to recent litigation and evidence of significant potential harm from these crop systems making such a finding automatically arbitrary and capricious. APHIS was required to consult before deregulating.

Here, APHIS attempted to artificially separate the effects of 2,4-D resistant soy from those of the herbicides the plant was created to tolerate, and proceeded to declare that the plant alone would have no effect on ESA-listed species. This was contrary to the plain language of the ESA. Then, instead of undertaking even an informal consultation about ecological effects, APHIS and FWS decided that, as a result of APHIS's erroneous jurisdictional legal argument allowing APHIS to ignore the impacts of half the cropping system it was approving, "consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or the NMFS are not required." DEA at 135. However, Section 7(a)(2) requires that APHIS's assessment also consider a deregulation's indirect effects, as well as the effects of all activities "interrelated or interdependent" with that action.¹⁵¹ Those indirect effects include the impacts of the herbicide use this crop was designed to facilitate.

Nor can APHIS substitute EPA's herbicide registration review process under FIFRA for the agency's independent duty to consider indirect effects under the ESA. *See* DEA at 136-40. However, as explained above numerous times, EPA's prior registration of these herbicides does not relieve APHIS of its duty to comply with environmental laws, including the ESA.¹⁵² APHIS improperly relied on the claim that EPA's future pesticide risk assessments will ensure protection of threatened and endangered species, although not before reporting that EPA is seeking comments on findings that 2,4-D is likely to jeopardize listed species and glufosinate "may effect" listed species. DEA at 138-39. Moreover, APHIS also professed to rely on DAS's self-interested assurances that the company will encourage (unenforceable) best practice use to eliminate the harms. DEA at 139. According to the agency:

There are legal precautions in place to reduce the possibility of exposure and adverse impacts to [threatened and endangered species] from application of 2,4-D and glufosinate to [2,4-D resistant soy]. These precautions include the EPA pesticide label restrictions and best practice guidance provided by [Dow] ... and Bayer Adherence to these label restrictions ... will ensure that the use of either herbicide will not adversely affect [threatened and endangered species] or critical habitat.

¹⁵¹ *Id.* at § 402.02.

¹⁵² *Wash. Toxics Coalition v. Env'tl. Prot. Agency*, 413 F.3d 1024, 1032 (9th Cir. 2005).

DEA at 139. Yet APHIS cannot rely on any “mitigation” measures from Dow or other companies that are beyond the agency’s control.¹⁵³ While at the same time dismissing its own responsibility based on the other agency’s activities, APHIS acknowledged that “EPA’s review of the pesticide under FIFRA is independent of APHIS’ review and regulatory decisions.” DEA at 137.

The jurisdictional conclusion arrived at by APHIS and FWS, and upon which APHIS bases its excuse for refusing to consult despite acknowledging that its action “may affect” protected species, was a legal determination about statutory interpretation, not an ecological assessment. It has no place in the ESA or its implementing regulatory structure. Critically, FWS did not conclude that deregulation was “not likely to adversely affect” any listed species or critical habitat. To the contrary, despite the ESA’s mandate that “[e]ach Federal agency” review actions’ effects on listed species and critical habitat, APHIS and FWS concluded that, because EPA assesses pesticides under FIFRA, APHIS’s duty to consider the effects of pesticide application that deregulation of 2,4-D resistant soy will facilitate was excused. DEA at 136. However, EPA’s consultation duties under the ESA on the direct and indirect impacts of its approval action in no way vitiate the ESA duties of any other agencies (such as APHIS) for the impacts of their own approval actions. APHIS’s interpretation of its ESA duties is entitled to no deference whatsoever.

