



THE CENTER FOR FOOD SAFETY

Docket No. APHIS–2010–0103
Regulatory Analysis and Development
PPD, APHIS
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Comments to USDA APHIS on Environmental Assessment for the Determination of Nonregulated Status of Herbicide-Tolerant DAS-40278-9 Corn, Zea Mays, Event DAS-40278-9

April 27, 2012

Docket No. APHIS–2010–0103

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-40278-9 corn (2,4-D resistant corn), which has been genetically engineered (GE) to provide increased tolerance to treatment with phenoxy auxin herbicides and resistance to resistance to aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCCase) inhibitor ("fop") herbicides. The introduced genetic material (DNA) results in the production of an aryloxyalkanoate dioxygenase (AAD-1) enzyme that inactivates herbicides of the aryloxyalkanoate family, including phenoxy auxins and AOPP ACCCase inhibitors. The most widely-used phenoxy auxin herbicide is the highly toxic 2,4-dichlorophenoxyacetic acid (2,4-D). Additionally, Dow has indicate that DuPont, the current registration of Quizalofop, one of the "fop" herbicides, will submit materials to the U.S. Environmental Protection Agency (EPA) to establish a new label for the use of Quizalofop on 2,4-D resistant corn.

Pursuant to the USDA's December 27, 2011 Federal Register Notice, the Center for Food Safety (CFS) submits the following comments concerning the inadequacy of the agency's draft Environmental Assessment (DEA) accompanying the petition for deregulation under the National Environmental Policy Act (NEPA), the Plant Protection Act (PPA), 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

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 the comments submitted herein, CFS is also two science comments (CFS Science Comments), separately submitted by Bill Freese and Martha Crouch. Finally, CFS is submitting 55,816 signatures to our organizational sign-on letter from CFS Food Network members opposing the deregulation of Event DAS-40278-9 Corn (Docket No. APHIS-2010-0103), and 101,394 additional signatures to the CFS sign-on letter from our partner organization, SumOfUs.org.

SUMMARY

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

The DEA is flawed in structure because it is overly narrow in scope. It fails to give meaningful consideration to any alternative besides full deregulation based on an erroneous interpretation of APHIS's authority under the Plant Protection Act.

The DEA is procedurally flawed and unlawful because, rather than informing APHIS's deregulation decision on 2,4-D resistant corn, the DEA's analysis is predicated on the pre-determined and separate conclusion in the Plant Pest Risk Assessment (PPRA) that APHIS can only deregulate DEA, making the entire NEPA analysis a foregone conclusion—a meaningless paper exercise.

The DEA is flawed in substance because its analysis of numerous impacts is inadequate to comply with NEPA. It entirely fails to address several significant issues, and its conclusions that 2,4-D resistant corn is not likely to cause significant impacts to the environment, U.S. agriculture, or public health are contrary to record evidence. Deregulation of 2,4-D resistant corn would have numerous significant impacts on U.S. agriculture and the environment that must be acknowledged, analyzed, and meaningfully considered.

The DEA's discussion of cumulative impacts is legally deficient, in particular for its abject failure to consider the emergence of herbicide-resistance weeds, the reasonably foreseeable stacking of multiple herbicide-resistance traits with 2,4-D resistant corn, and the injury to non-target crops from the reasonably foreseeable herbicide drift of 2,4-D application.

APHIS failed to comply with the procedural mandates of the Endangered Species Act (ESA), including requesting from the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS), in writing, whether listed species or critical habitat may be present in the proposed action area. APHIS also failed to consult with

¹ See generally <http://www.centerforfoodsafety.org>.

FWS on whether listed species or critical habitat may be adversely affected by the proposed action. A joint declaration by APHIS and FWS asserting that only EPA has authority over pesticides does not satisfy APHIS's ESA responsibilities for the direct and indirect impacts of its approval action.

APHIS's Preferred Alternative to deregulate 2,4-D resistant corn is arbitrary, capricious, and contrary to the mandates of the Plant Protection Act. The decision is not based on sound science, and the 2,4-D resistant corn crop system violates the PPA in that it 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.

COMMENTS

The following comments illustrate why the proposed deregulation should not be permitted until and unless APHIS prepares an EIS to comprehensively and meaningfully review 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 this crop system's approval based on its likely agronomic, environmental and economic harms pursuant to the PPA.

The National Environmental Policy Act

NEPA requires federal agencies such as USDA's APHIS to prepare a detailed environmental impact statement (EIS) for all "major Federal actions significantly affecting the quality of the human environment."² 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."³

If the federal action may significantly affect the environment, APHIS must prepare an EIS.⁴ As a preliminary step, an agency may prepare an environmental assessment (EA) to decide whether the environmental impact of a proposed action is significant enough to warrant preparation of an EIS.⁵ 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.⁶ "The statement of reasons is crucial to determining whether the agency took a "hard look" at the potential environmental impact[s] of a project."⁷ An EA must "provide sufficient evidence and analysis for determining whether to prepare an

² 42 U.S.C. § 4332(2)(C).

³ *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349(1989).

⁴ *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).

⁵ 40 C.F.R. § 1508.9.

⁶ *Save the Yaak v. Block*, 840 F.2d 714, 717 (9th Cir. 1988).

⁷ *Id.*

EIS or a finding of no significant impact”⁸ NEPA regulations require the analysis of direct, indirect, and cumulative effects in NEPA documents, including EAs.⁹ The assessment must be a “hard look” at the potential environmental impacts of its action.¹⁰ Therefore, APHIS’s decisions in this EA must be “complete, reasoned, and adequately explained.”¹¹

Whether there may be a significant effect on the environment requires consideration of two broad factors: context and intensity. A number of factors should be considered in evaluating intensity, including, “[t]he degree to which the proposed action affects public health or safety,” “[t]he degree to which the effects on the quality of the human environment are likely to be highly controversial,” “[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks,” “[t]he degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration,” “[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts,” and “[t]he degree to which the action may adversely affect an endangered or threatened species or its habitat.”¹² An action may be “significant” if just one of these factors is met.¹³

The Council on Environmental Quality (CEQ)

NEPA also established the Council on Environmental Quality and charged CEQ with the duty of overseeing the implementation of NEPA.¹⁴ 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.”¹⁵ CEQ’s regulations are applicable to and binding on all federal agencies.¹⁶ Among other requirements, CEQ’s regulations mandate that federal agencies address all “reasonably foreseeable” environmental impacts of their proposed programs, projects, and regulations.¹⁷

⁸ *Id.*

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

¹⁰ *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).

¹¹ *Northwest Coalition for Alternatives to Pesticides v. U.S. E.P.A.*, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008).

¹² 40 C.F.R. § 1508.27(b)(2), (4), (5), (6), (7), (9).

¹³ *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 361 F.3d 1108, 1125 (9th Cir.2004); 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.”).

¹⁴ See 42 U.S.C. §§ 4321, 4344.

¹⁵ 40 C.F.R. § 1500.3.

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

¹⁷ See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.

Plant Protection Act

On June 22, 2000, Congress repealed the former Plant Quarantine Act, the Federal Plant Pest Act, and the Federal Noxious Weed Act and replaced them with the Plant Protection Act (PPA), 7 U.S.C. § 7701-7772, as part of the Agricultural Risk Protection Act. APHIS regulates transgenic crops pursuant to the PPA, which consolidated these previous statutes and enhanced APHIS's authority to prevent the introduction or spread of both "plant pests" and "noxious weeds."¹⁸ 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."¹⁹ The PPA requires that all of APHIS's decisions "shall be based on sound science."²⁰

APHIS's implementing regulations concerning transgenic plants, 7 C.F.R. Part 340, were promulgated pursuant to its previous, narrower Federal Plant Pest Act authority and still only expressly reference plant pest harms,²¹ and not noxious weed harms, even though the agency has since 2008 proposed new regulations clarifying that all of its PPA authority applies to its transgenic crop oversight, including its noxious weed authority.²² Under these regulations, genetically engineered plants are "regulated articles" over which the agency retains control, prescribing how they may be "introduce[d]" into the environment and forbidding their release or movement in interstate commerce absent explicit approval.²³ Developers who want to commercialize a transgenic plant based on field trial data petition USDA for deregulation,²⁴ which APHIS can grant "in whole or in part."²⁵

Endangered Species Act

As the Supreme Court recognized, the ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation."²⁶ The ESA's statutory scheme "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies."²⁷ Federal agencies are

¹⁸ See, e.g., 7 U.S.C. § 7712(a) ("The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States."); see also 7 C.F.R. §§ 2.22(a), 2.80(a)(36) (delegating authority to APHIS).

¹⁹ 7 U.S.C. § 7701(1).

²⁰ *Id.* §§ 7701(4), 7711(b), 7712(b).

²¹ See 52 Fed. Reg. 22,908 (June 16, 1987); 58 Fed. Reg. 17,044 (March 31, 1993); 62 Fed. Reg. 23,945 (March 2, 1997).

²² 73 Fed. Reg. 60,008, 60,011 (Oct. 9, 2008).

²³ 7 C.F.R. § 340.0; see also *id.* § 340.1 (defining "introduce").

²⁴ 7 U.S.C. § 7711(c)(2), 7 C.F.R. § 340.6.

²⁵ 7 C.F.R. § 340.6(d)(3)(i).

²⁶ *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 180 (1978).

²⁷ *Id.* at 185.

obliged “to afford first priority to the declared national policy of saving endangered species.”²⁸

Section 7(a)(2) of the ESA requires every federal agency to consult the appropriate federal fish and wildlife agency—FWS, in the case of land and freshwater species, and NMFS in the case of marine species—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.²⁹ 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.”³⁰ A species’ “critical habitat” includes those areas identified as “essential to the conservation of the species” and “which may require special management considerations or protection.”³¹

To facilitate compliance with section 7(a)(2)’s prohibitions on jeopardy and adverse modification, the ESA requires each federal agency that plans to undertake an action to request information from FWS and/or NMFS “whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action.”³² If the expert agency advises the action agency that listed species or species proposed to be listed may be present, the agency must then prepare a biological assessment for the purpose of identifying any such species that are likely to be affected by the proposed agency action.³³

If, based on a biological assessment, an agency determines that its proposed action may affect any listed species and/or its critical habitat, the agency generally must engage in formal consultation with the expert agency.³⁴ At the end of the formal consultation, the expert agency must provide the agency with a “biological opinion” detailing how the proposed action will affect the threatened and endangered species and/or critical habitats.³⁵ If the expert agency concludes that the proposed action will jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, the biological opinion must outline “reasonable and prudent alternatives” to the proposed action that would avoid violating ESA section 7(a)(2).³⁶

Pending the completion of formal consultation with the expert agency, an agency is prohibited from making any “irreversible or irretrievable commitment of resources

²⁸ *Id.*

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

³⁰ 50 C.F.R. § 402.02.

³¹ 16 U.S.C. § 1532(5)(A).

³² 16 U.S.C. § 1536(c)(1); *see also* 50 C.F.R. § 402.12(c).

³³ *Id.*

³⁴ 50 C.F.R. § 402.14.

³⁵ 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14.

³⁶ 16 U.S.C. § 1536(b)(3)(A).

with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures.”³⁷

I. The Scope of APHIS’s Analyses in the DEA and the PPRA Violates the PPA, and Is Arbitrary and Capricious Under NEPA.

a. APHIS Has Broad PPA Authority to Consider Numerous Impacts Stemming from the Deregulation of the 2,4-D Resistant Corn Crop System and Crop Systems of Its Stacked Progenies.

In formulating its preferred alternative, APHIS erroneously abdicated its regulatory oversight over genetic engineered (GE) crops. There is no regulatory or statutory basis for APHIS’s repeated claim that “if APHIS determines ... that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provisions of the PPA and Part 340.” DEA at 4; *see* DEA at 1; 2; 46-48, 51. 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.³⁸ 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.”³⁹ Indeed, 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.* at 1 (APHIS aims to “improve agricultural productivity and competitiveness, and contributes to the national economy and public health.”); DEA at 2 (“[APHIS’s] mission is to protect America’s agriculture and environment ...”).

APHIS premised its assessment of 2,4-D resistant corn on the mistaken assumption that the agency is limited by its admittedly outdated regulations, codified at 7 CFR Part 340 (hereafter Part 340). APHIS declared that it must grant the petition in full when it “determines that it is unlikely to pose a plant pest risk.” DEA at 2. APHIS’s claim that Part 340 limits the scope of its authority is patently false. *See* DEA at 2. That the Part 340 regulations only expressly refer to “plant pest risks” because they were promulgated pursuant to the previous, narrower Plant Pest Act authority, does not restrict APHIS’s regulatory oversight over GE crops.⁴⁰ APHIS itself has admitted, in its proposed amended regulations in 2008, its ability to consider both “plant pest and noxious weed risks.”⁴¹ The Part 340 regulations do not preclude APHIS from considering both “plant pest risks” and “noxious weed risks” in its oversight of GE crops under the PPA. To the contrary, APHIS has separate regulations specifically addressing

³⁷ 16 U.S.C. § 1536(d).

