



# CENTER FOR FOOD SAFETY

Docket No. APHIS–2012–0026  
Regulatory Analysis and Development  
PPD, APHIS  
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## **Comments to USDA APHIS on Draft Environmental Assessment for the Determination of Nonregulated Status of Herbicide-Tolerant and Insect-Resistant Corn, Zea Mays, Event DP-ØØ4114-3**

April 29, 2013

Docket No. APHIS–2012–0026

Pioneer Hi-Bred International, Inc. (Pioneer) 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 DP-ØØ4114-3** corn (4114 corn), which has been genetically engineered (GE) to provide increased tolerance to glufosinate herbicide from the incorporation of the phosphinothricin-acetyl-transferase (PAT) protein and also produce three insecticidal crystalline proteins: Cry1F; Cry34Ab1; and Cry 35Ab1 (Cry proteins or Bt traits). Additionally, Pioneer has indicated that its intention is to stack and “pyramid” these traits with other deregulated GE traits in order to create corn hybrids with various other herbicide resistances and insecticidal proteins (4114-containing corn hybrids).

Pursuant to the USDA's February 27, 2013 Federal Register Notice, the Center for Food Safety (CFS) submits the following comments concerning the inadequacy— under the National Environmental Policy Act (NEPA), the Plant Protection Act (PPA), and the Endangered Species Act (ESA)—of the agency's draft Environmental Assessment (DEA) accompanying the petition for deregulation.

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.<sup>1</sup> CFS represents more than 300,000 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.

### **SUMMARY**

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

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

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. It rejects out of hand alternatives that could reduce environmental and economic damage to Americans.

The DEA is procedurally flawed and unlawful because, rather than informing APHIS's deregulation decision on 4114 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, 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 4114 corn and 4114-containing corn hybrids are not likely to cause significant impacts to the environment, U.S. agriculture, or public health are contrary to record evidence. Deregulation of 4114 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 full effects of reasonably foreseeable stacking of multiple herbicide-resistance traits in 4114-containing corn hybrids, and the injury to non-target crops from the reasonably foreseeable spread of glufosinate throughout the human environment.

APHIS failed to comply with the procedural mandates of the Endangered Species Act (ESA), including consulting with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS), 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 4114 corn is arbitrary, capricious, and contrary to the mandates of the Plant Protection Act (PPA). The decision is not based on sound science, and the 4114 corn crop system violates the PPA in that it promotes the proliferation of plant disease agents and other plant pest harms, including Bt trait resistant insects; 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 including APHIS to prepare an EIS for all “major Federal actions significantly affecting the quality of the human environment.”<sup>2</sup> If the action may significantly affect the environment, APHIS must prepare an EIS.<sup>3</sup> 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.”<sup>4</sup>

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.<sup>5</sup> NEPA regulations require the analysis of direct, indirect, and cumulative effects.<sup>6</sup> The assessment must be a “hard look” at the potential environmental impacts of its action.<sup>7</sup>

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

### *Plant Protection Act*

APHIS regulates transgenic crops pursuant to the PPA, which consolidated several previous statutes and enhanced APHIS’s authority to prevent both “plant pest” and “noxious weed” harms.<sup>12</sup> 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.”<sup>13</sup> All of APHIS’s decisions “shall be based on sound science.”<sup>14</sup>

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<sup>2</sup> 42 U.S.C. § 4332(2)(C).

<sup>3</sup> *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).

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

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

<sup>6</sup> *See* 40 C.F.R. §§ 1508.8, .9, .13, .18.

<sup>7</sup> *Blue Mountains Biodiversity v. Blackwood*, 161 F.3d 1208, 1211 (9<sup>th</sup> 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).

<sup>8</sup> *See* 42 U.S.C. §§ 4321, 4344.

<sup>9</sup> 40 C.F.R. § 1500.3.

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

<sup>11</sup> *See* 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.

<sup>12</sup> *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).

<sup>13</sup> 7 U.S.C. § 7701(1).

<sup>14</sup> *Id.* §§ 7701(4), 7711(b), 7712(b).

## *Endangered Species Act*

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

### **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 4114 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 “A GE organism is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 when USDA-APHIS determines that it is unlikely to pose a plant pest risk.” DEA at 3; *see* DEA at 5; 48; 132-33. 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.<sup>19</sup> 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.”<sup>20</sup>

APHIS premised its assessment of 4114 corn on the mistaken assumption that the agency is limited by its admittedly outdated regulations, codified at 7 C.F.R. 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 3. APHIS’s claim that Part 340 limits the scope of its authority is patently false. 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.<sup>21</sup> APHIS itself has admitted, in its

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

<sup>16</sup> *Id.* at 185.

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

<sup>18</sup> 50 C.F.R. § 402.02.

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

<sup>20</sup> 7 U.S.C. § 7701(1).

<sup>21</sup> 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).

proposed amended regulations, its ability to consider both “plant pest and noxious weed risks.”<sup>22</sup> 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 traditional plant pests and traditional noxious weeds, in addition to its GE crop regulations.<sup>23</sup>

### *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 4114 corn does not pose a plant pest risk after examining the plant pest risks from “the inserted genetic material, weedy characteristics, atypical responses to disease, insects or plant pests in the field, effects on non-targets [*sic*] or beneficial organisms . . . , changes to agricultural practices, and horizontal gene transfer” PPRA at 13.

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.”<sup>24</sup> 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.” 7 C.F.R. § 340.6(c)(4). As discussed in detail below, and in the separately submitted CFS Science Comments, the potential deregulation of 4114 corn presents numerous environmental, economic, and health risks, including, *inter alia*, the risk of transgenic contamination, increased herbicide use, the threat of herbicide-resistant weeds, and Bt-trait-resistant insects. These harmful effects are plant pest risks that “directly or indirectly injure” organic, conventional, specialty, and GE corn production and threaten cultivation of corn in the United States. APHIS’s analysis of Pioneer’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. *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (failure to consider an important part of the problem is arbitrary and capricious agency action).

### *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.<sup>25</sup>

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<sup>22</sup> 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.” (emphasis added)); *see also id.* at 60,013 (“evaluation of noxious weed risk expands what we can consider”).

<sup>23</sup> See 7 C.F.R. Part 330 (traditional plant pests); 7 C.F.R. Part 360 (traditional noxious weeds).

<sup>24</sup> 7 U.S.C. § 7702(10); 7 U.S.C. § 7712(a).

<sup>25</sup> See APHIS, PLANT PROTECTION AND QUARANTINE 5 (2009), [http://www.aphis.usda.gov/plant\\_health/plant\\_pest\\_info/weeds/downloads/weed\\_action\\_plan.pdf](http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weed_action_plan.pdf) (noting the PPA

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.”<sup>26</sup> 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.<sup>27</sup> 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.<sup>28</sup>

Yet, the DEA is largely silent on indirect noxious weed risks 4114 corn presents, fostering “superweeds” with acquired resistance to glufosinate and other herbicides. Nor did the PPRA reach any formal determination regarding 4114 corn’s noxious weed risks. Rather, the PPRA devoted three pages to analyzing 4114 corn’s “weediness potential” and likelihood of contaminating weedy relatives. PPRA at 7-9. Despite acknowledging in both the DEA and PPRA that volunteer 4114 corn can pose a significant problem because herbicide tolerance means volunteers require additional “[m]echanical or chemical measures,” PPRA at 7, and that volunteer 4114 will resist insect pests with Cry proteins, PPRA at 8, APHIS concluded that 4114 corn itself “is not likely to have increased weediness compared to conventional maize varieties.” PPRA at 9. As explained in detail below, and in 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 4114 corn and stacked hybrids.<sup>29</sup>

APHIS cannot ignore the PPA’s expansive statutory mandates.<sup>30</sup> The agency’s failure to consider plant pest and noxious weed risks associated with 4114 corn and stacked 4114-containing hybrids is arbitrary and capricious. APHIS should set aside its current PPRA and DEA and prepare new assessments that adequately considers 4114 corn’s plant pest risks and noxious weed risks.