The DEA is littered with evidence that the use of 2,4-D, glufosinate, and other herbicides on 2,4-D resistant soy and its stacked progeny “may affect” threatened and endangered species and their critical habitats, admissions that triggered the need to consult. For example, APHIS noted that EPA has recently requested formal consultation to address the potential effects of 2,4-D on the California Red-legged Frog and the Alameda Whipsnake. DEA at 138. APHIS also admitted that a biological opinion issued by NMFS in March 2011 concluded that further use of 2,4-D is likely to jeopardize the continued existence of 28 salmonid populations, and also destroy critical habitats for 26 of them. DEA at 138. The agency explained that studies show the ecological toxicity of 2,4-D “exceed[s] the Level of Concern for most organisms including non-target [threatened and endangered species].” DEA at 138. According to APHIS, soybean fields “provide browse for rabbits, deer, rodents, other mammals; birds such as upland gamebirds, while also providing a forage base for insects.” DEA at 43. Moreover, 2,4-D persists in the soil, since its soil half-life ranges up to 30.5 days, with an average of 10 days. DEA at 84.

Similarly, glufosinate remains in soil an average of 7 days, where it is “highly mobile.” DEA at 36. APHIS acknowledged that “environmental assessments of the toxicity of glufosinate to animal species indicated a relatively low direct risk, but high risk to plants composing the animals’ habitat.” DEA at 44. As a result, the EPA has concluded that use of glufosinate “may affect” listed species and thus is currently conducting a comprehensive ecological risk assessment of application of this herbicide. DEA at 139. For a more detailed discussion of the specific harms to threatened &

¹⁵³ *Ctr. For Biological Diversity v. Rumsfeld*, 198 F. Supp. 2d 1139, 1152 (D. Ariz. 2002).

endangered species posed by the deregulation of 2,4-D resistant soy, please see separately submitted CFS comments.

Finally, APHIS is aware that the use of an herbicide-resistant cropping system may threaten the continued existence of endangered species and destroy critical habitats. APHIS entered Section 7(a)(2) consultation with FWS, from which it now claims immunity, when APHIS previously proposed to deregulate Monsanto's Roundup Ready bentgrass, and FWS issued a biological opinion with a jeopardy determination.¹⁵⁴ APHIS must consult with FWS and NMFS regarding the specific impacts of herbicides in conjunction with the release of 2,4-D resistant soy and the anticipated release of a stacked soy variety combining resistance to 2,4-D, glufosinate, and glyphosate.

By failing to complete Section 7(a)(2) consultation based on an erroneous interpretation of its statutory authority, APHIS has based its decision on factors Congress did not intend for it to consider. Deregulating 2,4-D resistant soy without properly completing this consultation would therefore be arbitrary, capricious, and contrary to the mandates of the ESA.

IX. APHIS's Decision Lacks Any Basis in Sound Science

As discussed in Section I, *supra*, APHIS violated the PPA, NEPA and APA by improperly cabinining its analysis and by excluding significant harms that fall within its statutory purview because *inter alia* they “directly or indirectly injure ... plants,” harms such as contamination, superweeds and herbicide impacts. The agency's review also violates the PPA because it mandates that decisions affecting regulated products “shall be based on sound science.”¹⁵⁵

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. As discussed in detail in the separately-submitted CFS Comments, the PPRA and DEA are both largely based on Dow's own studies, which are largely not peer-reviewed or objective.

Even under the agency's narrow interpretation of “plant pest risks,” APHIS has failed to adequately assess potential negative impacts from the expression of the inserted transgene. CFS's separately-submitted comments discuss in detail how the deregulation of 2,4-D resistant soy will have an effect on pollinators, a key biodiversity issue that is insufficiently addressed in the DEA. Recent headlines on the poor condition of bees and other pollinators in the U.S. should be a sufficient alarm for APHIS to have better-assessed this issue, and now it is demonstrably a large enough impact to merit an EIS. Further, despite the fact that the PPRA claimed to have analyzed the transgene for “expression of the gene product” and “new enzymes, or changes to plant metabolism,” PPRA at 1, APHIS completely ignored well-known studies on how expressions of the

¹⁵⁴ U.S. Fish & Wildlife Serv., *Draft Biological Opinion, Roundup Ready Bentgrass* (July 2009).