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

³⁹ 7 U.S.C. § 7701(1).

⁴⁰ The PPA replaced and combined the USDA’s previous statutory oversight under the Plant Quarantine Act, Plant Pest Act, and Noxious Weed Act. 52 Fed. Reg. 22,908 (June 16, 1987).

⁴¹ 73 Fed. Reg. 60,008, 60,011 (Oct. 9, 2008) (We are proposing to revise the scope of the regulations in § 340.0 to make it clear that decisions regarding which organisms are regulated remain science-based and take both plant pest and noxious weed risks into account.”); *see also id.* at 60,013 (“evaluation of noxious weed risk expands what we can consider”).

traditional plant pests and traditional noxious weeds, in addition to its GE crop regulations.⁴²

Plant Pest Risks

APHIS's arbitrary limitation of what can constitute "plant pest risks" also undercuts the agency's analyses in the DEA and PPRA, making its review of the crop's actual impacts non-existent. APHIS concluded that 2,4-D resistant corn does not pose a plant pest risk after examining the plant pest risks from "the inserted gene material" only, the transgenic crop's "weediness characteristics" and responses to "diseases or plant pests in the field," the crop's effects on other organisms and "the lack of concerns of horizontal gene transfer." PPRA at 14.

However, "plant pest risks" cover 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."⁴³ Part 340 provides that, in determining whether to grant or deny a deregulation petition, 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."⁴⁴ As discussed in detail below, and in the two separately submitted CFS's Science Comments, the potential deregulation of 2,4-D resistant corn presents numerous environmental, economic, and health risks, including, *inter alia*, the risk of transgenic contamination, increased herbicide use, and the threat of herbicide-resistant weeds. These harmful effects are plant pest risks that "directly or indirectly injure" organic and GE corn production and threaten cultivation of corn in the United States. APHIS's analysis of Dow's petition for deregulation is unlawful, arbitrary and capricious until and unless APHIS has properly analyzed these plant pest risks in the PPRA and DEA.⁴⁵

Noxious Weed Risks

APHIS also improperly failed to acknowledge and exercise its authority under the PPA to consider noxious weed risks. The PPA significantly expanded APHIS's authority over noxious weeds, providing the agency new tools with which to carry out its mandate.⁴⁶

⁴² See 7 C.F.R. Part 330 (traditional plant pests); 7 C.F.R. Part 360 (traditional noxious weeds).

⁴³ 7 U.S.C. § 7702(10) (emphasis added); 7 U.S.C. § 7712(a).

⁴⁴ 7 C.F.R. § 340.6(c)(4).

⁴⁵ *Motor Vehicles*, 463 U.S. 29 at 43 (failure to consider an important part of the problem is arbitrary and capricious agency action).

⁴⁶ See APHIS, *The Plant Protection Act*,

http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/fs_phproact.html (noting the PPA "grants significant new regulatory authority for noxious weeds") (last viewed September 21, 2011); ; *Int'l Ctr. for Tech. Assessment v. Johanns (ICTA)*, 473 F. Supp. 2d 9, 25 & n.15 (D.D.C. 2007) (citing and quoting APHIS documents acknowledging that PPA provides "a much wider and more flexible set of criteria for identifying and regulating noxious weeds").

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.”⁴⁷ Since the definition of noxious weed includes both direct and indirect harms, noxious weed risks encompass both regulation of the weeds themselves as well as any agricultural pathways of such weeds.⁴⁸ APHIS’s 2008 proposed regulations also illustrate the agency’s own understanding of its existing statutory obligation under the PPA to prevent noxious weed risks and apply that authority when it approves commerce in a crop, as it proposes here.⁴⁹

Yet, the DEA is completely silent on both the direct and indirect noxious weed risks 2,4-D resistant corn presents. Nor did the PPRA reach any formal determination regarding 2,4-D resistant corn’s noxious weed risks. Rather, the PPRA devoted but one page to analyzing 2,4-D resistant corn’s “weediness potential.” PPRA at 10-11. Despite acknowledging in both the DEA and PPRA that volunteer 2,4-D resistant corn can pose a significant problem “because [its] greater ... resistance to herbicides” makes “measures that can be used to remove volunteer [2,4-D resistant corn] ... more limited.” PPRA at 10, APHIS concluded that 2,4-D resistant corn itself “lacks the ability to persist as a troublesome or invasive weed.” PPRA at 10. As explained in detail below, and in the two accompanying CFS Science Comments, 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 corn and stacked hybrids.⁵⁰

APHIS cannot ignore the PPA’s expansive statutory mandates.⁵¹ The agency’s failure to consider plant pest and noxious weed risks associated with 2,4-D resistant corn is arbitrary and capricious. APHS should set aside its current PPRA and DEA and prepare new assessments that adequately considers 2,4-D resistant corn’s plant pest risks and noxious weed risks.

b. APHIS’s NEPA Analysis Also Is Impermissibly Narrow and Improperly Predetermined.

APHIS’s failure to acknowledge its authority under the PPA to (1) prevent noxious weed harms, and (2) consider a variety of plant pest risks including but not

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

⁴⁸ *See, e.g.*, 7 C.F.R. § 360.400 (restricting the import and requiring the pre-import treatment of *Guizotia abyssinica* (niger seed) because it common harbors noxious weed seeds.).

⁴⁹ 73 Fed. Reg. 60,008, 60,011 (Oct. 9, 2008) (We are proposing to revise the scope of the regulations in § 340.0 to make it clear that decisions regarding which organisms are regulated remain science-based and take both plant pest and noxious weed risks into account.”); *see also id.* at 60,013 (“evaluation of noxious weed risk expands what we can consider”).

⁵⁰ 7 U.S.C. § 7702(10) (emphasis added); 7 U.S.C. § 7712(a).

⁵¹ *See, e.g., Alaska Dep’t of Health & Soc. Servs. v. Ctrs. For Medicare & Medicaid Servs.*, 424 F.3d 931, 939-40 (9th Cir. 2005) (“We cannot equate compliance with the ... regulations as conclusive proof of compliance with the broader statutory requirement.”).

limited to prevent transgenic contamination, herbicide drift, and increased herbicide use, also led 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.⁵² An agency's decision is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem."⁵³ Agencies cannot define the project so narrowly that it forecloses a reasonable consideration of alternatives, nor can they "define [their] purpose and need so as to winnow down the alternatives until only the desired one survives."⁵⁴

The DEA violated NEPA because, *inter alia*, APHIS limited its assessment to 2,4-D resistant corn's plant pest risks. APHIS begins its discussion of alternatives in the DEA by stating that "APHIS has concluded that [2,4-D resistant corn] is unlikely to pose a plant pest risk. Therefore, APHIS must determine that 2,4-D resistant corn is no longer subject to Part 340 or the plant pest provisions of the PPA." DEA at 46 (emphases added). This is legally incorrect, and undermines the structure and scope of the DEA's analysis of potentially significant impacts.

Similarly, the DEA's conclusions are pre-determined by APHIS's PPRA, which is itself deficient. *See supra* Section I; *infra* Section V. The policy behind NEPA is "to ensure that an agency has at its disposal all relevant information about environmental impacts *before* the agency embarks on the project."⁵⁵ The DEA should inform the agency's decision-making process, not the other way around (i.e., have the agency's forgone conclusion limit and prejudge the NEPA analysis). Yet, rather than preparing the DEA to inform the agency and foster its decision on whether to deregulate 2,4-D resistant corn, the decision to deregulate 2,4-D resistant corn has already been determined by the outcome of APHIS's 14-page PPRA. DEA at 2 ("If APHIS determines based on its [PPRA] ... that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provision of the PPA and Part 340.").

The PPRA is not a lawful substitute for APHIS's independent duty to prepare an EA or EIS under NEPA. The history of APHIS's oversight of GE crops, as well as the law, contradicts APHIS's current position that the PPRA dictates the outcome of the agency's determination on a petition for deregulation: 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 as recently as 2007.⁵⁶ PPRAs were apparently invented out of whole cloth by the agency to circumvent the requirement to perform a NEPA analysis, as soon as courts began to require meaningful such assessments of the agency.

In short, APHIS's reasoning here turns the NEPA process on its head, relying on its determination from its PPRA (which itself also impermissibly confines the agency's PPA

⁵² See 42 U.S.C. § 4321; 40 C.F.R. § 1501.1(c).

⁵³ *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

⁵⁴ *Klamath-Siskiyou Wildlands Ctr v. U.S. Forest Serv.*, 373 F. Supp. 2d 1069 (E.D. Cal. 2004).

⁵⁵ *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1356 (9th Cir.1994).

⁵⁶ See http://www.aphis.usda.gov/biotechnology/not_reg.html.

authority) to preclude any meaningful alternatives analysis. The conclusion reached in the DEA therefore is arbitrary and capricious.

II. The DEA's Alternatives Analysis Is Inadequate.

The DEA's alternatives analysis is legally deficient. The alternatives analysis is the "heart" of NEPA review.⁵⁷ "NEPA requires that alternatives ... be given full and meaningful consideration, whether the agency prepares an EA or EIS."⁵⁸ The alternatives analysis should ensure that the agency has before it, and takes into account, all possible approaches to a particular project.⁵⁹ To that end, "[i]t 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."⁶⁰

NEPA's requirement that alternatives be studied, developed, and described both guides the substance of environmental decisionmaking and provides evidence that the mandated decisionmaking process has actually taken place.⁶¹ Meaningful consideration of alternatives "furthers the goals of NEPA by guaranteeing that "informed decision-making and informed public participation."⁶²

Where an agency has statutory authority to address environmental impacts, efforts to limit itself through regulations or otherwise will not allow it to circumvent NEPA compliance.⁶³ 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 resistant corn. DEA at 46. APHIS failed to meaningfully consider any alternative other than the Preferred Alternative because, as explained above, the agency erroneously concluded that its PPRA for 2,4-D resistant corn dictates unconditional deregulation. *See supra* Section I. NEPA requires that the agency must rigorously explore and objectively evaluate all reasonable alternatives, including the no action alternative.⁶⁴ Rather than assessing the impacts of continuing 2,4-D resistant

⁵⁷ 40 C.F.R. § 1502.14.

⁵⁸ *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).

⁵⁹ *Calvert Cliffs' Coordinating Comm. v. U.S. Atomic Energy Commission*, 449 F.2d 1109, 1114 (D.C. Cir. 1971).

⁶⁰ 40 C.F.R. § 1502.14.

⁶¹ *Westlands Water District v. U.S. Dep't of Interior*, 376 F.3d 853, 872 (9th Cir. 2004).

⁶² *Id.*

⁶³ *See Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1213 (9th Cir. 2008) ("This court has recognized that 'NEPA's legislative history reflects Congress's concern that agencies might attempt to avoid any compliance with NEPA by narrowly construing other statutory directives to create a conflict with NEPA. Section 102(2) of NEPA therefore requires government agencies to comply 'to the fullest extent possible.'"); *see also Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 105 (D.D.C. 2006) ("The holding in [*Dep't of Transp. v. Public Citizen*, 541 U.S. 752, 767-70 (2004)] extends only to those situations where an agency has 'no ability' because of lack of 'statutory authority' to address the impact. NPS, in contrast, is only constrained by its own regulation from considering impacts on the Preserve from adjacent surface activities." (emphases added in part, in original in part)).

⁶⁴ 40 C.F.R. § 1502.14.

corn's status as a regulated article, APHIS dismissed the No Active Alternative "because APHIS has concluded through [its PPRA] that [2,4-D resistant corn] is unlikely to pose a plant pest risk." DEA at 46.

APHIS also rejected out of hand several reasonable alternatives. *See* DEA at 47-49. APHIS considered, but rejected from further consideration: (1) an alternative that would prohibit the release of 2,4-D resistant corn entirely; (2) an alternative that would approve the petition in part, such as an alternative that would partially deregulate 2,4-D resistant corn by imposing isolation distances and/or geographical restrictions; and (3) an alternative that would require mandatory testing for transgenic contamination. DEA at 47-49. APHIS rejected these alternatives without "studying, developing, and describing" them, once again stating that the agency's conclusion in the PPRA for 2,4-D resistant corn precluded the agency from considering any of the alternatives. *See* DEA at 48 ("[B]ecause APHIS has concluded that [2,4-D resistant corn] is unlikely to pose a plant pest risk ..., an alternative requiring isolation distances would be inconsistent"); ([The geographical restrictions] alternative was rejected ... because APHIS has concluded that [2,4-D resistant corn] does not pose a plant pest risk ...); DEA at 49 ([B]ecause [2,4-D resistant corn] does not pose a plant pest risk ... , the imposition of any type of testing requirements is inconsistent with the plant pest provision of the PPA).