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“expands the definition of noxious weed. . . . Under the PPA, noxious weeds are regulated similarly to Plant Pests.”); *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”).

<sup>26</sup> 7 U.S.C. § 7702(10) (emphases added); *see also ICTA*, 473 F. Supp. 2d at 25 & n.15.

<sup>27</sup> *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.).

<sup>28</sup> 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”).

<sup>29</sup> 7 U.S.C. § 7702(10) (emphasis added); 7 U.S.C. § 7712(a).

<sup>30</sup> *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.”).

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 limited to prevent transgenic contamination, environmental herbicide spread, 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.<sup>31</sup> An agency's decision is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem."<sup>32</sup> 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."<sup>33</sup>

The DEA violated NEPA because, *inter alia*, APHIS limited its assessment to 4114 corn's plant pest risks. APHIS begins its discussion of alternatives in the DEA by stating that "APHIS has concluded that Pioneer 4114 [corn] is unlikely to pose a plant pest risk. Therefore, USDA-APHIS must determine that Pioneer 4114 Maize is no longer subject to 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000." DEA at 48 (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."<sup>34</sup> 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 prejudice the NEPA analysis). Yet, rather than preparing the DEA to inform the agency and foster its decision on whether to deregulate 4114 corn, the decision to deregulate 4114 corn has already been determined by the outcome of APHIS's 13-page Plant Pest Risk Assessment. DEA at 3 ("A GE organism is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 when USDA-APHIS determines that it is unlikely to pose a plant pest risk.").

The PPRA is not a lawful substitute for APHIS's independent duty to prepare an EIS under NEPA, and it does not stand-in for an EA that determines if an EIS is warranted. 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 DEAs assessing impacts of deregulation of previous GE crops did not make any reference to PPRA's of the same GE crops until as recently as 2007.<sup>35</sup> PPRA's 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 such meaningful assessments.

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<sup>31</sup> *See* 42 U.S.C. § 4321; 40 C.F.R. § 1501.1(c).

<sup>32</sup> *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>33</sup> *Klamath-Siskiyou Wildlands Ctr v. U.S. Forest Serv.*, 373 F. Supp. 2d 1069 (E.D. Cal. 2004).

<sup>34</sup> *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1356 (9th Cir.1994).

<sup>35</sup> *See* USDA, Biotechnology, Petitions for Determination of Nonregulated Status, [http://www.aphis.usda.gov/biotechnology/petitions\\_table\\_pending.shtml#not\\_reg](http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml#not_reg) (last visited Apr. 29, 2013).

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 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.<sup>36</sup> “NEPA requires that alternatives . . . be given full and meaningful consideration, whether the agency prepares an EA or EIS.”<sup>37</sup> The alternatives analysis should ensure that the agency has before it, and takes into account, all possible approaches to a particular project.<sup>38</sup> 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.”<sup>39</sup>

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.<sup>40</sup> Meaningful consideration of alternatives furthers “the goals intended by NEPA: open, thorough public discussion promoting informed decision-making.”<sup>41</sup>

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.<sup>42</sup> 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 4114 corn. DEA at 48-49. Throughout the comparison of the alternatives the DEA makes conclusory assumptions that both alternatives will have the same effects in all respects—making the alternatives analysis a meaningless paper exercise. APHIS failed to meaningfully consider any alternative other than the Preferred Alternative because, as explained above, the agency erroneously concluded that its PPRA for 4114 corn dictates unconditional deregulation. *See*

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<sup>36</sup> 40 C.F.R. § 1502.14.

<sup>37</sup> *Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1217-18 (9th Cir. 2008) (alteration in original; internal quotation marks and citation omitted).

<sup>38</sup> *Calvert Cliffs’ Coordinating Comm. v. U.S. Atomic Energy Commission*, 449 F.2d 1109, 1114 (D.C. Cir. 1971).

<sup>39</sup> 40 C.F.R. § 1502.14.

<sup>40</sup> *Westlands Water District v. U.S. Dep’t of Interior*, 376 F.3d 853, 872 (9th Cir. 2004).

<sup>41</sup> *Westlands Water District v. U.S. Dep’t of Interior*, 376 F.3d 853, 872 (9th Cir. 2004).

<sup>42</sup> *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)).



*supra* Section I. NEPA requires that the agency must rigorously explore and objectively evaluate all reasonable alternatives, including the no action alternative.<sup>43</sup> Rather than assessing the impacts of continuing 4114 corn's status as a regulated article, APHIS dismissed the No Active Alternative "because . . . APHIS has concluded through a PPRA that Pioneer 4114 [corn] is unlikely to pose a plant pest risk." DEA at 48.

APHIS also rejected out of hand several reasonable alternatives. *See* DEA at 49-51. APHIS considered, but rejected from further consideration: (1) an alternative that would prohibit the release of 4114 corn entirely; (2) an alternative that would approve the petition in part under 7 C.F.R. § 340.6(d)(3)(i); (3) an alternative that would partially deregulate 4114 corn by imposing isolation distances and/or geographical restrictions; and (4) an alternative that would require mandatory testing for transgenic contamination. DEA at 49-51. APHIS rejected these alternatives without analyzing and weighing them, once again stating that the agency's conclusion in the PPRA for 4114 corn precluded the agency from considering any of the alternatives. *See* DEA at 49 ("[P]rohibiting the release of Pioneer 4114 [corn], including denying any permits associated with the field testing. . . is not appropriate given that Pioneer 4114 [corn] is unlikely to pose a plant pest risk."); DEA at 50("Because . . . APHIS has concluded that Pioneer 4114 Maize is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act of 2000 for considering approval of the petition only in part."); DEA at 50 ("[B]ecause . . . APHIS has concluded that Pioneer 4114 [corn] is unlikely to pose a plant pest risk . . . , an alternative based on requiring isolation distances would be inconsistent with the statutory authority . . ."); DEA at 51 ("[B]ecause Pioneer 4114 [corn] does not pose a plant pest risk . . . , the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act of 2000, the regulations at Part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework.").

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 glufosinate, glyphosate, other herbicides, or a combination).
- A partial deregulation alternative with mandatory restrictions to prevent or mitigate substantial harms to agriculture through crop injury from glufosinate and other herbicide damages to neighboring farms that is a reasonably foreseeable consequence of unrestricted deregulation of 4114 corn.
- A partial deregulation alternative with mandatory restrictions to reduce the induced evolution of corn insect pests resistant to Cry proteins.