¹⁵⁵ 7 U.S.C. § 7701(4).

transgene may make the engineered 2,4-D resistant soy more toxic to organisms that eat soy tissues. APHIS disregarded the fact that the data submitted by Dow wrongly did not assess gene expression in pollen (which is normally part of an environmental assessment of a GE crop), and therefore did not reveal that gene expression was much higher in pollen, which may be toxic to beneficial insects such as honeybees. *See* separately-submitted CFS Comments. APHIS's discussion of the plant's metabolism also completely ignores the difference in the composition of 2,4-D resistant soy that result from the activity of the AAD-12 and PAT proteins. As demonstrated in CFS Science Comments, the AAD-12 protein is an enzyme that is likely to produce toxic metabolites that do not naturally occur in non-GE soy. This is the antithesis of sound science.

Finally, sound science would counsel that APHIS should properly inform its PPA decision with its NEPA analysis, which was not done here. The PPRA makes no reference to conclusions under NEPA and declares that its decision is controlled wholly by APHIS regulation 7 CFR 340.6(c), walling off the PPRA from the informed decision-making required by NEPA. *See* PPRA at 1. Further, even if the agency *had* informed the PPA decision with its NEPA assessment, the DEA is chock full of unsound science—errors of 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.

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.”¹⁵⁶ 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

¹⁵⁶ 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/.

- 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.”¹⁵⁷

APHIS has frequently violated the tenants of sound science in numerous ways in its decision-making documents on GE crops, 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 DEA, data and information well-known to the agency, 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 the 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.

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). The ultimate goal—contained in the second half of the first finding—is the protection of US agriculture and economy. Disregarding significant adverse economic impacts on the agricultural economy, as discussed *supra*, further violates the PPA.

CONCLUSION

In this unprecedented and irresponsible proposed action, APHIS has abdicated its duties under numerous laws, in the process completely abandoning farmers, businesses, the public, natural ecosystems, and protected species to the foreseeable resulting adverse impacts of its proposed action. APHIS proposes this unnecessary result without even adequately analyzing those myriad significant impacts, without even consulting the expert agencies on those impacts, and without even considering denying approval or taking more limited action, such as a partial deregulation, in order to prevent or limit those harmful impacts. The eye-opening 31,880 public comments filed on APHIS’s

¹⁵⁷ *Id.*

proposed approval from farmers, scientists, businesses and concerned citizenry underscore its significance and controversy, and confirm that it is the antithesis of good policy, not to mention being contrary to sound science and controlling law.

The record shows that the unrestricted approval of Dow's 2,4-D resistant crop system will cause, among other adverse direct, indirect and cumulative impacts: massive increases in current and new herbicide use and uncontrollable destructive drift, causing grave harm to both non-GE crops and native ecosystems alike; widespread transgenic contamination and resulting socioeconomic and environmental harm; exacerbation and ratcheting up the current herbicide-resistant, noxious superweeds epidemic; impacts from intended stacking of this crop with future transgenic varieties and from volunteers; health harms to farm workers and the public; adverse climate change impacts; and adverse impacts to conservation tillage.

APHIS needs to go back to the drawing board and begin this process anew. It must prepare an EIS that complies with NEPA and adequately, impartially, and meaningfully analyzes these myriad significant impacts. It then must apply that rigorous analysis to inform any future decision, rather than making NEPA procedure a meaningless paper exercise. Further, pursuant to the ESA, APHIS must consult with the expert wildlife agency(ies) on the acknowledged potential direct and indirect impacts to protected species and critical habitats of its approval of this crop system, and then inform any decision with that analysis, in order to ensure that no species are jeopardized or results in the destruction of critical habitat. And finally, APHIS must apply its full statutory authority and affirmative mandate under the PPA to protect all agriculture, not just the biotech industry, as well as the environment and public health, by analyzing and restricting this unprecedented crop system's acknowledged agronomic, environmental and economic impacts. Anything less would be arbitrary and capricious, an abuse of discretion, and contrary to law.

Respectfully Submitted,

/s/
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