APHIS's failure to mention and consider several other reasonable alternatives also reduces its alternative analysis to a pointless exercise. Specifically, the DEA failed to mention, let alone consider:

- A partial deregulation alternative with requirements to reduce the development of weed resistance (including resistance to 2,4-D, "fop" herbicides, glyphosate, or to a combination of herbicides)
- 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 corn.

The DEA repeatedly acknowledged, and in fact identified as the main reason for considering the deregulation of 2,4-D resistant corn, the epidemic of superweeds resistant to glyphosate resulting from the commercialization of GE, glyphosate-resistant "crop systems." DEA at 107, 109; DEA at 3 (stating that weed resistance is "a concern in agricultural production" due to the "wide-spread adoption of herbicide-tolerant crops, especially GE-derived glyphosate-tolerant crops... ."). The DEA further admitted that 2,4-D resistant corn, once deregulated, will be "stacked" with other herbicide-resistance traits—beginning with glyphosate resistance—to create a stacked GE corn variety that will be resistant to multiple herbicide modes of action. *See, e.g.*, DEA at 4. 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 and "fop" herbicides (including 2,4-D and Quizalofop) a "reasonably foreseeable" consequence that must be analyzed in the

DEA.⁶⁵ Nonetheless, APHIS failed to consider a deregulation alternative that would impose methods to reduce the development of herbicide-resistant weeds (including weeds resistant to 2,4-D, “fop” herbicides, or glyphosate).

Similarly, the DEA recognized that herbicide drift is “a concern for non-target susceptible plants growing proximate to fields herbicides are used in the production of 2,4-D resistant corn.” DEA at 81. The threat of damage to non-target crops in nearby fields is so grave that on April 18, 2012, a grassroots coalition of conventional farmers petitioned APHIS prepare an EIS to consider the negative impacts of herbicide drift from synthetic auxin herbicides such as 2,4-D and dicamba.⁶⁶ 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 corn.

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. In the DEA, APHIS acknowledges that it has the authority to “approve the petition in whole or in part.” DEA at 48. Nonetheless, APHIS claims it can only approve a petition “in part” if there is a plant pest risk associated with some but not all lines requested in the petition. (DEIS at 12). There is no basis in the statute or regulations for this extremely limited interpretation 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.⁶⁷ 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.⁶⁸

“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.’”⁶⁹ The unconditional deregulation of 2,4-D resistant corn 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 corn poses to agriculture, finalizing the current draft without fully

⁶⁵ 40 C.F.R. § 1508.7.

⁶⁶ Carey Gillam, Reuters, Farm Group Seeks U.S. Halt on “Dangerous” Crop Chemicals, Chicago Tribune, Apr. 18, 2012, available at <http://www.chicagotribune.com/business/sns-rt-us-crops-petitionbre83h010-20120418,0,5889068.story> (last visited April 20, 2012).

⁶⁷ *Monsanto v. Geertson Seed Farms*, 130 S. Ct. 2743, 2759-60 (2010).

⁶⁸ 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.

⁶⁹ *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)).

analyzing reasonable alternatives would be arbitrary and capricious and contrary to law and required procedure.

III. The DEA's Analysis of the Threat of Transgenic Contamination and Its Interrelated Economic Impacts Is Woefully Insufficient.

a. 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."⁷⁰

Transgenic Contamination from Gene Flow

It is well known that transgenic contamination between corn fields is not only likely, but commonplace. Ohio State University opines that if "only a small percentage of the total pollen shed by a field of corn drifts into a neighboring field, there is considerable potential for contamination through cross pollination."⁷¹ The DEA admits that that contamination of non-GE corn varieties by 2,4-D resistant corn is possible. DEA at 21 ("Corn will cross-pollinate readily ..."); DEA at 22 ("Gene flow between cultivated corn varieties is likely to occur ..."); DEA at 37 ("Corn is a cross-pollinating crop in which most pollination results from pollen dispersed by wind and gravity.")

According to Emerson Nafziger, Professor of Agronomy at the University of Illinois:

It is possible for corn pollen to move on the wind for more than a mile. Even under low wind conditions, some corn plants on the edge of a field are normally pollinated by pollen from outside the field. ... [P]roducers of white corn often see the light yellow kernels that result from pollination by yellow corn pollen, and they report that low frequencies of such kernels often occur throughout a field.⁷²

As discussed in detail in the two separately submitted CFS Science Comments, the importance of wind speed during pollen shed is difficult to overemphasize. Purdue University agronomist R.L. Nielsen reports that "with only a 15 mph wind, pollen grains

⁷⁰ *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).

⁷¹ Peter Thomison, *Managing 'Pollen Drift' to Minimize Contamination of Non-GMO Corn*, AGF-153, Ohio State University Extension Fact Sheet, <http://ohioline.osu.edu/agf-fact/0153.html> (last accessed July 7, 2011).

⁷² Emerson Nafziger, *How are 'GMO-free soybeans and corn labeled?* University of Illinois-Urbana-Champaign Extension Service, http://faq.aces.uiuc.edu/?project_id=28&faq_id=590. (Last accessed 1/20/09).

can travel as far as ½ mile within those couple of minutes [of pollen viability].”⁷³ Discussing the difficulties of preventing contamination of organic corn by GE corn, Iowa State University plant physiologist Mark Westgate stated that: “Six hundred feet of isolation doesn't mean a thing if the wind is blowing your way at 20 miles an hour.”⁷⁴

When an agency determines that a potential environmental impact is not only possible, but nearly a foregone conclusion, NEPA requires that the environmental impact be analyzed.⁷⁵ Nonetheless, in the DEA, APHIS dismisses the risk of transgenic contamination from gene flow between 2,4-D resistant corn and non-GE corn varieties because the agency concluded that gene flow “between sexually compatible corn varieties and related species is no greater for [2,4-D resistant corn] than it is for other non-GE ... cultivars.” DEA at 93. However, the court in *Geertson* has already rejected this reasoning, holding that “[n]othing in NEPA, the relevant regulations, or the caselaw support such a cavalier response.”⁷⁶ Conversely, in stating that gene flow from 2,4-D resistant corn is just as likely as existing GE corn varieties, APHIS is actually conceding that gene flow is likely to occur.

In two recent court decisions, the United States District Court for the Northern District of California confirmed that 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.⁷⁷ 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, conventional varieties.⁷⁸ APHIS should properly assess the risks of gene flow from 2,4-D resistant corn to non-GE varieties of corn, and any and all environmental and intertwined socio-economic impacts of such contamination, by preparing an EIS.

Other Modes of Contamination

The DEA also recognized that contamination may occur through a variety of other pathways, including: seed spillage, seeds remaining in seed cleaning and other farm equipment, volunteer growth, cross-pollination not just by wind, but by insect or animal, post-harvest mixing in the grain-handling system, weather events, and simple human

⁷³ R.L. Nielsen, *Tassel Emergence & Pollen Shed*, Purdue University Extension Service (July 2010), available at <http://www.agry.purdue.edu/ext/corn/news/timeless/Tassels.html> (last accessed July 11, 2011).

⁷⁴ J. Perkins, *Genetically modified mystery*, Des Moines Register, Aug. 10, 2003.

⁷⁵ *Metcalfe v. Daley*, 214 F.3d 1135, 1141 (9th Cir. 2000) (NEPA “establishes ‘action-forcing’ procedures that require agencies to take a ‘hard look’ at environmental consequences.”) (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 348 (1989)).

⁷⁶ *Geertson*, 2007 WL 518624, at *10 (rejecting APHIS’s reasoning that the development of glyphosate-resistant weeds is not a significant impact because weed resistance to herbicides has occurred in other contexts).

⁷⁷ *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*”).

⁷⁸ *Geertson*, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007) *aff’d*, 541 F.3d 938 (9th Cir. 2008); *Sugar Beets I*, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009).

error. DEA at 22, 37, 91. APHIS acknowledged that “gene flow through handling and processing is especially problematic if product handling facilities where corn is dried, cleaned and stored do not maintain adequate separation between varieties Such admixtures . . . have been reported for varieties of GE corn and conventional corn.” DEA at 91. Nonetheless, APHIS failed to analyze contamination from such other pathways in the DEA.

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.⁷⁹ The level of contamination was typically far greater than the minimum levels that can be detected. “*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), while corn is highly out-crossing. Therefore, the contamination of soybean seed is likely to be largely from causes other than cross-pollination. Such causes could include seed mixing or human error, and the contamination suggests that these sources may be at least as important as cross-pollination, and must also be analyzed.

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 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.⁸⁰

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.⁸¹ Thus, transgenic contamination through human error and human behavior, such as composting, exchanging seeds, or mislabeling seeds, must be addressed in an EIS.

Past Contamination Episodes

Past contamination episodes from GE crops, specifically the past contamination incident with GE StarLink corn, further illustrate why contamination is an impact that must be adequately considered in an EIS here. Transgenic contamination is widespread

⁷⁹ M. Mellon and J. Rissler, Union of Concerned Scientists, *Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply* (2004).

⁸⁰ 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).

⁸¹ 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).

and has been documented around the world.⁸² A report from an environmental organization documented 39 cases in 2007 and more than 200 in the last decade.⁸³ Contamination incidents have not been limited to a single crop or region; corn, rice, canola and other crops have all been contaminated by transgenes

The StarLink corn contamination showed how much damage a GE-crop can do to the agricultural economy. StarLink is a variety of corn genetically engineered to produce the Cry9C insecticidal toxin to kill certain corn pests.⁸⁴ 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.⁸⁵ 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).⁸⁶ 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

⁸² 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.

⁸³ 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>.

⁸⁴ For the following discussion of StarLink, see Bill Freese, *Friends of the Earth, The StarLink Affair*, (July 2001), available at www.foe.org/safefood/starlink.pdf (last accessed July 11, 2011).

⁸⁵ 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).

⁸⁶ 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).

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.⁸⁷

The extent of the contamination is startling when one considers that StarLink never represented more than 0.43% of U.S. corn acreage. While post-harvest mixing was responsible for much of the contamination, there is also abundant evidence that popcorn, sweet corn, white corn and seed corn stocks were also contaminated with StarLink.⁸⁸ 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 2001.⁸⁹ 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.⁹⁰

Recent contamination events in other crops illustrate how difficult it is to prevent contamination at detectable and economically important levels. Of particular interest is the recent contamination of rice by the unapproved GE LL601 "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 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.⁹¹ Despite an extensive investigation, USDA was unable to determine exactly how the contamination occurred.⁹²

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

⁸⁷ 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.

⁸⁸ 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.

⁸⁹ Bill Freese, Friends of the Earth, *The StarLink Affair*, (July 2001), available at www.foe.org/safefood/starlink.pdf (last accessed July 11, 2011).

⁹⁰ *Tests to Detect Allergens in Altered Foods Fall Short*, ST. LOUIS POST-DISPATCH, June 12, 2002.

⁹¹ G. Vogel, *Tracing the transatlantic spread of GM rice*, 313 *Science* 1714 (2006).

⁹² USDA, *REPORT OF LIBERTY LINK RICE INCIDENTS 1* (2007), available at www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf.

Idaho.⁹³ Five years later, contamination is widespread and rampant, covering an estimated 27 square miles. The experimental GE grass, developed by Scotts Company and Monsanto, was field tested in Oregon in trials that had ended over five years earlier.⁹⁴ The field trials were successfully challenged in litigation against USDA for its failure to comply with the National Environmental Policy Act in assessing them.⁹⁵ During that litigation, EPA scientists found the GE grass had escaped the trial, cross-pollinated with wild varieties and was growing in a protected national grassland over twelve miles away.⁹⁶ USDA fined Scotts \$500,000⁹⁷ in 2007 and presumed the issue resolved, until the shocking discovery of new populations again growing in the wild over five years later.⁹⁸ The U.S. Fish and Wildlife Service (FWS), in the most recent draft of a Biological Opinion on the effects of Roundup Ready Bentgrass, prepared pursuant to the ESA, also noted 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.”⁹⁹ (In 2010, after APHIS engaged in consultation with the U.S. Fish and Wildlife Service (FWS) under the ESA’s Section 7 consultation mandate, FWS concluded that allowing Roundup Ready bentgrass’ commercialization would likely cause the extinction of two endangered plants in Oregon because the engineered bentgrass would spread the transgenic resistance to wild relatives, which would then take over the species’ critical habitat and be impossible to eradicate.¹⁰⁰).