The DEA repeatedly acknowledged, and in fact identified as an important reason for considering the deregulation of 4114 corn, the epidemic of superweeds resistant to glyphosate resulting from the commercialization of GE, glyphosate-resistant, "crop systems." DEA at 34-

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<sup>43</sup> 40 C.F.R. § 1502.14.

35; *see, e.g.*, DEA at 20 (“The practice of using herbicides with alternative modes of action could potentially diminish the populations of glyphosate-resistant weeds and reduce the likelihood of the development of new herbicide-resistant weed populations.”). At the same time the DEA acknowledged that the narrow field of two alternatives would have no potential positive impact on superweed or superbug development, assuming that the agency is powerless to halt these menaces to American agriculture. *See* DEA at 64 (“Trends related to the development of and the management of Bt-resistant insect pests and glyphosate-resistant weed populations are not anticipated to be substantially different for the Preferred and No Action Alternatives.”). The DEA further admitted that 4114 corn, once deregulated, will be “stacked” and “pyramided” 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 2. The demonstrated trend of glyphosate-resistant weeds emergence and spread after the deregulation of GE glyphosate-resistant crop system makes the development of rapid evolution of weeds resistant to glufosinate a “reasonably foreseeable” consequence that must be analyzed in the DEA.<sup>44</sup> Nonetheless, APHIS failed to consider a deregulation alternative that would impose methods to reduce the development of herbicide-resistant weeds and Bt-trait-resistant insects that will proliferate around stacked 4114-containing corn hybrids.

The DEA seeks to side-step most issues of stacked 4114-containing hybrids by asserting that such seeds will only replace similar existing seeds on the market and no change in farmer practices is foreseeable. *See, e.g.*, DEA at 64. However, aside from citing assertions from Pioneer, the agency does not give any reasoned analysis why a new product, stacked into numerous corn hybrids covering tens of millions of acres of farmland, will not serve farmers differently and affect their agricultural practices. Assuming at the outset that the only two alternatives considered will result in mirror-image effects and then “analyzing” those two alternatives against one another falls short of the reasoned analysis required by NEPA.

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 50. 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. DEA at 50. There is no basis in the statute or regulations for this interpretation of the agency’s authority. On the contrary, the U.S. Supreme Court has recognized that APHIS has the discretion and authority to partially deregulate a GE crop, by imposing geographic restriction and isolation distances, in order to eliminate harms from transgenic contamination and weed resistance.<sup>45</sup> 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.<sup>46</sup>

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<sup>44</sup> 40 C.F.R. § 1508.7.

<sup>45</sup> *Monsanto v. Geertson Seed Farms (Monsanto)*, 130 S.Ct. 2743, 2759-60 (2010).

<sup>46</sup> 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](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](http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_fonsi_rtc.pdf).

“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.’”<sup>47</sup> The unconditional deregulation of 4114 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 4114 corn poses to agriculture, finalizing the current draft without fully 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.”<sup>48</sup>

#### *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.”<sup>49</sup> The DEA admits that that contamination of non-GE corn varieties by 4114-containing corn hybrids is possible. DEA at 65 (“The adventitious presence of GE corn with organic corn is a concern for some, knowing that corn naturally cross-pollinates . . .”); DEA at 24 (same); DEA at 9 (“Corn is a wind-pollinated, monoecious, annual grass species . . .”). According to Emerson Nafziger, Professor of Agronomy at the University of Illinois:

[I]t 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.<sup>50</sup>

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<sup>47</sup> 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)).

<sup>48</sup> Geertson Seed Farms v. Johanns (*Geertson*), 2007 WL 518624 at \*5 (N.D. Cal. Feb. 13, 2007), *aff’d*, 541 F.3d 938 (9th Cir. 2008).

<sup>49</sup> Peter Thomison, *Fact Sheet: Managing ‘Pollen Drift’ to Minimize Contamination of Non-GMO Corn*, AGF-153, OHIO STATE UNIVERSITY EXTENSION, <http://ohioline.osu.edu/agf-fact/0153.html> (last visited April 24, 2013).

<sup>50</sup> 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](http://faq.aces.uiuc.edu/?project_id=28&faq_id=590) (last visited April 24, 2013).

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 can travel as far as ½ mile within those couple of minutes [of pollen viability].”<sup>51</sup> 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.”<sup>52</sup> With these facts at hand the DEA’s suggestion that seed certification management practices completely eliminate contamination is unsupported. In fact, the DEA asserts this, stating: “Current practices for maintaining the purity of hybrid seed production in corn are typically successful for maintaining 99% genetic purity, though higher instances of out-crossing can occur.” DEA at 92. While failing to properly analyze pollen contamination, APHIS herein demonstrates why further study under an EIS is required by the facts.

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.<sup>53</sup> Nonetheless, in the DEA, APHIS dismisses the risk of transgenic contamination from gene flow between 4114-containing corn hybrids and non-GE corn varieties because “Pioneer 4114 [corn] is expected to present a no greater risk of cross-pollination than that of existing corn cultivars . . . .” DEA at 66. 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.”<sup>54</sup> Conversely, in stating that gene flow from 4114-containing corn hybrids is just as likely as existing GE corn varieties, APHIS is actually conceding that gene flow is likely to occur.

In two seminal 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.<sup>55</sup> 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.<sup>56</sup> APHIS should properly assess the risks of gene flow from 4114 corn to non-GE varieties of corn, and any and all environmental and intertwined socio-economic impacts of such contamination, by preparing an EIS.

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<sup>51</sup> 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 visited April 24, 2013).

<sup>52</sup> J. Perkins, *Genetically modified mystery*, DES MOINES REGISTER, Aug. 10, 2003.

<sup>53</sup> *Metcalf 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)).

<sup>54</sup> *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).

<sup>55</sup> *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 (Sugar Beets I)*, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009).

<sup>56</sup> *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).

### *Other Modes of Contamination*

The DEA also recognized that contamination may occur through other pathways, including seed mixing in product handling facilities, or in transport. DEA at 25, 67, 93. However the document fails to analyze the possibility of seed spillage, seeds remaining in seed cleaning and other farm equipment, volunteer growth, cross-pollination by insect- or animal-based pollen or seed movement, post-harvest mixing in the grain-handling system, weather events, and simple human error. Indeed, when the DEA mentions contamination other than gene flow, it only does so to laud unnamed and unanalyzed industry practices. *See* DEA at 25, 67, 93 (“procedures for managing identity of specific varieties are already in place to minimize gene flow challenges arising from admixtures during handling”). APHIS acknowledged that “[g]ene 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 93. 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 percent or more of the certified non-GE corn, canola, and soybean seed has been contaminated with transgenes.<sup>57</sup> 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 contamination in 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 as foreseeable impacts.

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.<sup>58</sup>

Another route of contamination that is unpredictable, but likely over time, is human error. Importantly, APHIS’s failure to analyze contamination assumes that industry practices will operate without any such 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

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<sup>57</sup> M. MELLON AND J. RISSLER, UNION OF CONCERNED SCIENTISTS, *GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY* (2004).

<sup>58</sup> DAVID ANDOWET ET AL., UNION OF CONCERNED SCIENTISTS, *A GROWING CONCERN: PROTECTING THE FOOD SUPPLY IN AN ERA OF PHARMACEUTICAL AND INDUSTRIAL CROPS* (Dec. 2004).