Courts have found these and other contamination incidents sufficient evidence of the likelihood of contamination. The district court in *Sugar Beets I* stated: “The Court finds it significant that there have been instances in which genetically engineered corn, cotton, soybean and rice have mixed with and contaminated the conventional crops.”¹⁰¹ The “significance” of these events is further evidence that 2,4-D resistant can cause significant impacts through contamination, whether via gene flow or other pathways. These impacts must be analyzed in an EIS.

⁹³ Mitch Lies, *GMO bentgrass found in Eastern Oregon*, CAPITAL PRESS, Nov. 9, 2010, available at <http://www.capitalpress.com/oregon/ml-gmo-bentgrass-111210>.

⁹⁴ *Id.*

⁹⁵ *ICTA*, 473 F.Supp.2d at 28.

⁹⁶ *ICTA*, 473 F.Supp. at 21; Jay R. Reichman, et al., *Establishment of Transgenic Herbicide-Resistant Creeping Bentgrass (Agrostis solonifera L.) in Nonagronomic Habitats*, MOLECULAR ECOLOGY (2006).

⁹⁷ Christopher Doering, *Scotts to Pay \$500,000 Fine over Biotech Bentgrass*, REUTERS, Nov. 26, 2007, available at <http://www.reuters.com/article/2007/11/27/us-scotts-usda-idUSN2643698720071127>.

⁹⁸ Mitch Lies, *Coba Presses Scotts for Bentgrass Plan*, CAPITAL PRESS, Feb. 10, 2011, available at <http://www.capitalpress.com/oregon/ml-coba-letter-021111>.

⁹⁹ FWS, *Draft Biological Opinion, Roundup Ready Bentgrass* (2010) (included in references submitted with comments).

¹⁰⁰ *Id.*

¹⁰¹ See, e.g., *Sugar Beets I*, 2010 WL 964017, at *2.

b. Interrelated Economic Impacts of Transgenic Contamination Not Considered

APHIS's conclusion that the deregulation will not have significant interrelated economic impacts also is fundamentally flawed. DEA at 109, 112. Economic effects are relevant under NEPA, and must be examined "when they are interrelated with natural or physical environmental effects."¹⁰² Here, contamination of non-GE conventional and organic corn, and corn products that rely on non-GE corn, will in fact cause significant economic harm that must be addressed under NEPA. As the court explained in *Geertson*: "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 species' [sic] DNA through the transmission of the genetically engineered gene to organic and conventional alfalfa."¹⁰³ The court continued, "APHIS was required to consider those effects in assessing whether the impact of its proposed action is 'significant.'"¹⁰⁴

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 corn. APHIS admits in the DEA that "net returns from organic acres continue to be greater than net return from conventional acres," DEA at 24, with organic corn production receiving a 16% price premium in 2008. DEA at 24. Yet, APHIS entirely ignores socioeconomic impacts to organic farmers if transgenic contamination occurs, summarily concluding that 2,4-D resistant corn "is not expected to have significant impact on organic corn production." DEA at 63. APHIS based this conclusion on the assumption that organic farmers will "be using practices on their farm to protect their crop from unwanted substances and thus maintain their price premium." DEA at 62. As has become APHIS's practice, it 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 22. This argument—that the National Organic Standards is merely a process-based standard—completely misses the mark. DEA at 22 ("Organic certification is a process-based certification, not a certification of the end product.") 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

¹⁰² *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 944 (9th Cir. 2005) (quoting 40 C.F.R. § 1508.14).

¹⁰³ *Geertson*, 2007 WL 518624 at *8.

¹⁰⁴ *Id.*

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 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.¹⁰⁵

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.”¹⁰⁶ Dismissing potential impacts based on the process argument ignores that, when consumers become aware of the likelihood of contamination, consumers may reject organic foods as not truly “organic.”

The *Geertson* Court found that “[E]ven APHIS is uncertain whether farmers can still label their products organic under the federal government’s organic standards. Second, many farmers and consumers have higher standards than what the federal government currently permits; to these farmers and consumers organic means not genetically engineered, even if the farmer did not intend for his crop to be so engineered. . . . Third, and most importantly, APHIS’s comment simply ignores that these farmers do not want to grow . . . genetically engineered alfalfa, regardless of how such alfalfa can be marketed.”¹⁰⁷

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,¹⁰⁸ the speed and extent of cross-pollination among these GE canola plants surpassed even the most conservative predictions. Volunteer canola plants carrying GE traits were found in non-GE fields after only two seasons of commercial cultivation.¹⁰⁹ 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.¹¹⁰ Today, canola crops and oil from

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

¹⁰⁶ *Id.* at 13534-35 (Mar. 13, 2000).

¹⁰⁷ *Geertson*, 2007 WL 518624 at *7.

¹⁰⁸ JOSH BRANDON AND LOUISE SALES, GREENPEACE GE CANOLA OUT OF CONTROL IN CANADA 3 (2007), available at <http://www.greenpeace.org/australia/resources/reports/GE/gecanola-out-of-control-in.pdf>.

¹⁰⁹ M. Marvier and R. Van Acker, *supra* note 175.

¹¹⁰ Stuart Smyth, et al., *Liabilities and Economics of Transgenic Crops*, 20 NATURE BIOTECH. 6 (June 2002).

western Canada cannot be marketed as organic or non-GE because of the risk of contamination.¹¹¹

Impacts on Export and GE-Sensitive Domestic Markets

Conventional, GE-sensitive markets are also at significant risk and APHIS is similarly required to consider the economic effects of deregulating 2,4-D resistant corn, yet has failed to adequately do so in the DEA. According to APHIS, the U.S. exports about 15 to 20% of its current corn production; the majority of which are exported to Egypt, the European Union, Japan, Mexico, South Korea, and Southeast Asia. DEA at 11. None of these countries have currently approved 2,4-D resistant corn for importation. One significant contamination event similar to LL601 LibertyLink Rice, or Starlink Corn, could impact the corn exports to these countries and economically devastate American farmers and producers of corn products.

The DEA is silent on how the deregulation of 2,4-D resistant corn may affect U.S. export markets for corn, despite the fact that APHIS recognized that the majority of the export markets have not approved the importation of 2,4-D resistant corn. DEA at 112. Instead, APHIS assumes that “producers who sell their products to markets sensitive to GE traits ... [are] using practices ... to protect their crop from unwanted substances and thus maintain their price premium.” DEA at 63. Market rejection of corn contaminated by 2,4-D resistant corn, 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.¹¹² 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.¹¹³ 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.¹¹⁴ As a result, rice farmers in the South

¹¹¹ 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).

¹¹² R. Weiss, *Gene-altered profit-killer*, *Washington Post*, Sept. 21, 2006.

¹¹³ R. Weiss, *Firm Blames Farmers, ‘Act of God’ for Rice Contamination*, *Washington Post*, Nov. 22, 2006.

¹¹⁴ USDA APHIS. *Statement by Dr. Ron DeHaven regarding APHIS hold on Clearfield CL131 long-grain rice seed*, Mar. 5, 2007.

experienced a severe shortage of seed rice for the 2007 season.¹¹⁵ APHIS conducted an investigation into the contamination episodes, but was unable to determine precisely how they occurred.¹¹⁶ Courts have subsequently found Bayer negligent in every bellwether case, with total damages estimated at a billion dollars.¹¹⁷ The litigation was eventually settled in part for \$750 million dollars.¹¹⁸

The genetic engineering of papaya in Hawaii (no other country in the world grows it) has also resulted in widespread contamination¹¹⁹ and huge losses in export income to papaya growers there, and reduced prices, due to rejection of the GE papaya overseas.¹²⁰ U.S. corn exporters lose about \$300 million per year in exports due to European Union rejection of engineered corn.¹²¹ 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.¹²² 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%.¹²³ Finally, 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.¹²⁴

http://www.aphis.usda.gov/newsroom/content/2007/03/ge_riceseed_statement.shtml (last accessed July 7, 2011).

¹¹⁵ D. Bennett, *Arkansas' emergency session on CL 131 rice*, Delta Farm Press, March 1, 2007.

¹¹⁶ USDA, *Report of LibertyLink Rice Incidents*, Oct. 2007, available at <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf> (last accessed July 11, 2011).

¹¹⁷ 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).

¹¹⁸ Andrew Harris and David Beasley, *Bayer Agrees to Pay \$750 Million to End Lawsuits Over Genetically 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>.

¹¹⁹ 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).

¹²⁰ GREENPEACE INT'L, THE FAILURE OF GE PAPAYA IN HAWAII (May 2006), available at <http://www.greenpeace.org/international/press/reports/FailureGEPapayainHawaii>

¹²¹ Pew Initiative on Food and Biotechnology, *US v. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food* (2005) at 3-4.

¹²² *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).

¹²³ *Id.*

¹²⁴ See APHIS, *Roundup Ready Alfalfa FEIS*, at 58-59, 169-170, App. R at R-3, R-14 to R-15 (2010), available at http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf.

Burden on Organic and Specialty Corn Productions

Organic and specialty corn growers bear completely the onerous burden of reducing the risk of contamination under the Preferred Alternative. DEA at 23 (“Organic farming plans should include how the risk of GE pollen or co-mingling of seed will be monitored.”); DEA at 64 (stating that specialty corn growers can avoid contamination with existing management practices such as buffer zones and isolation distances). APHIS concludes that organic farmers wishing to avoid transgenic contamination should isolate their farms, create physical barriers and buffer zones, and communicate with neighbors to delay or stagger planting. DEA at 23. 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, leaving organic farmers alone in the fight against contamination. For example, the practice of “delayed plantings” often forces organic corn farmers to miss the optimum time for planting, reducing crop yield. DEA at 23. Moreover, as APHIS recognized in the DEA, farmers are increasingly planting corn in consecutive seasons, making it more challenging for organic farmers to stagger planting to “avoid pollen contamination from GE fields which have been planted earlier.” DEA at 24; DEA at 13 (noting “increased adoption of corn-to-corn rotation” in conventional and GE corn production). 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 corn on both organic and conventional non-GE corn in an EIS prior to adopting a deregulation decision.

Harm to Organic Industry Overall

APHIS also entirely failed to assess the socioeconomic impacts of transgenic contamination on the entire organic industry, especially in light of the importance of corn as animal feed. The National Organic Program excludes the use of GE materials in food production.¹²⁵ Organic products require 100% organic feed; there is no *de minimus* exception.¹²⁶ The DEA acknowledged that “corn comprises approximately 95% of the total feed grain production and use,” yet is silent on any potential impacts on the organic industry should organic corn feed be contaminated by 2,4-D resistant corn. DEA at 42. Under these standards, contamination of organic feed corn with the transgene will render the corn ineligible for organic certification and will eliminate that it as a permissible feed for organic livestock.

APHIS is well-aware that contamination of organic feed threatens entire organic industries that rely on such feeds; the agency received many comments from organic

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

¹²⁶ *Id.* § 205.237(a).

dairy producers, cattle ranchers, organic product manufacturers and organic grocers opposing the unconditional deregulation of its draft EIS on Roundup Ready alfalfa, another important feed.¹²⁷ APHIS's omission of the impact on the organic industry from potential contamination of organic corn feed is arbitrary and capricious. An EIS is required.

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 organic corn is growing as much as 20 percent each year.¹²⁸ The same article concluded that there is a significant shortage of organic corn feed. As previously noted, APHIS recognized that more and more farmers are planting corn in consecutive seasons without crop rotation, making it increasingly difficult for organic farmers to plant corn for fear of contamination from nearby GE corn fields. *See supra*; *see* DEA at 13. Yet, the DEA boldly assumed that organic farmers can rely on measures such as isolation distances and buffer zones to reduce the chance of contamination. DEA at 22-23. Yet if APHIS deregulates the crop without restrictions and post-market limitations, there will be no federally enforced mandatory measures to protect farmers. Current corn contamination (as well as contamination in other crops) shows that industry voluntary measures are wholly inadequate. In any event the EIS threshold is a low one: if the addition of 2,4-D resistant corn might increase contamination, the agency must prepare an EIS. The deregulation of 2,4-D resistant corn presents yet another GE corn, putting more pressure on organic corn production, reducing the availability of organic corn feed. The DEA has failed to analyze the potential impacts of deregulating 2,4-D resistant corn on the supply of organic corn feed.

Cost of GE Testing and 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 48-49 (rejecting imposition of "testing, criteria, or limits of GE material in non-GE systems" as "inconsistent with the plant pest provision of the PPA"). APHIS's outright dismissal of GE testing and the agency's failure to account for such costs in its discussion of the socioeconomic impacts of deregulating 2,4-D resistant corn is nonsensical. As the U.S. Supreme Court found in *Monsanto*, the burden of testing one's crops is a cognizable injury.¹²⁹

¹²⁷ APHIS, *Roundup Ready Alfalfa FEIS*, App. F (2010), available at http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf.

¹²⁸ Dininny, S., "Organic Dairies Test Supply of Feed," Associated Press, Dec. 20, 2007.

¹²⁹ *Monsanto v. Geertson Seed Farms*, 130 S. Ct. 2743, 2755 (2010).

Impacts on the Public's and Farmers' Fundamental Right to Choose, as well as the Environmental Component of Transgenic Contamination

Beyond the often severe economic harm to farmers and the loss of choice for farmers and consumers, transgenic contamination is first and foremost an environmental harm.¹³⁰ The economic effects are an interrelated, direct result of the initial impact on the environment: “the alteration of a plant specie’s [*sic*] DNA through the transmission of the genetically engineered gene to [non-engineered plants].”¹³¹ Thus, as the Supreme Court held, the “injury has an environmental as well as an economic component.”¹³² The loss of biodiversity due to contamination, and the potential elimination or reduction of conventional and organic varieties of corn is environmental injury.¹³³

Further, harm to organic production systems is also harm to the environment, because organic is an environmentally sustainable production system, in sharp contrast with transgenic crop systems. Consumers choose organic products in large part because organic agriculture is an ecologically beneficial agricultural model.¹³⁴ Organic agriculture results in healthier, more productive soils; elimination of synthetic pesticide and fertilizer use and associated adverse impacts; and increased biodiversity through a holistic production management system. Indeed, the very definition of organic production is a system that integrates “cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.”¹³⁵ These ecological benefits lie at the core of the organic industry and drive consumer choices.

APHIS also violated NEPA when it did not consider the impact that deregulating 2,4-D resistant corn will have on the public’s right to choose non-GE corn. NEPA and its implementing regulations provide that where a social or economic effect is tied to a

¹³⁰ *Geertson Seed Farms*, 2007 WL 518624, at *9 (“An action which potentially eliminates or least greatly reduces the availability of a particular plant—here, non-engineered alfalfa—has a significant effect on the human environment.”).

¹³¹ *Id.* at *8 (“Here, the economic effects on the organic and conventional farmers of the government’s deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment; namely, the alteration of a plant specie’s DNA through the transmission of the genetically engineered gene to organic and conventional alfalfa.”); *id.* at 11 (“As the Court explained, *supra*, however, economic interests that are interrelated with natural or physical environmental effects fall within NEPA’s zone of interests. The alfalfa farmer plaintiffs’ potential economic injury arises directly from the environmental impact of APHIS’s decision to deregulate Roundup Ready alfalfa.”).

¹³² *Monsanto*, 130 S.Ct. at 2756 (“Respondents now seek injunctive relief in order to avert the risk of gene flow to their crops—the very same effect that the District Court determined to be a significant environmental concern for purposes of NEPA. The mere fact that respondents also seek to avoid certain economic harms that are tied to the risk of gene flow does not strip them of prudential standing.”).

¹³³ *Geertson Seed Farms*, 2007 WL 518624, at *9 (“An action which potentially eliminates or least greatly reduces the availability of a particular plant—here, non-engineered alfalfa—has a significant effect on the human environment.”).

¹³⁴ See, e.g., Organic Trade Association, *Consumer Profile Facts*, <http://www.ota.com/organic/mt/consumer.html>.

¹³⁵ 7 C.F.R. § 205.2 (2011).

physical impact, those effects must be discussed.¹³⁶ NEPA aims to “maintain, wherever possible, an environment which supports diversity and a variety of individual choice.”¹³⁷ 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].”¹³⁸ 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.”¹³⁹ “An action which potentially eliminates or at least greatly reduces the availability of a particular plant...has a significant effect on the environment.”¹⁴⁰

The DEA noted that there are organic and export markets that are “sensitive to GE traits,” yet skips over any discussion of the impacts of deregulating 2,4-D resistant corn by stating that that farmers selling to such markets are “assumed to be using practices on their farm to protect their crop from unwanted substances and thus maintain their price premium.” DEA at 62. This is not the hard look that NEPA requires. As discussed above, for the public organic means GE-free, not “with a little GE” or “de minimis GE contamination.” If organic foods are continuously contaminated by an onslaught of GE crops, they will lose their integrity, and the public will lose a vessel that currently provides them a choice. This impact was conspicuously absent from the EA. APHIS must analyze the public’s right to choose in an EIS.

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.¹⁴¹ 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.

Research and development is not the only area that suffers from seed market concentration. The privatization and concentration of the world’s seed supply is a serious and continuously evolving problem, compounded with each new GE crop deregulation. “It is estimated that the top ten seed corporations around the globe hold 49-51% of the commercial seed market, and the top ten agro-chemicals control 84% of the agrochemicals market. Likewise, all genetically modified (GM) seeds are bio-patented by multinational corporations and 13 commercial corporations own 80% of the GM food

¹³⁶ 40 C.F.R. § 1508.14.

¹³⁷ *Id.*

¹³⁸ *Geertson*, 2007 WL 518624 at *8

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Sugar Beets I*, Huber Decl., ¶¶ 17-18 (April 13, 2010); Emily Waltz, *Under Wraps*, 27 *Nature Biotechnology* 880, 882 (2009).

market.”¹⁴² As the practical options become limited to varieties patented by Monsanto and the major seed companies, 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 corn, and the cost of groceries.

The increased seed market concentration has already made it hard for farmers to purchase conventional corn and soy seeds.¹⁴³ With increased seed market concentration, the once diverse selection of conventional seed is disappearing. As a result, farmers are forced to purchase GE seed and with that pay hefty 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 108; DEA at 108 (“Growers adopting [2,4-D resistant corn would be expected to pay a technology fee to access this variety.”). Nonetheless, APHIS summarily disregards the economic impact of the higher cost of 2,4-D resistant corn to farmers because “APHIS has no control over the establishment of these technology fees.” DEA at 108.

The Department of Justice has noticed the effects. In August of 2009, it announced that it would investigate anticompetitive conduct in the seed industry, the recent ability to patent seed having led to unprecedented seed industry concentration.¹⁴⁴ 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. It has been estimated that Monsanto can exercise influence in pricing and vending practices for over 90 percent of the germplasm of corn and soybeans, even though their market share is in the 30 to 40 percent range for these two major crops. The commercialization of 2,4-D resistant corn will influence Dow AgroScience’s control over seed process and market consolidation. The general public is adversely affected, 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.¹⁴⁵

For these and other reasons, the DEA does not adequately address the cumulative impact of seed market concentration. The seed market concentration impacts of a deregulation of 2,4-D resistant corn constitute a significant intertwined socioeconomic

¹⁴² Yamuna Ghale and Bishnu Raj Upreti, Concentration and Monopolisation of Seed Market: Impact on Food Security and Farmer’s Rights in Mountains, *available at* http://docs.google.com/viewer?a=v&q=cache%3A3CPrhC0TuVIJ%3Awww.mtnforum.org%2Frs%2Fol%2Fcounter_docdown.cfm%3Ffid%3D2056.pdf+seed+market+concentration&hl=en&gl=us&sig=AHIEtbTwpX0MzR5HZZ8CUBA8qoWofinQvw&pli=1.

¹⁴³ CFS, *Monsanto v. US Farmers*, Jan. 13, 2005, *available at* <http://truefoodnow.files.wordpress.com/2009/12/cfsmontantovsfarmerreport1-13-05.pdf>.

¹⁴⁴ *Sugar Beets I*, Harl Decl. ¶ 5

¹⁴⁵ *Rapid Rise in Seed Prices Draws U.S. Scrutiny*, N.Y. Times B1 (March 12, 1010).

impact that is reasonably foreseeable. APHIS's failure to adequately address the issue of seed market concentration is arbitrary and capricious.

Moreover, APHIS completely ignores the potential socio-economic, cultural, and agricultural impacts faced by farmers in Mexico and other parts of the world where traditional maize varieties and wild relatives play a crucial role in the socio-economic stability of farmers. In particular, farmers in Mexico are already suffering the effects of genetic contamination from other GE crops, which harm beneficial insects, soil fertility, and impair the availability of natural pesticides. APHIS did not consider the possible impacts that yet another genetic trait can have on farmers in Mexico and around the world where native maize and wild corn relatives are not only grown, but an indispensable part of their culture and the economy.¹⁴⁶

In short, there is overwhelming evidence that the deregulation of 2,4-D resistant corn will result in the contamination of non-GE corn 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." 40 C.F.R. 1502.8. APHIS's failure to analyze and disclose the interrelated economic impacts of deregulating 2,4-D resistant corn violated NEPA and is arbitrary, capricious and an abuse of its discretion.

IV. The DEA's Analysis of Numerous Cumulative Impacts Is Inadequate to Comply with NEPA.

NEPA requires agencies to consider possible cumulative impacts of deregulation.¹⁴⁷ 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.¹⁴⁸

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."¹⁴⁹

¹⁴⁶ Greenpeace International, *Maize Under Threat: GE Maize Contamination in Mexico* (Aug. 2003) available at <http://www.greenpeace.org/raw/content/international/press/reports/maize-under-threat-ge-maize.pdf> (last accessed Aug. 11, 2011).

¹⁴⁷ 40 C.F.R. § 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).

¹⁴⁸ 40 C.F.R. §1508.7.

¹⁴⁹ *Kern v. Bureau of Land Mgmt.*, 284 F.3d 1062, 1075 (9th Cir. 2002).

a. Increased Herbicide Use

APHIS's conclusion that deregulating 2,4-D resistant corn will not increase overall herbicide use on corn is based on mistaken baseline, flawed assumptions, and directly defies numerous admission regarding herbicide use on herbicide-resistant GE crop systems elsewhere in the DEA. [For detailed comments, *see* CFS Science Comments (submitted separately by Bill Freese and Martha Crouch)].

First, APHIS uses an inaccurate baseline to compare the changes in herbicide use due to the adoption of 2,4-D resistant corn. APHIS wrongly assumes that 2,4-D resistant corn will simply displace existing herbicide-resistant GE corn acreage, despite the agency's recognition elsewhere in the DEA that corn acreage planted in the U.S. has been increasing due to favorable corn prices. DEA at 11. APHIS disregards the projected increase in corn acreage from its cumulative impacts analysis as irrelevant because it is driven by market demand rather than the availability of 2,4-D resistant corn. *See* DEA at 53-54. This is an arbitrary and capricious standard contrary to the regulatory 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 projected increases in corn acreage, due to other of APHIS's deregulations of GE crops, from the DEA. Secondly, as explained in detail in the two separately submitted CFS Science Comments, APHIS misstates the total percentage of existing corn acreage that is planted with an herbicide-resistant corn variety as 23%, when it is in fact 72%. *See* DEA at 53. This sort of fundamental baseline error renders the entire analysis arbitrary and capricious.

The analysis of the reasonably foreseeable increase in use of 2,4-D on 2,4-D resistant corn also is lacking. APHIS admits that with 2,4-D resistant corn, there will be an increase in the use of 2,4-D on corn. DEA at 58. 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 corn will be identical to the current maximum allowance of 2,4-D on conventional corn. DEA at 59 ("The proposed application rates for 2,4-D and total maximum annual application for use on [2,4-D resistant corn] are consistent with current rates."). Yet, as discussed in detailed in the two separately submitted CFS Science Comments, present average use of 2,4-D on conventional corn is just over 1/10 of the maximum permitted.

APHIS's oversight is particularly egregious in light of the DEA's open admission that as of 2005, 2,4-D was applied on less than 8% of the total corn acreage in the U.S. DEA at 20. According to estimates by one agricultural scientist, widespread planting of 2,4-D resistant corn could lead to as much as a 30-fold increase in 2,4-D use on corn by the end of the decade, given 2,4-D's current limited use on corn.¹⁵⁰ This would increase overall 2,4-D use in U.S. agriculture from the existing 27 million lbs per year to over 100

¹⁵⁰ *See* <http://www.centerforfoodsafety.org/projected-increase-in-24-d-use-with-introduction-of-24-d-resistant-corn-through-2019-benbrook2012/>.

million pounds per year.¹⁵¹ That the use of 2,4-D on corn 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.