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.<sup>59</sup> 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 and has been documented around the world.<sup>60</sup> A report from an environmental organization documented 39 cases in 2007 and more than 200 in the last decade.<sup>61</sup> 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.<sup>62</sup> 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)

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<sup>59</sup> 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).

<sup>60</sup> 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.

<sup>61</sup> 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>.

<sup>62</sup> For the following discussion of StarLink, see Bill Freese, Friends of the Earth, *The StarLink Affair*, (July 2001), available at <http://www.foodallergyangel.com/documents/GMO/StarlinkReport.pdf>.

segregate StarLink corn and buffer strip corn for distribution only to non-food channels.<sup>63</sup> 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 percent of total U.S. corn acreage (year 2000).<sup>64</sup> Despite the limited acreage planted in StarLink, and the conditions attaching to its cultivation, testing initiated by public interest groups and subsequently conducted by the U.S. Food and Drug Administration (FDA) found that over 300 corn products in grocery stores around the country were contaminated with StarLink. The USDA found StarLink contaminating 9-22 percent of grain samples.<sup>65</sup>

The extent of the contamination is startling when one considers that StarLink never represented more than 0.43 percent 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.<sup>66</sup> 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.<sup>67</sup> 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.<sup>68</sup>

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 had mandated confinement requirements. It had not been grown at all for several years when contamination of the U.S. rice supply was detected at low levels that have nonetheless caused great economic harm to the domestic 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

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<sup>63</sup> 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), available at [http://www.epa.gov/pesticides/chem\\_search/cleared\\_reviews/csr\\_PC-006466\\_undated\\_001.pdf](http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-006466_undated_001.pdf).

<sup>64</sup> 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).

<sup>65</sup> A. Shadid, *Genetically Engineered Corn Appears in One-Tenth of Grain Tests*, BOSTON GLOBE, May 3, 2001; A. Shadid, *Testing Shows Unapproved, Altered Corn More Prevalent Than Thought*, BOSTON GLOBE, May 17, 2001.

<sup>66</sup> 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](http://www.usda.gov/news/releases/2001/06/0101.htm); A. Hovey, *StarLink protein found in other crops*, LINCOLN STAR JOURNAL, Mar. 29, 2001.

<sup>67</sup> Bill Freese, Friends of the Earth, *The StarLink Affair*, (July 2001), available at <http://www.foodallergyangel.com/documents/GMO/StarlinkReport.pdf>.

<sup>68</sup> *Tests to Detect Allergens in Altered Foods Fall Short*, ST. LOUIS POST-DISPATCH, June 12, 2002.

recommendation considerably, but still experienced contamination.<sup>69</sup> Despite an extensive investigation, USDA was unable to determine exactly how the contamination occurred.<sup>70</sup>

In late 2010, contamination stemming from a 2005 field trial of Roundup Ready Bentgrass was discovered in Ontario, Oregon, four miles from the field trial location in Idaho.<sup>71</sup> Five years later, contamination is widespread and rampant, covering an estimated twenty-seven 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.<sup>72</sup> The field trials were successfully challenged in litigation against USDA for its failure to comply with NEPA.<sup>73</sup> 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.<sup>74</sup> USDA fined Scotts \$500,000<sup>75</sup> in 2007 and presumed the issue resolved, until the shocking discovery of new populations growing in the wild over five years later.<sup>76</sup> FWS, in 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.”<sup>77</sup>

Courts have found these and other contamination incidents sufficient evidence of the likelihood of contamination. “[T]he 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.”<sup>78</sup> The “significance” of these events is further evidence that 4114 corn can cause significant impacts through contamination, whether via gene flow or other pathways. These impacts must be analyzed in an EIS.

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<sup>69</sup> G. Vogel, *Tracing the transatlantic spread of GM rice*, 313 SCIENCE 1714 (2006).

<sup>70</sup> USDA, REPORT OF LIBERTY LINK RICE INCIDENTS 1 (2007), available at [www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf](http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf).

<sup>71</sup> Mitch Lies, *GMO bentgrass found in Eastern Oregon*, CAPITAL PRESS, Nov. 9, 2010, available at <http://www.capitalpress.com/oregon/ml-gmo-bentgrass-111210>.

<sup>72</sup> *Id.*

<sup>73</sup> *ICTA*, 473 F.Supp.2d at 28.

<sup>74</sup> *ICTA*, 473 F.Supp.2d at 21; Jay R. Reichman, et al., *Establishment of Transgenic Herbicide-Resistant Creeping Bentgrass (Agrostis solonifera L.) in Nonagronomic Habitats*, MOLECULAR ECOLOGY (2006).

<sup>75</sup> 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>.

<sup>76</sup> Mitch Lies, *Coba Presses Scotts for Bentgrass Plan*, CAPITAL PRESS, Feb. 10, 2011, available at <http://www.capitalpress.com/oregon/ml-coba-letter-021111>.

<sup>77</sup> FWS, *Draft Biological Opinion, Roundup Ready Bentgrass* (2010). 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. *Id.*

<sup>78</sup> 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. *See* DEA at 106-08, 129-131. Economic effects are relevant under NEPA, and must be examined "when they are interrelated with natural or physical environmental effects."<sup>79</sup> 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*: "[T]he 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 [*sic*] DNA through the transmission of the genetically engineered gene to organic and conventional alfalfa."<sup>80</sup> The court continued, "APHIS was required to consider those effects in assessing whether the impact of its proposed action is 'significant.'"<sup>81</sup>

*Market Rejection of Contaminated Organic and Conventional GE-Sensitive Products*

APHIS failed to adequately assess the potential impact on organic farming from contamination by 4114 corn. APHIS admits in the DEA that "net returns . . . from organic acres continue to be greater than net return from conventional acres, with a 16% premium received for organic growers reported in 2008." DEA at 24. Yet, APHIS entirely ignores socioeconomic impacts to organic farmers if transgenic contamination occurs, summarily concluding that 4114 corn "is not expected to have a substantial impact on organic corn production." DEA at 66. 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 65. 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 23. This argument—that the National Organic Standards merely represent 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 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

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<sup>79</sup> *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 944 (9th Cir. 2005) (quoting 40 C.F.R. §1508.14).

<sup>80</sup> *Geertson*, 2007 WL 518624 at \*8.

<sup>81</sup> *Id.*

of organic foods runs counter to consumer expectations, foods produced with these methods will not be permitted to carry the organic label.<sup>82</sup>

Furthermore, USDA has acknowledged that organic is more than simply a labeling process, amounting to 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.”<sup>83</sup> 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:

even 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.<sup>84</sup>

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,<sup>85</sup> 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.<sup>86</sup> 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.<sup>87</sup> Today, canola crops and oil from western Canada cannot be marketed as organic or non-GE because of the risk of contamination.<sup>88</sup>

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<sup>82</sup> 65 Fed. Reg. 13512, 13513-14 (March 13, 2000).

<sup>83</sup> *Id.* at 13535.

<sup>84</sup> *Geertson*, 2007 WL 518624 at \*7.