APHIS's analysis of the predictable increase in use of "fop" herbicides on corn is similarly deficient. The DEA stated that Quizalofop and other "fop" herbicides are not currently registered for use in corn production because of damage to conventional corn crop. DEA at 20. The DEA also stated that deregulation of 2,4-D resistant corn "would result in an increase in the use of 2,4-D in corn, as well as the new use of Quizalofop." DEA at 58. Yet, as with its discussion of 2,4-D use on corn, APHIS concluded that there are no cumulative impacts on existing herbicide use because the agency expects that "the increase in use of these two herbicides would coincide with the concomitant reduction in the use of other herbicides." DEA at 58. APHIS's conclusion is arbitrary and capricious, particularly since the agency also admitted that "the future development and cultivation of a stacked corn variety ... may result in an increase in acres of corn being treated with glyphosate," DEA at 60, which the DEA identified as the most used herbicide applied to corn in 2002. DEA at 19.

APHIS's Conclusion That 2,4-D and "Fop" herbicides Will Simply Displace Existing Herbicide Applications on Corn Belies Data on Herbicide Usage Since the Adoption of Glyphosate-Resistant Crop System.

APHIS's assumptions that 2,4-D and "fop" herbicides will simply replace existing herbicide use on corn crops directly contradicts existing data on herbicide usage on GE, glyphosate-resistant crops, and APHIS's assertion that overall herbicide use on corn has declined due to the adoption of GE crops is patently false. As discussed in detail in the two CFS Science Comments, APHIS based its entire discussion of herbicide use from its assertion that currently, only 23% of the GE corn crop is herbicide-resistant. DEA at 3, 14, 27, 53, 65. Yet, as USDA's own public data plainly demonstrates, the figure is actually closer to 72%.¹⁵² APHIS's analysis of overall herbicide applied on herbicide-resistant corn in the DEA is fatally flawed due to this erroneous starting point.

To the contrary, GE crops have dramatically increased overall pesticide and herbicide use in the past thirteen years.¹⁵³ The DEA itself recognizes this fallacy, admitting that that "introduction of herbicide-tolerant corn varieties ... has not significantly affected corn acreage managed with total herbicide application." DEA at 15. APHIS attributed the massive increase in glyphosate use from 1992 to 2002 to the adoption of glyphosate-resistant crop systems, but recognized that during the same ten year period, use of 2,4-D remained the same. DEA at 19. APHIS also noted in the DEA

¹⁵¹ Based on EPA (2011), *Pesticide Industry Sales and Usage: 2006 and 2007 Market Estimates*, Table 3.6, which shows 25-29 million lbs. 2,4-D used agriculturally in 2007.

¹⁵² See CFS Science Comments submitted by Bill Freese; CFS Science Comments submitted by Martha Crouch; USDA, *Genetically Engineered Corn Varieties by State and United States, 2000-2011*, available at <http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm>.

¹⁵³ Charles Benbrook, the Organic Center, *Impacts of Genetically Engineered Crops on Pesticide Use: The First Thirteen Years* (Nov. 2009).

that “[w]hile the applications of atrazine and acetochlor in corn have been relatively stable, application rates for glyphosate have increased.” DEA at 15. Thus, glyphosate has not eliminated nor replaced the use of more toxic herbicides such as atrazine. DEA at 14. These errors are discussed in further detail in separately submitted CFS Science 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 corn is to enable growers to use 2,4-D and “fop” herbicides 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 and “fop” herbicides—as well as glyphosate, after development of stacked varieties—will follow the deregulation of 2,4-D resistant crop systems. *Compare* DEA at 18 (“[2,4-D-resistant corn] was developed to provide growers with alternative herbicides to use in corn, with a specific emphasis of managing weeds which have developed resistance to glyphosate.”) *with* DEA at 16-17 (“The practice of using herbicides with alternative modes of action could potentially ... reduce the likelihood of the development of new herbicide-resistant weed populations”). APHIS is aware of, and has identified in the DEA, the existence of weeds that are already resistant to 2,4-D and “fop” herbicides. *See* DEA at 16, tbls. 2-2 to 2-4 (listing weeds resistant to 2,4-D and “fop” herbicide). The past is prologue for this pesticide treadmill: APHIS’s failure to analyze the likelihood and impacts of reasonably foreseeable weed resistance to 2,4-D and “fop” herbicides is arbitrary and capricious.

APHIS’s assumption that growers are engaged in weed management practices to stall the inevitable 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 18-19; 32-33. APHIS’s assumption that growers will utilize proper weed management practices to avoid weed resistance to 2,4-D and “fop” herbicides” 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 “since the introduction of glyphosate-tolerant crops, ... many growers relied exclusively on glyphosate for weed control.”) DEA at 33. APHIS also recognized, but failed to analyze, the fact that farmers are increasingly planting consecutive rotations of corn, resulting in further increase in herbicide use. DEA at 13 (“consecutive plantings of corn frequently require at-planting or pre-plant herbicide treatments to control corn pests ...”). APHIS’s blind reliance on unproven weed management practices to mitigate the

threat of weed resistance does not comply with NEPA, runs contrary to the evidence and is arbitrary and capricious.¹⁵⁴

Moreover, the DEA is 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. The DEA's silence on this issue is arbitrary and capricious, because the development and potential deregulation of 2,4-D resistant soybean, another crop within the 2,4-D resistant crop system, is reasonably foreseeable.¹⁵⁵ The DEA recognized that, excluding the increasing practice of consecutive corn cultivation, a "corn-soy rotation" is the most common practice with corn production. DEA at 32. 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.¹⁵⁶ The DEA admitted that "[w]hen a crop like corn is cultivated year after year in the same fields, using the same cultivation practices, the likelihood is high that weed and pest species will increase" DEA at 32. 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 "fop" 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 "[m]any growers, faced with glyphosate-resistant weeds, have returned to tillage and other cultivation techniques to physically control these species when herbicides prove ineffective." DEA at 67. Yet, the DEA fail to include any 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 is also lacking any analysis of the impact of "stacking" 2,4-D resistant corn with additional herbicide or insecticide resistant traits. 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

¹⁵⁴ 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.").

¹⁵⁵ APHIS, USDA, Petitions for Nonregulated Status Granted or Pending by APHIS as of April 27, 2012, http://www.aphis.usda.gov/biotechnology/not_reg.html; see *More Herbicide-Resistant Crops in Pipeline*, AgProfessional, Mar. 25, 2010, http://www.agprofessional.com/agprofessional-magazine/more_herbicide-resistant_crops_in_pipeline_120033049.html.

¹⁵⁶ See CFS Science Comments (submitted separately).

undertakes such other actions.”¹⁵⁷ In its factsheet on 2,4-D resistant corn, released concurrently with the DEA, APHIS stated that the principle use of 2,4-D resistant corn is that it “may be deregulated with glyphosate and other herbicide-tolerance traits to generate commercial hybrid with multiple herbicide tolerances.”¹⁵⁸ APHIS readily admits that “[Petitioner Dow] has announced its intention to create stacked hybrids, using conventional breeding techniques to combine the traits of 2,4-D resistant corn with nonregulated glyphosate-tolerant varieties.” DEA at 85; *see* DEA at 4, 46-47, 52, 99. APHIS also recognized that Petitioner Dow also intends to stack 2,4-D resistant corn with glufosinate resistance in the near future. DEA at 52, 114. Finally, the DEA states that “[t]he range of potential stacked varieties is quite broad, and includes stacked hybrids incorporating glufosinate tolerance, insect resistance, or other traits.” DEA at 52; *see also* DEA at 61. Despite the plainly foreseeable future stacked varieties of 2,4-D resistant crops that would have additional resistance to glyphosate, glufosinate, and other toxic herbicides and pesticides, APHIS entirely excluded any potential impacts of the stacked 2,4-D resistant corn varieties from its cumulative impacts analysis. *See, e.g.*, DEA at 66 (“Except for the potential future changes in herbicide use associated with stacking and new product formulations ...”); *accord* 69 and 72 (same).

APHIS’s failure to consider the environmental impacts of stacking 2,4-D resistant corn with additional herbicide and/or insecticide resistant traits is arbitrary and capricious, especially since the DEA acknowledged the potential harms of stacking 2,4-D resistant corn with glyphosate resistance. Specifically, APHIS recognized that stacking 2,4-D and glyphosate resistance “may result in an increase in the acres of corn being treated with glyphosate.” DEA at 60. APHIS also admitted that “as stacked crops are developed expressing multiple herbicide tolerance traits, the options for volunteer control [will] become more limited.” DEA at 89-90. Yet, APHIS stated that it has satisfied its NEPA duties because the PPRA for 2,4-D resistant corn found that there are no plant pest risk associated with stacked corn varieties with multiple resistant traits. DEA at 113. APHIS once again has the NEPA process backward. As noted above, APHIS’s conclusion that the agency had no authority to regulate stacked GE corn varieties once APHIS determined that they are unlikely to create plant pest risks is plainly contrary to PPA’s broad statutory mandate. Further, it is arbitrary and capricious to ignore such risks to agriculture and the environment from future stacked varieties, harms that plainly fit within the PPA’s broad statutory definition of direct and indirect plant pest risks, not to mention noxious weed risks.

APHIS’s analysis of the issue in the PPRA is insufficient to comply with NEPA. The PPRA devoted but one paragraph to issue of stacked 2,4-D resistant corn hybrid varieties with resistance to multiple modes of herbicides. PPRA at 4-5.¹⁵⁹ APHIS’s

¹⁵⁷ 40 C.F.R. § 1508.7.

¹⁵⁸ APHIS, USDA, Questions and Answers: Request for Comments on Dow, Inc., Petition on DAS-40278-9 2,4-D Tolerant Corn (Dec. 2011), *available at* http://www.aphis.usda.gov/publications/biotechnology/2011/24D_tolerant_corn.pdf.

¹⁵⁹ The inclusion of this harm in the PPRA, however, belies APHIS’s inconsistent claim elsewhere that it lacks authority over this harm, and thus APHIS should have analyzed it fully in an EIS.

conclusion in the PPRA that stacked corn varieties combining 2,4-D resistant corn with glyphosate resistance bears no plant pest risks because “[w]ithin the U.S. there have not been any weeds that have shown resistance to either glyphosate or atrazine and either a synthetic auxin or a “fop” herbicide,” DEA at 4, plainly contradicts the agency’s acknowledgment elsewhere in the PPRA and the DEA that weed resistance to glyphosate exploded after the introduction of glyphosate-resistant crops. *See, e.g.*, DEA at 18. As explained in more detail in the separately submitted CFS Science Comments, the epidemic of glyphosate resistant weeds forecast the evolution of weeds resistance to multiple herbicides. Indeed, the PPRA acknowledged that weeds showing resistance to multiple modes of herbicide actions already exist. PPRA at 5.

Contrary to APHIS’s assumption, studies show that stacking of GE crops may create significant environmental impacts that have not before been analyzed anywhere, such as “super-herbicide tolerance.”¹⁶⁰ As Dr. David Mortensen has explained, mutated weeds with resistance to different herbicide actions, such as glyphosate and synthetic auxin and “fop” herbicides (specifically 2,4-D and Quizalofop) “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).¹⁶¹ This will result in more frequent applications of different toxic herbicides, perhaps over the entire growing season of the crop. The end result is a vicious circle of rising herbicide use to control resistant weeds, followed by increased weed resistance, which in turns drives still more chemical use. Since the DEA admitted that stacking 2,4-D resistant corn is reasonably foreseeable, the impacts of stacking is a cumulative impact that APHIS must address in an EIS.

d. Volunteer Corn

The DEA’s discussion of the harms posed by volunteer corn also is inconclusive. APHIS acknowledged that control of herbicide-resistant volunteered corn “is a potential concern.” DEA at 89. Volunteer corn reduces crop yields by competing with the intended crop “for light, soil moisture, and nutrients.” DEA at 34. The DEA acknowledged that volunteer corn is already an increasing problem in subsequent crop productions on the same fields. DEA at 34 (a 2005 survey of soybean cultivation in Illinois identified a soybean field with up to 500,000 volunteer corn plants per acre). APHIS also admitted that “[a]s stacked crops are developed expressing multiple herbicide tolerance traits, the options for volunteer control become more limited.” DEA at 89. APHIS’s analysis of the volunteer corn problem stops there. APHIS summarily dismisses the problem of volunteer corn, stating that it can be controlled by applying different modes of herbicides, or relying on “non-chemical methods of weed control.” DEA at 90.

¹⁶⁰ *Mortensen et al.*, Navigating a Critical Juncture for Sustainable Weed Management, 62(1) *BioScience* 75-84 (2012).

¹⁶¹ *Id.*

APHIS's lack of analysis here violates NEPA. NEPA requires that mitigation measures must be described "in detail,"¹⁶² and an analysis explaining the effectiveness of the measures is "essential."¹⁶³ Further, the effectiveness of mitigation measures must be supported by studies and analytical data in the record.¹⁶⁴ Here, APHIS failed to provide any estimates or analysis of the cost to farmers to controlling volunteer corn, despite the agency's admission that the use of different herbicides to eliminate 2,4-D resistant volunteer corn is only effective "assuming that there has been no ... stacking or cross-pollination with other corn lines that have resistant traits to those herbicides." PPRA at 10. APHIS's assessment is insufficient under NEPA.

e. Conservation Tillage

Throughout the DEA, APHIS repeatedly touts the promotion of conservation tillage associated with the deregulation of 2,4-D resistant corn as an environmental benefit relative to conventional corn production. *See, e.g.*, DEA at 16, 27-29, 67. However, the DEA itself shows that APHIS's assumption that 2,4-D resistant corn will promote conservation tillage is inconsistent and erroneous. The DEA assumes in certain places that 2,4-D resistant corn will promote the continuation of conservation tillage practices, but in other places asserts that 2,4-D resistant corn would have no impact on cultivation practices of corn, including tillage. . *Compare* DEA at 53 ("A determination of nonregulated status of DAS-40278-9 corn is not expected to result in changes in the current corn cropping practices...") *with* DEA at 70 ("The cultivation of a corn variety stacking multiple modes of action, in this case, tolerance to 2,4-D and Quizalofop, along with glyphosate tolerance, provides growers with an opportunity to stay with their conservation tillage strategies."). Moreover, as explained above, APHIS also admitted the 2,4-D resistant corn would lead to the development of herbicide-resistant corn and persistent volunteer corn that would require tillage for control. DEA at 89-90; *see supra*.

As explained in detail in the CFS Science Comments, USDA itself has called into question whether herbicide-resistant crop systems such as 2,4-D resistant corn is the direct cause of increased conservation tillage practices.¹⁶⁵ Based on a study of glyphosate-resistant soybeans and different tillage practices, USDA concluded that "[f]armers using no-till were found to have a higher probability of adopting herbicide-

¹⁶² *Ore. Natural Res. Council v. Marsh*, 832 F.2d 1489, 1493-94, 1493 (9th Cir. 1987) (emphases added), *rev'd on other grounds*, *Marsh v. Ore. Natural Res. Council*, 490 U.S. 360 (1989).

¹⁶³ *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.").

¹⁶⁴ *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).

¹⁶⁵ Fernandez-Cornejo, J. and W.D. McBride (2002). "Adoption of Bioengineered Crops," U.S. Dept. of Agriculture, Economic Research Service, Agricultural Economic Report No. 810, May 2002. Available at <http://www.ers.usda.gov/publications/aer810/aer810.pdf>.

tolerant seed, but using herbicide-tolerant seed did not significantly affect no-till adoption. The result seems to suggest that farmers already 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.”¹⁶⁶

Because the development of herbicide-resistant weeds and volunteer corn are reasonably foreseeable impacts of 2,4-D resistant corn cultivation, APHIS’s failure to consider the negative impacts on conservation tillage is arbitrary and capricious.

f. Harm from 2,4-D and “Fop” Herbicides

The DEA entirely fails to independently analyze the potential harm to plants, wildlife, and humans from 2,4-D and “fop” herbicides. 2,4-D resistant corn is specifically designed to be used with such herbicides. The DEA acknowledged that 2,4-D resistant corn “was developed to provide growers with alternative herbicides to use in corn.” DEA at 18. Just as the DEA refers to the glyphosate-resistant “crop system”, DEA at 107, 2,4-D resistant corn 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 corn will come hand in hand, especially since 2,4-D is only used on less than 8% of current conventional corn acreage and the use of “fop” herbicides on corn has not yet been approved. DEA at 20. Therefore, the impacts from their use on 2,4-D resistant corn are “reasonably foreseeable” risks that must be analyzed by the agency. Instead, the DEA improperly sidesteps the discussion by relying on EPA’s authority to regulate herbicide use under FIFRA. 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.¹⁶⁷

APHIS’s reliance on EPA’s FIFRA registration of 2,4-D and Quizalofop is unlawful. As the DEA recognized, 2,4-D resistant corn will provide growers with “new uses” of 2,4-D and Quizalofop. Dow has applied for label amendment for 2,4-D formulations being used on 2,4-D resistant corn, as well as registering Quizalofop for use on corn. DEA at 40-41; 52. EPA’s prior reregistration of 2,4-D was seven years ago, in 2005, before the petition for deregulation of 2,4-D resistant corn was submitted to APHIS. Thus, EPA’s FIFRA analysis never accounted for the potential adoption of 2,4-D resistant corn and the increased use of 2,4-D on corn. Quizalofop’s prior registration is similarly outdated. In fact, EPA is currently in the process of reregistration of

¹⁶⁶ *Id.* at 59.

¹⁶⁷ *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.”).

Quizalofop, a process the agency anticipate will not be completed until 2013.¹⁶⁸ 2,4-D is also up for registration review in 2014. Relying on EPA's outdated analyses of 2,4-D and Quizalofop 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.¹⁶⁹ At a minimum, APHIS should wait for EPA to complete its process of registering Quizalofop and 2,4-D for the new uses on 2,4-D resistant corn so that the agency may independently assess and incorporate EPA's analyses into its NEPA process and PPA risk assessment.

Herbicide Drift

As explained in detail in CFS Science Comments, the DEA failed to adequately analyze reasonably foreseeable harm from drift of 2,4-D and "fop" herbicides to non-target crops in nearby 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.¹⁷⁰ Drift from 2,4-D will injure most broadleaf plants, such as grapes, tomatoes, cottons, soybeans, sunflower and lettuce, at extremely low levels.¹⁷¹ 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 pesticides.¹⁷² Tellingly, APHIS admitted that "[s]pray drift is a concern for non-target susceptible plants growing proximate to fields when herbicides are used in the production of [2,4-D resistant corn]." DEA at 81.

The DEA also acknowledged that the cultivation of 2,4-D resistant corn "does not require use of drop nozzles for post-emergent application" currently required for 2,4-D applications to post-emergent stages of corn. APHIS recognized that "the current use of drop nozzles has the additional benefit of limiting drift and volatilization of the compound," yet fails to consider how this may be injurious to plants on neighboring fields. This is arbitrary and capricious.

APHIS tries to dismiss the significant harms and crop injury stemming from drift of 2,4-D applications by relying, once again, on the EPA's regulatory oversight under

¹⁶⁸ EPA, Quizalofop Final Work Plan: Registration Review (June 2008), *available at* http://www.epa.gov/oppsrrd1/registration_review/quizalofop/index.htm.

¹⁶⁹ 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).

¹⁷⁰ See CFS Science Comments Submitted by Bill Freese; CFS Science Comments submitted by Martha Crouch; 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.

¹⁷¹ ¹⁷¹ 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>.

¹⁷² AAPCO (1999 & 2005). "1999/2005 Pesticide Drift Enforcement Survey," Association of American Pesticide Control Officials, *available at* <http://aapco.ceris.purdue.edu/htm/survey.htm>. Survey periods 1996-1998 and 2002-2004, respectively.

FIFRA. However, as discussed before, EPA’s FIFRA registration does not obviate APHIS’s independent statutory duties to consider the reasonably foreseeable impacts of herbicide drift under NEPA, and to assess the potential of 2,4-D use on 2,4-D resistant corn to “damage ... any plants” under the PPA.¹⁷³ 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. “Some information suggesting ... lower volatility and decreased drift” of the new 2,4-D formulation is insufficient to satisfy the rigorous analysis that NEPA demands. DEA at 72.

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. On April 18, 2012, a coalition of conventional farmers (Save Our Crops Coalition), filed a citizens’ petition with the APHIS, demanding that APHIS shelve the current DEA and postpone any decision on Dow’s petition for deregulation of 2,4-D resistant corn until APHIS has prepared an EIS that specifically addresses the significant impact of 2,4-D drift, not just from 2,4-D resistant corn, but also including use of 2,4-D in other reasonably foreseeable 2,4-D resistant GE crop systems, that are now pending before the agency.¹⁷⁴ As this comment and the CFS Science Comments make plain, the DEA did not adequately assess the use of 2,4-D and the inevitable drift of this highly volatile herbicide in the 2,4-D resistant crop system. CFS concurs with and endorses the Save Our Crops Coalition petition. The pending releases of other 2,4-D resistant crops (such as 2,4-D resistant soy 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 corn.

Yet APHIS must go further than the petition: in preparing the requested EIS, APHIS must also consider other cumulative impacts discussed in this comment and the CFS Science Comments, including but not limited to: harm from transgenic contamination and its interrelated economic impacts; impact on the overall environment from increased herbicide use, specifically the combined use of 2,4-D, “fop” herbicides, glyphosate and/or glufosinate in stacked 2,4-D resistant varieties; herbicide-resistant weeds; impacts of the 2,4-D resistant crop system on conservation tillage and global warming; and harm to endangered species and their critical habitat from both the genetically engineered 2,4-D resistant corn plant itself and the use of its intended herbicides.

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 Quizalofop herbicides to conclude that 2,4-D and Quizalofop use on 2,4-D

¹⁷³ 7 U.S.C. § 7702(10) (emphasis added); 7 U.S.C. § 7712(a).

¹⁷⁴ Save Our Crops Coalition (SOCC), Citizen’s Petition to Direct Preparation of an Environmental Impact Statement to Consider the Cumulative Effects of Synthetic Auxin Herbicide Tolerant Crops (Apr. 18, 2012), available at <http://saveourcrops.org/wp-content/uploads/2012/04/FINAL-Petition-to-APHIS-041812-Electronic.pdf>.

resistant corn would not endanger the health and safety of farm workers. *See* DEA at 100. However, EPA's FIFRA registration does not obviate APHIS's own independent NEPA duties.¹⁷⁵

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 corn would allow more frequent, over-the-top applications of 2,4-D, increasing workers' exposure to the toxic herbicide. DEA at 6. The DEA also mentions, but did not assess that drop nozzles, which are required for existing post-emergent application of 2,4-D and not required for applications on 2,4-D resistant corn, has the "additional benefit of ... limiting worker exposure to the product." DEA at 100. APHIS also failed to consider how the introduction of Quizalofop, an herbicide that is not currently used in corn production, would increase workers' overall exposure to toxic chemicals. DEA at 101 (acknowledging "fop" herbicides are not currently registered for use in corn fields).

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 corn. As discussed in detail in the separately submitted CFS Science 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.¹⁷⁶ 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.¹⁷⁷

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."¹⁷⁸ 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.

¹⁷⁵ *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).

¹⁷⁶ Tanner, C.M., *et al.*, *Occupation and Risk of Parkinsonism*, 66 Archives of Nuerology 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).

¹⁷⁷ EPA, *Reregistration Eligibility Decision (RED) for 2,4-D* (June 2005).

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

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.

APHIS's assertion that 2,4-D resistant corn will reduce global warming impacts is also predicated upon the DEA's erroneous conclusion that 2,4-D resistant crop will increase the use of conservation tillage. *See* DEA at 73. As discussed in the CFS Science Comments and in the section on Conservation Tillage in this comment, *supra*, it 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. As discussed in CFS Science Comments, submitted separately by Dr. Martha Crouch, 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.¹⁷⁹ 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.

APHIS minimizes the fact that the increased use of 2,4-D and the entirely new use of Quizalofop in corn production, made possible only by deregulation of 2,4-D resistant corn, promotes global warming. APHIS inaccurately assumes that the 2,4-D resistant corn crop system would not result in "any changes in corn production practices or an expansion of corn acreage." DEA at 74. Yet, the DEA recognized that 2,4-D resistant corn would allow 2,4-D, which was only applied to less than 8% of total corn acreage in the U.S. in 2005, and Quizalofop (and other herbicides in its class), which is not currently registered for use on corn, to be applied to the genetically engineered corn. DEA at 20. APHIS also readily acknowledged that, 2,4-D resistant corn will be stacked with a glyphosate-resistant variety, thus increasing the variety and use of herbicides that will be applied on corn. DEA at 1. APHIS' continued reliance on erroneous information undermines and negates its analysis and conclusions regarding climate change impacts. If the agency begins with this erroneous presumption, as it has several times in the DEA, the arguments that stem from this presumption are also flawed.

Additionally, APHIS assumes that farmers and producers will adhere to label restrictions for herbicide use. DEA at 103, 106, 121, 127. 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 Quizalofop class herbicides on the 2,4-D-Resistant crop system. Nor can the agency pass the buck on its NEPA duties to another agency, or

¹⁷⁹ *See* CFS Science Comments submitted by Martha Crouch.

industry guidance. APHIS must properly analyze the climate change impacts of its action in an EIS.