<sup>85</sup> JOSH BRANDON AND LOUISE SALES, GREENPEACE GE CANOLA OUT OF CONTROL IN CANADA 3 (2007), available at <http://gefreebc.files.wordpress.com/2011/01/ge-canola-out-of-control-in.pdf>.

<sup>86</sup> M. Marvier and R. Van Acker, *supra* note 59.

<sup>87</sup> Stuart Smyth, et al., *Liabilities and Economics of Transgenic Crops*, 20 NATURE BIOTECH. 6 (June 2002).

<sup>88</sup> 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>; *Is USDA Accounting for the Costs to Farmers from Contamination Caused by Genetically Engineered 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)*, available at <http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg49777/pdf/CHRG-110hhrg49777.pdf>.

### *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 4114 corn, yet has failed to adequately do so in the DEA. According to APHIS, the U.S. exports about 15 to 20 percent 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 47. None of these countries have currently approved 4114 corn for importation. Assuming, as the DEA does, that all of these countries will approve the crop in due time represents a flawed NEPA analysis. One significant contamination event similar to LL601 LibertyLink Rice, or Starlink Corn, could impact the corn exports to these countries and hasty deregulation will economically devastate American farmers—both those who knowingly grow 4114-containing corn hybrids and those who are contaminated against their will—and producers of corn products.

The DEA is silent on how the deregulation of 4114 corn may affect U.S. export markets for corn, despite the fact that APHIS recognized that key export markets have not approved the importation of 4114 corn. DEA at 131. 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 65. Market rejection of corn contaminated by 4114 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.<sup>89</sup> 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.<sup>90</sup> 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.<sup>91</sup> As a result, rice farmers in the South experienced a severe shortage of seed rice for the 2007 season.<sup>92</sup> APHIS conducted an investigation into the contamination episodes, but was unable to determine precisely how they occurred.<sup>93</sup> Courts have subsequently found Bayer negligent in every bellwether case, with total

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<sup>89</sup> R. Weiss, *Gene-altered profit-killer*, WASHINGTON POST, Sept. 21, 2006.

<sup>90</sup> R. Weiss, *Firm Blames Farmers, ‘Act of God’ for Rice Contamination*, WASHINGTON POST, Nov. 22, 2006.

<sup>91</sup> News Release, USDA APHIS, *Statement by Dr. Ron DeHaven regarding APHIS hold on Clearfield CL131 long-grain rice seed*, Mar. 5, 2007. [http://www.aphis.usda.gov/newsroom/content/2007/03/ge\\_riceseed\\_statement.shtml](http://www.aphis.usda.gov/newsroom/content/2007/03/ge_riceseed_statement.shtml).

<sup>92</sup> D. Bennett, *Arkansas’ emergency session on CL 131 rice*, DELTA FARM PRESS, March 1, 2007.

<sup>93</sup> 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).

damages estimated at a billion dollars.<sup>94</sup> The litigation was eventually settled in part for \$750 million.<sup>95</sup>

The genetic engineering of papaya in Hawaii (not approved for cultivation in any other country) has also resulted in widespread contamination<sup>96</sup> and huge losses in export income to papaya growers there, as well as reduced prices due to rejection of the GE papaya overseas.<sup>97</sup> U.S. corn exporters lose about \$300 million per year in exports due to European Union rejection of engineered corn.<sup>98</sup> Similarly, the potential approval in the U.S. of GE 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.<sup>99</sup> 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 percent of their total exports, resulting in a net loss in the price paid to farmers of between 32 and 35 percent.<sup>100</sup> Finally, the 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.<sup>101</sup>

#### *Burden on Organic & Specialty Corn Production*

Organic and specialty corn growers bear completely the onerous burden of reducing the risk of contamination under the Preferred Alternative. DEA at 24 (“Organic farming plans should include how the risk of GE pollen or co-mingling of seed will be monitored.”); DEA at 24 (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 65. APHIS failed to analyze the potential efficacy of these measures, or the costly land-use implications associated with them. *See* DEA at 65 (“A minimum isolation distance of 250 feet between varieties is

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<sup>94</sup> *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).

<sup>95</sup> Andrew Harris and David Beasley, *Bayer Agrees to Pay \$750 Million to End Lawsuits Over Gene-Modified Rice*, BLOOMBERG NEWS, July 1, 2011, available at <http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html>

<sup>96</sup> 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 percent were found on the island of Hawaii); HAWAII SEED, FACING HAWAII'S FUTURE, HARVESTING ESSENTIAL INFORMATION ABOUT GMOS 44 (2006).

<sup>97</sup> GREENPEACE INT'L, THE FAILURE OF GE PAPAYA IN HAWAII (May 2006), available at <http://www.greenpeace.org/international/en/publications/reports/FailureGEPapayainHawaii/>.

<sup>98</sup> PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, US v. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD 3-4 (2005).

<sup>99</sup> *Cost of Genetically Engineered Plants: Hearing before the Subcomm. on Domestic Policy of the H. Comm. on Oversight and Gov't Reform*, 110<sup>th</sup> Cong. 7 (Mar. 13, 2008) (Statement of Todd Leake, Conventional and GE grain grower).

<sup>100</sup> *Id.*

<sup>101</sup> *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](http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf).

recommended; whereas, 700 feet is preferred for complete isolation”). 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 24. 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 58 (noting “the trend in increase in corn acreage is a function of market conditions driving growers to substitute corn for other crops, including the decision to adopt corn-to-corn production.”). This burdening of organic and specialty corn farmers 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 4114 corn on both organic and conventional non-GE corn in an EIS prior to adopting a deregulation decision.

#### *Harm to Overall Organic Industry*

APHIS also entirely failed to assess the socioeconomic impacts of transgenic contamination on the entire organic industry, especially in light of the importance of corn as animal feed. The National Organic Program excludes the use of GE materials in food production.<sup>102</sup> Organic products require 100 percent organic feed; there is no *de minimus* exception.<sup>103</sup> The DEA acknowledged that “corn comprises approximately 95% of the total feed grain produced and used,” yet is silent on any potential impacts on the organic industry should organic corn feed be contaminated by 4114-containing corn hybrids. DEA at 103-04. Under these standards, contamination of organic feed corn with the transgene will render the corn ineligible for organic certification and will eliminate it as a permissible feed for organic livestock.

APHIS is aware that contamination of organic feed threatens entire organic industries that rely on such feeds; the agency received many comments on its draft EIS from organic dairy producers, cattle ranchers, organic product manufacturers and organic grocers opposing the unconditional deregulation on Roundup Ready alfalfa, another important feed.<sup>104</sup> 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

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<sup>102</sup> 7 C.F.R. § 205.105; 7 C.F.R. § 205.2.

<sup>103</sup> *Id.* § 205.237(a).

<sup>104</sup> APHIS, Roundup Ready Alfalfa FEIS, App. F (2010), *available at* [http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt\\_alfalfa%20\\_feis.pdf](http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf).

growing as much as 20 percent each year.<sup>105</sup> 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 12, 22, 58. 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 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 4114-containing corn hybrids to the market might increase contamination, the agency must prepare an EIS. The deregulation of 4114 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 4114 corn on the supply of organic corn feed.