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

Failure to Consult

APHIS failed to consult with the FWS as required under Section 7 of the Endangered Species Act (ESA) on the potential effects on threatened and endangered species and their critical habitats. To the limited extent APHIS conferred with the U.S. Fish and Wildlife Service (FWS), APHIS did not follow mandatory procedures of the Endangered Species Act (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.¹⁸⁰ APHIS must prove its deregulation will neither jeopardize any species, nor harm any critical habitat, anywhere the crop system may be grown.¹⁸¹

The initial request for information from FWS and/or NMFS is a prerequisite for further agency action and cannot be ignored.¹⁸² There is no evidence in the DEA that APHIS took the first steps of consultation with FWS and/or NMFS to determine whether the deregulation of 2,4-D resistant corn may harm listed species or habitat. Instead, APHIS relied almost exclusively on the petitioner’s analysis and the agency’s independent review to reach its conclusion that the deregulation of 2,4-D resistant corn will have “no effect” on listed species or their critical habitats. DEA at 118. APHIS violated Section 7(a)(2) of the ESA by failing to consult with FWS or NMFS—informally or formally—about the effects of 2,4-D resistant corn deregulation on listed species and critical habitat.

APHIS’s claim in the DEA that because the agency independently reached a “no effect” determination, the agency need not formally or informally consult with FWS and/or NMFS, is legal error. In fact, APHIS has previously been found to have violated the ESA when it skipped this initial, mandatory step of obtaining information about listed species and critical habitats from FWS and/or NMFS.¹⁸³ There, the court emphasized that regardless of whether there is any evidence that species or habitat may be harmed in any way, “an agency violates the ESA when it fails to follow the procedures mandated by Congress, and an agency will not escape scrutiny based on the fortunate outcome that no listed plant, animal, or habitat was harmed.”¹⁸⁴

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

¹⁸¹ *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1035 (9th Cir. 2005).

¹⁸² *Pac. Rivers Council*, 30 F.3d at 1054 n.8.

¹⁸³ *Center for Food Safety v. Johanns*, 451 F.Supp.2d 1165, 1182 (D. Hawaii 2006).

¹⁸⁴ *Id.*

APHIS's decision not to initiate formal or informal consultation with FWS or NMFS is arbitrary and capricious. To comply with ESA, APHIS must make a written request to the expert agencies for a list of the listed species (or species proposed to be listed) in the proposed action area that may be present.¹⁸⁵ This request is crucial to the ESA decision process. Input from these expert agencies "based on the best scientific and commercial data available" will determine whether APHIS must enter consultation. Here, APHIS did not make any such request.

Impact on Threatened & Endangered Species from Associated Herbicide Use

APHIS's decision that it need not analyze the potential impacts on threatened and endangered species and their critical habitats from the use of herbicides that 2,4-D resistant corn 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."¹⁸⁶ 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.¹⁸⁷ "Indirect effects are 'those that are caused by the proposed action and are later in time, but still reasonably certain to occur.'"¹⁸⁸ Here, the DEA makes plain that the application of 2,4-D and "fop" class herbicides are certain to accompany the deregulation of 2,4-D resistant corn. These include effects of the herbicide it is undisputed will be used with the deregulated crop, since its use is the crop's very purpose.

Congress specified in Section 7 the process that "[e]ach Federal agency" must follow to "insure" against jeopardy. 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.¹⁸⁹

This proposed deregulation is unrestricted, nationwide. APHIS knows that a large number of protected species are found on or near the acreage in question 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 "Fop" herbicides on [2,4-D resistant corn, including potential impacts on [threatened and endangered species] and critical habitat." DEA at 118 (emphasis added). APHIS's acknowledgment that its action "may affect" endangered species and their habitat triggered the need for consultation.

Here, APHIS and FWS made an (erroneous) legal determination, not an ecological one. FWS did not conclude that deregulation was "not likely to adversely

¹⁸⁵ 16 U.S.C. § 1536(c)(1).

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

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

¹⁸⁸ *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).

¹⁸⁹ 50 C.F.R. § 402.14(a).

affect” any listed species or critical habitat. Instead, the two agencies conferred before APHIS even began its analysis, based on their interpretation of another agency’s statutory authority (EPA’s)—an interpretation that is entitled to no deference whatsoever.

The ESA prohibits the agency from deregulating 2,4-D resistant corn until and unless FWS or NFMS either (1) concurs in writing that deregulation is “not likely to adversely affect” listed species or critical habitat; or (2) concludes in a biological opinion that deregulation will not jeopardize listed species or critical habitat. The ESA “reveals a conscious decision by Congress to give endangered species priority over the ‘primary missions’ of federal agencies.”¹⁹⁰

APHIS has broad authority under the PPA to restrict the crop system’s harms in order to protect endangered species and their habitat. Nothing in the PPA or regulations precludes APHIS from including in its plant pest risk analysis the effects of the herbicide that is an integral part of this herbicide-dependent crop system. APHIS’s noxious weed authority also includes broad authority over direct and indirect environmental harms caused by a plant APHIS introduces into commerce. In fact, including a determination that a herbicide-resistant crop system did not present plant pest risks because it would “not harm threatened or endangered species” was a routine APHIS practice,¹⁹¹ prior to recent litigation and recent evidence of significant potential harm from these crop systems. Since APHIS has broad discretion to apply its noxious weed and plant pest authorities to control the direct and indirect harms 2,4-D resistant corn threatens, and the PPA nowhere forces APHIS to allow its commercialization despite those harms, APHIS was required to consult before deregulating.

Nor can APHIS substitute the EPA’s herbicide registration review process under FIFRA for the agency’s independent duty to consider indirect effects under the ESA. *See* DEA at 119. APHIS concluded that “EPA’s core pesticide risk assessment and regulatory processes ensure that protections are in place for [threatened and endangered species].” DEA at 120. APHIS further assumed that EPA’s label restrictions and best practice guidance provided by petitioner DOW and DuPont, the manufacturer of Quizalofop, will “reduce the possibility of exposure and adverse impacts to [threatened and endangered species] from 2,4D and Quizalofop to [2,4-D resistant corn].” DEA at 121. Similarly, APHIS assumed that the “the label use restrictions and best practices in place for the use of glyphosate are intended to reduce the possibility of exposure of [threatened and endangered species].” DEA at 122. Based on these findings, APHIS concluded, that “the potential future use of a new formulation of 2,4-D and the development and cultivation of a stacked variety expressing tolerance to herbicides with multiple modes of action will not adversely impact listed species ... and designed critical habitat[s].” DEA at 122.

¹⁹⁰ *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 185 (1978).

¹⁹¹ 70 Fed. Reg. 36,917, 36,918 (June 27, 2005) (first deregulation of Roundup Ready Alfalfa); *see e.g.*, 70 Fed. Reg. 13,007, 13,008 (Mar. 17, 2005) (Roundup Ready sugar beets); 65 Fed. Reg. 52,693, 52,694 (Aug. 30, 2000) (Roundup Ready corn); 64 Fed. Reg. 22,595, 22,595 (Apr. 27, 1999); (herbicide-tolerant rice); 61 Fed. Reg. 42,581 (Aug. 16, 1996) (herbicide-tolerant soybeans).

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.¹⁹² Contrary to APHIS's conclusion, the DEA is littered with evidence that the use of the associated herbicides (2,4-D, "Fop" herbicides and glyphosate) on 2,4-D resistant corn 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, since EPA's most recent reregistration analysis of 2,4-D, "EPA has requested initiation of formal [Section 7] consultation ... to address the potential effects of 2,4-D on [the California Red-legged Frog] and the [Alameda Whipsnake]." DEA at 120. APHIS also admitted that "the EPA is also currently undertaking a separate consultation with the NMFS on potential detrimental effects of 2,4-D on endangered and threatened pacific salmonids," and that the biological opinion issued by NMFS in March of 2011 concluded that "the continued use of 2,4-D is likely to jeopardize the continued existence of 28 ESU and ... destroy critical habitats for 26 of these ESUs for these endangered and threatened salmonids." DEA at 120.

Similarly, APHIS acknowledged that Quizalofop is currently undergoing reregistration review by the EPA, and that the EPA has stated that "there are several ... ecological data gaps A thorough review of the fish and aquatic invertebrate toxicity tests has shown that these data are not adequate to support a complete ecological risk assessment." DEA at 121.

Finally, APHIS is aware that the use of a 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.¹⁹³ APHIS must consult with FWS and NMFS regarding the specific impacts of herbicides in conjunction with the release of 2,4-D resistant corn and the anticipated release of a stacked corn variety combining resistance to 2,4-D, Quizalofop, and glyphosate.

Pending the completion of formal or informal consultation, an agency is prohibited from making any "irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures."¹⁹⁴ Nor can APHIS rely on any "mitigation" measures from Dow or other industry that are beyond the agency's control.¹⁹⁵

¹⁹² "[C]ompliance with FIFRA requirements does not overcome an agency's obligation to comply with environmental statutes with different purposes." *Wash. Toxics Coalition v. Env'tl. Prot. Agency*, 413 F.3d 1024, 1032 (9th Cir. 2005).

¹⁹³ U.S. Fish & Wildlife Serv., *Draft Biological Opinion, Roundup Ready Bentgrass* (July 2009).

¹⁹⁴ 16 U.S.C. § 1536(d).

¹⁹⁵ *Ctr. For Biological Diversity v. Rumsfeld*, 198 F. Supp. 2d 1139, 1152 (D. Ariz. 2002).

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

For a more detailed discussion of the specific harms to threatened & endangered species posed by the deregulation of 2,4-D resistant corn, please see separately submitted CFS Science Comments.

V. The PPRA Violates the PPA’s “Sound Science” Requirement

As discussed in Section I, *supra*, APHIS violated the PPA by limiting its analysis in the PPRA and the DEA only “plant pest risks,” and by excluding significant harms that “directly or indirectly injure . . . plants”¹⁹⁶ from its PPRA. Moreover, the analysis in the PPRA and DEA violate the PPA, which mandates that decisions affecting regulated products “shall be based on sound science.”¹⁹⁷

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 two separately submitted CFS Science Comments, the PPRA and DEA is 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,” the agency has failed to adequately assess potential negative impacts from the expression of the inserted transgene. As made clear in CFS Science Comments 2, submitted separately by Dr. Martha Crouch, 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,” APHIS completely ignored well-known studies on how expressions of the transgene may make the engineered 2,4-D resistant corn more toxic to organisms that eat corn tissues. APHIS disregarded the fact that the data submitted by Dow show that the gene expression was much higher in pollen, which may be toxic to beneficial insects such as honeybees. APHIS’s discussion of the plant’s metabolism also completely ignores the difference in the composition of 2,4-D resistant that result from the activity of the AAD-1 protein. As demonstrated in CFS Science Comments 2, the AAD-1 protein is an enzyme that is likely to produce toxic metabolites that do not naturally occur in non-GE corn.

Finally, “sound science” would counsel that APHIS should properly inform its PPA decision, with its NEPA analysis, which was not done here. Instead, APHIS stated that the PPRA considered “plant pest risks” of 2,4-d resistant corn itself, while “other

¹⁹⁶ 7 U.S.C. § 7702(10) (emphasis added); 7 U.S.C. § 7712(a).

¹⁹⁷ 7 U.S.C. § 7701(4).

issues related to agricultural or cultivation practices, ... non-target organisms, beneficial organisms, threatened and endangered species and other environmental impacts” are addressed in the DEA. PPA at 7. Further, even if the agency *had* informed the PPA decision with its NEPA assessment, the DEA is chock full of unsound sciences – 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.”¹⁹⁸ President Obama established several core principles that indicate what constitutes scientific integrity, including:

- Having “appropriate rules and procedures to ensure the integrity of the scientific process within the agency,”
- Subjecting scientific or technological information “to well-established scientific processes, including peer review,”
- “Appropriately and accurately reflect[ing] that information in complying with and applying relevant statutory standards,”
- Making “available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions,”
- Putting “in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised,” and
- Adopting additional procedures, such as whistle blower protections, in order to “ensure the integrity of scientific and technological information and processes on which the agency relies.”¹⁹⁹

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

¹⁹⁸ 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/.

¹⁹⁹ *Id.*

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) (emphasis added). 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 restricted action, in order to prevent or limit those harmful impacts. The eye-opening record 367,000-plus public comments filed on APHIS’s 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 corn crop system will cause, among other adverse direct, indirect and cumulative impacts: massive increases in current and new herbicide use and 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 have it be a meaningless paper exercise. Further, pursuant to the ESA, APHIS must consult with the expert wildlife

agenc(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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