#### *Cost of GE Testing & Certification*

The DEA's silence on the private cost<sup>106</sup> 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 51 (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 4114 corn is nonsensical. As the U.S. Supreme Court found in *Monsanto*, the burden of testing one's crops is a cognizable injury.<sup>107</sup>

#### *Impacts on the Public's and Farmers Fundamental Right to Choose and Contamination's Environmental Component*

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.<sup>108</sup> 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]."<sup>109</sup> Thus, as the Supreme Court held, the "injury has an

<sup>105</sup> Dininny, S., *Organic Dairies Test Supply of Feed*, ASSOCIATED PRESS, Dec. 20, 2007.

<sup>106</sup> In declining to assess government testing as an alternative the DEA states: "Such a requirement would be extremely difficult to implement and maintain." DEA at 51. This burden is thereby shifted to small farmers in the market.

<sup>107</sup> *Monsanto*, 130 S.Ct. at 2755.

<sup>108</sup> *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.").

<sup>109</sup> *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

environmental as well as an economic component.”<sup>110</sup> The loss of biodiversity due to contamination, and the potential elimination or reduction of conventional and organic varieties of corn is an environmental injury.<sup>111</sup>

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.<sup>112</sup> 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.”<sup>113</sup> 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 4114 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 physical impact, those effects must be discussed.<sup>114</sup> NEPA aims to “maintain, wherever possible, an environment which supports diversity and a variety of individual choice.”<sup>115</sup> 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].”<sup>116</sup> 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.”<sup>117</sup> Significant to APHIS’s determination here, “An action which potentially eliminates or at least greatly reduces the availability of a particular plant . . . has a significant effect on the environment.”<sup>118</sup>

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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.”).

<sup>110</sup> *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.”).

<sup>111</sup> *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.”).

<sup>112</sup> *See, e.g.*, Organic Trade Association, Consumer Profile Facts, <http://www.ota.com/organic/mt/consumer.html> (last visited Apr. 29, 2013).

<sup>113</sup> 7 C.F.R. § 205.2 (2011).

<sup>114</sup> 40 C.F.R. § 1508.14.

<sup>115</sup> *Id.*

<sup>116</sup> *Geertson*, 2007 WL 518624 at \*8.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

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 4114 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 65. 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 market segment that currently provides consumers with a choice. This impact was conspicuously absent from the DEA. APHIS must analyze the public’s right to choose in an EIS.

### *Seed Market Concentration*

The DEA failed to discuss seed market concentration. Research and development suffer from seed market concentration. Seed companies have aggressively undermined independent researchers’ ability to fully investigate their patented crops’ performance.<sup>119</sup> These companies often want the right to review and 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 [companies] control 84% of the agrochemicals market. . . . [all GE]seeds are bio-patented by multinational corporations and 13 commercial corporations own 80% of the GM food market.”<sup>120</sup> As the practical options become limited to varieties patented by Pioneer and the other 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, as well as the cost of groceries.

The increased seed market concentration has already made it hard for farmers to purchase conventional corn and soy seeds.<sup>121</sup> 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 large 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 105. Nonetheless, APHIS summarily disregards the economic impact of the higher cost of 4114-containing corn hybrids to farmers because it might be possible for farmers to offset their costs in certain ways. DEA at 105. This lack of analysis is insufficient under NEPA.

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<sup>119</sup> *Sugar Beets I*, Huber Decl., ¶¶ 17-18 (April 13, 2010); Emily Waltz, *Under Wraps*, 27 NATURE BIOTECHNOLOGY 880, 882 (2009).

<sup>120</sup> Yamuna Ghale and Bishnu Raj Upreti, Concentration and Monopolisation of Seed Market: Impact on Food Security and Farmer’s Rights in Mountains, Mountain Forum, *available at* <http://www.mtnforum.org/sites/default/files/pub/2056.pdf>.

<sup>121</sup> *CFS, MONSANTO V. US FARMERS* (2005), *available at* <http://www.centerforfoodsafety.org/files/cfsmonsantovsfarmerreport11305.pdf>.



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.<sup>122</sup> 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 4114 corn will influence Pioneer'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.<sup>123</sup>

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 4114 corn constitute a significant intertwined socioeconomic 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.<sup>124</sup>

In short, there is overwhelming evidence that the deregulation of 4114 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 4114 corn violates NEPA.

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<sup>122</sup> *Sugar Beets I*, Harl Decl. ¶ 5.

<sup>123</sup> William Neuman, *Rapid Rise in Seed Prices Draws U.S. Scrutiny*, N.Y. TIMES, Mar. 12, 2010, at B1.

<sup>124</sup> GREENPEACE INTERNATIONAL, MAIZE UNDER THREAT: GE MAIZE CONTAMINATION IN MEXICO (Aug. 2003), available at <http://www.greenpeace.org/international/PageFiles/24249/maizeunderthreat.pdf>.

#### **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.<sup>125</sup> 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.<sup>126</sup>

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.”<sup>127</sup> Nonetheless, the DEA makes assumptions that allow the agency to circumvent foreseeable actions significantly impacting the human environment.

##### **a. Increased Herbicide Use**

APHIS's conclusion that deregulating 4114 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).

First, APHIS uses an inaccurate baseline to compare the changes in herbicide use due to the adoption of 4114 corn. APHIS wrongly assumes that 4114 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. *See* DEA at 106. 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 4114 corn. *See* DEA at 55. 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 APHIS's other deregulations of GE crops, from the DEA. Importantly, the acres newly given over to corn production were likely previously either fallowed or planted with less chemically-intensive crops than corn, and thus the further deregulation of another corn trait will serve to speed whatever market forces are causing this trend, which is having such large effects on the human environment. Secondly, between the PPRA and DEA APHIS loses 16 million acres of corn cultivation. *Compare* DEA at 55 (“In 2012, corn was cultivated on over 96 million acres”) *with* PPRA at 1 (“Corn production in the U.S. has risen over time and is currently

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<sup>125</sup> 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).

<sup>126</sup> 40 C.F.R. § 1508.7.

<sup>127</sup> *Kern v. Bureau of Land Mgmt.*, 284 F.3d 1062, 1075 (9th Cir. 2002).

about 80 million acres annually.”). This discrepancy is larger than West Virginia. This sort of fundamental baseline error renders the entire analysis arbitrary and capricious.

The analysis of the reasonably foreseeable increase in use of glufosinate on stacked 4114-containing corn hybrids also is lacking. APHIS assumes that the deregulation of 4114 corn will not change glufosinate use in corn production. *See, e.g.*, DEA at 64, 76. APHIS was required to, but completely failed to, assess the market forces of a new stacked trait’s effects on herbicide use in the future. APHIS relies heavily on the assumptions that because EPA label restrictions probably will not change, and 4114 may replace similar GE traits on the market, tomorrow’s glufosinate usage will be exactly like today’s. DEA at 76. Yet, the deregulation of a new crop will change the market, and as noted above APHIS punts on the issue of spreading cornfields because this flows from market forces—the agency’s attempt to avoid assessing foreseeable changes in the market caused by deregulation, and in turn causing changes in farming practices, falls short of its duty. APHIS’s oversight is particularly egregious in light of the DEA’s open admission that currently glufosinate is applied 2 to 6 percent of the total corn acreage in the U.S., DEA at 76, while the agency also mentions the possibility of increased glufosinate usage on glyphosate-resistant weeds. DEA at 130. That the use of glufosinate and other herbicides on stacked 4114-containing corn hybrids genetically engineered to withstand multiple herbicide applications will be much greater is a reasonably foreseeable consequence, one APHIS has entirely failed to assess.

The agency’s analysis leaves out as many important issues as it possibly can. As explained in the separately submitted CFS Science Comments, glufosinate changes 4114-containing corn hybrids’ structure and agronomic needs, and the further expansion of the herbicide over more acres of corn will potentially have a large impact on farming practices that goes unnoticed in APHIS’s analyses.

APHIS’s analysis of the predictable stacked 4114-containing corn hybrids is similarly deficient, and takes shortcuts that do not satisfy its duties to assess foreseeable impacts. The DEA stated that it was only assessing the stacking of 4114 corn with glyphosate resistance. DEA at 110 (other than glyphosate resistance “additional stacks of insect resistant traits were not assessed”). This ignores other GE herbicide tolerance traits and GE Bt traits already on the market, as well as Pioneer’s stated goal of stacking 4114 with as many other traits as it possibly can. Yet, as with its lack of consideration of increased glufosinate use on corn, APHIS also concluded that there is no duty on its part to assess glyphosate because APHIS had discussed glyphosate in previous deregulation documents. DEA at 111. By relying on scientific analyses going back as far as 1996, APHIS fails to base its analysis on the best science available. More importantly to cumulative impacts analysis: this lack of weighing both herbicides eviscerates reasoned analysis—albeit an already cabined and limited one—because the stacked dual-herbicide tolerance will not be analyzed in terms of the intended dual use of these herbicides on corn crops.

*APHIS's Conclusion That Glufosinate 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 glufosinate will simply replace existing herbicide use on corn crops directly contradicts existing data on herbicide usage on GE, glyphosate-resistant crops.

To the contrary, GE crops have dramatically increased overall pesticide and herbicide use.<sup>128</sup> The DEA itself recognizes this fallacy, admitting that herbicide usage resulting from GE crops is "the subject of intense debate." DEA at 114. Such intense scientific debate must factor in the agency's determination of significance, because when the "degree to which the effects on the quality of the human environment are likely to be highly controversial"—precisely the case here—impacts are more likely to be significant, requiring the agency to prepare an EIS. *See* 40 C.F.R. § 1508.27(b)(4). Glyphosate has not eliminated nor replaced the use of more toxic herbicides as the DEA asserts. DEA at 17. This demonstrates that assumptions that glufosinate use will offset glyphosate or not increase along with glyphosate over time are erroneous. These errors are discussed in further detail in separately submitted CFS Science Comments.

b. Resistant Weeds and Insects

The DEA's discussion of the issue of weed resistance is inconsistent and contradictory. On the one hand, APHIS states the purpose of 4114 corn is to enable growers to use glufosinate to manage glyphosate-resistant weeds that have developed due to APHIS's previous deregulations of glyphosate-resistant crops; on the other hand, the agency dismisses the likelihood that a similar epidemic of superweeds resistant to glufosinate—as well as glyphosate, after development of stacked varieties—will follow the deregulation of 4114 corn crop systems. *Compare* DEA at 62 ("growers will likely continue to experience the continued emergence of Bt-resistant insect pests and glyphosate-resistant weeds. These trends require modifications of crop management practices to address these challenges, including the use of alternative herbicides for weed control . . . , [and] alternative insect control strategies (including alternative PIPs)'), *with* DEA at 34 ("The emergence of herbicide [resistant weeds] is not limited to any one herbicide or production system."), and DEA at 34 ("Italian Ryegrass resistant to both glyphosate and glufosinate has been identified in Oregon."). APHIS is aware of, and has identified in the DEA, the existence of weeds that are already resistant to glufosinate and glyphosate. *See* DEA at 34-35, tbls. 2-3 & 2-5. The past is prologue for this pesticide treadmill: APHIS's failure to analyze the likelihood and impacts of reasonably foreseeable weed resistance glufosinate and glyphosate as a result of changed use patterns associated with 4114 corn deregulation 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

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<sup>128</sup> Charles Benbrook, the Organic Center, *Impacts of Genetically Engineered Crops on Pesticide Use: The First Thirteen Years* (Nov. 2009).

resistance. *See, e.g.*, DEA at 83, 62. APHIS’s assumption that growers will utilize proper weed management practices to avoid weed resistance to glufosinate directly contradicts the DEA’s admission that weed management strategies such as alternating different herbicide modes of actions and crop rotations have not been followed. Indeed, the DEA stated that the “introduction of glyphosate-resistant crops, including corn, resulted in growers changing historical weed management strategies, . . . and relying on a single herbicide, glyphosate, to control weeds in the field.” DEA at 83. APHIS also recognized, but failed to analyze, the fact that farmers are increasingly planting consecutive rotations of corn, resulting in further increase in the same herbicide use. DEA at 12.

This lack of crop rotation has an even more dire effect on the development of superbug insects that develop resistance to Bt traits, and the DEA seeks to blame individual farmers for developing such pests by ignoring best practices. DEA at 78. Since the DEA proves that a handful of farmers can develop exceptional superbug pests through common faulty practices, it shows that APHIS has a duty to consider alternatives that would prevent this from occurring with 4114 corn—this analysis should come in an EIS. APHIS’s blind reliance on insufficient hortatory weed and insect management practices to mitigate the threat of weed resistance does not comply with NEPA, runs contrary to the evidence and is arbitrary and capricious.<sup>129</sup>

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 glufosinate-resistant soy and cotton are already deregulated. DEA at 84, 153. The DEA recognized that, excluding the increasing practice of consecutive corn cultivation, a corn-soy or corn-cotton rotation is common. DEA at 12. 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.<sup>130</sup> The DEA admitted that “[c]onsecutive plantings of corn require more management than corn-soybean rotations, and increases risk of disease and insect pest pressure.” DEA at 13. APHIS must take into account the reasonably foreseeable impact of other glufosinate-resistant crop systems in analyzing the development of superweeds that are resistant to glufosinate.

Finally, weed and pest resistance is an increasingly expensive and environmentally harmful problem faced by US farmers. However, APHIS’s discussion of increased cost to farmers is cursory and inconclusive. The DEA recognized that glufosinate requires more water, has a more narrow window of application, and costs more than glyphosate. DEA at 19. It also acknowledged that volunteer 4114 corn would need to be tilled out of the ground or sprayed with novel herbicides. DEA at 124. Yet, the DEA failed to include any discussions of increasing

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<sup>129</sup> *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.”).

<sup>130</sup> *See* CFS Science Comments (submitted separately).

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 of weed resistance is arbitrary and capricious. APHIS must prepare an EIS.

c. Stacking

The DEA is also fails to assess the foreseeable stacks of 4114-containing corn hybrids. Under NEPA, APHIS must assess the "incremental impact of the [proposed action] when added to other past, present, and reasonably foreseeable future actions regardless of what agency . . . or person undertakes such other actions."<sup>131</sup> Pioneer has made clear to APHIS that 4114 corn will be used as a base for stacks that include many different traits already on the market, DEA at 48, and presumably the company intends to stack 4114 corn with other crops currently undergoing agency review. APHIS clearly states "4114 [corn] is not intended to be a stand-alone commercial product, but will be combined with other approved events using conventional breeding to create stacked and pyramided products with multiple modes of action for control of insect pests and corn weeds." DEA at 2. Despite the plainly foreseeable future stacked varieties of 4114 corn that would have additional resistance to other toxic herbicides and pesticides, expressing the full range of deregulated Bt traits on the market, APHIS excluded any potential impacts of the stacked 4114-containing corn hybrids except for the single stack of 4114 corn and glyphosate resistance. This is insufficient under NEPA and the agency has a duty to assess the stacks that it indicates will occur after deregulation of 4114 corn.

APHIS's failure to consider the environmental impacts of stacking 4114 corn with multiple herbicide and/or insecticide resistant traits is arbitrary and capricious, especially since the DEA acknowledged the potential harms of stacking 4114 corn with glyphosate resistance. 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 124. In avoiding analysis of this problem and relying only on the PPRA's unsound science 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 does not fully analyze any stacks, which, as explained above, the DEA acknowledges are the intended use of 4114 corn. The fact that the DEA recognizes there are already weeds that have resistance to both glyphosate and glufosinate shows why a PPRA of 4114 corn would necessarily have to look at the plant pest and noxious weed risks created by this crop system. 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. It is foreseeable that 4114 corn's deregulation will speed this evolution and therefore full analysis under an EIS is required.

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<sup>131</sup> 40 C.F.R. § 1508.7.

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."<sup>132</sup> As Dr. David Mortensen has explained, mutated weeds with resistance to different herbicide actions "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).<sup>133</sup> 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 turn drives still more chemical use. Since the DEA admitted that stacking 4114 corn is reasonably foreseeable, the impacts of stacking represent cumulative impacts 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 scientists are concerned with the possibility of herbicide-resistant volunteer corn. DEA at 36. Volunteer corn reduces crop yields by competing with the intended crop "for light, soil moisture, and nutrients." DEA at 36. The DEA acknowledged that volunteer corn is already an increasing problem in subsequent crop productions on the same fields. DEA at 36 (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 124. APHIS's analysis of the volunteer corn problem stops there. APHIS summarily dismisses the problem of volunteer corn, while acknowledging "[i]f the volunteer corn is stacked to contain both a glyphosate- and glufosinate-tolerant trait, inter-row cultivation is the only option for post-emergent [volunteer] control within corn." DEA at 37. This labor-intensive "only option" is a foreseeable significant impact on the environment and the economic health of American corn farmers.

APHIS's lack of analysis here violates NEPA. NEPA requires that mitigation measures must be described "in detail,"<sup>134</sup> and an analysis explaining the effectiveness of the measures is "essential."<sup>135</sup> Further, the effectiveness of mitigation measures must be supported by studies and analytical data in the record.<sup>136</sup> Here, APHIS failed to provide any estimates or analysis of

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<sup>132</sup> Mortensen et al., *Navigating a Critical Juncture for Sustainable Weed Management*, 62 *BIOSCIENCE* 75-84 (2012).

<sup>133</sup> *Id.*

<sup>134</sup> *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).

<sup>135</sup> *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.").

<sup>136</sup> *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.

the cost to farmers to controlling volunteer corn, despite the agency's admission that the use of different herbicides to eliminate 4114 volunteer corn is only effective "provided that the Pioneer 4114 [corn] or its progeny does not carry tolerance to these other herbicides" obtained through stacking or contamination. DEA at 124. This assumption is unsupportable and APHIS's assessment is insufficient under NEPA.

e. Conservation Tillage

Throughout the DEA, APHIS touts the promotion of conservation tillage associated with the deregulation of 4114 corn after first acknowledging that GE herbicide-tolerant corn has not increased conservation tillage. *Compare* DEA ("The cultivation of a corn variety stacking multiple modes of action, in this case, tolerance to glufosinate ammonium, along with glyphosate-tolerance, provides growers with an opportunity to maintain their conservation tillage strategies."); *with* DEA at 11 ("the change in tillage practices in [GE] corn was less dramatic than other crops such as soybean or cotton, as many growers of corn had already changed to conservation tillage systems as a means to reduce soil erosion"), *accord* DEA at 57; *and* DEA at 57 (regarding a slight uptick in conservation tillage in corn acres from 1998 to 2010 "this adoption of no-till practices was likely caused by shifts from growers already using conservation tillage and not conventional tillage practices"). The DEA itself shows that APHIS's assumption that 4114-containing corn hybrids will promote conservation tillage is inconsistent and erroneous. Not only does the DEA assert that the weak correlation between conservation tillage and GE corn does not represent a causal relationship, as discussed above the DEA recognizes that 4114 corn will create more volunteer corn problems for farmers, requiring more manual extraction. To the extent that 4114 corn deregulation will neither encourage or even maintain conservation tillage acres in corn APHIS has a duty under NEPA to fully assess the environmental impacts of its action.

USDA itself has called into question whether herbicide-resistant crop systems such as 4114 corn is the cause of increased conservation tillage practices.<sup>137</sup> Based on a study of glyphosate-resistant soybeans and different tillage practices, USDA concluded that:

Farmers using no-till were found to have a higher probability of adopting herbicide-tolerant seed, but using herbicide-tolerant seed did not significantly affect no-till adoption. The result seems to suggest that farmers already 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.<sup>138</sup>

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'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).

<sup>137</sup> U.S. DEP'T. OF AGRICULTURE, ECONOMIC RESEARCH SERVICE, FERNANDEZ-CORNEJO, J. AND W.D. MCBRIDE, ADOPTION OF BIOENGINEERED CROPS, AGRICULTURAL ECONOMIC REPORT NO. 810 (May 2002), *available at* <http://www.ers.usda.gov/publications/aer810/aer810.pdf>.

<sup>138</sup> *Id.* at 59.



Because the development of herbicide-resistant weeds and volunteer corn are reasonably foreseeable impacts of 4114 corn cultivation, APHIS's failure to consider the negative impacts on conservation tillage is arbitrary and capricious.

f. Harm from Glufosinate

The DEA entirely fails to independently analyze the potential harm to plants, wildlife, and humans from glufosinate. 4114 corn is specifically designed to be used with glufosinate. The DEA acknowledged that 4114 corn is intended "as a foundation stock for production of hybrid varieties containing multiple stacked traits." DEA at 120. Just as the DEA refers to the glyphosate-resistant "crop system", DEA at 46, 4114 corn is part of the glufosinate-resistant crop system. The use of glufosinate and the commercialization of 4114 corn will come hand in hand, especially since glufosinate is only used on between 2 and 6 percent of current conventional corn acreage, DEA at 58, and this deregulation has the potential to change farming practices. Therefore, the impacts from glufosinate use on 4114 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 simply because the EPA had registered the same herbicides under FIFRA.<sup>139</sup>

APHIS's reliance on EPA's FIFRA registration of glufosinate is unlawful. EPA's prior reregistration of glufosinate was thirteen years ago, in 2000, before the petition for deregulation of 4114 corn was submitted to APHIS. Thus, EPA's FIFRA analysis never accounted for the potential adoption of 4114 corn and the increased use of glufosinate on corn. In fact, EPA is currently in the process of reregistration of glufosinate,<sup>140</sup> a process the agency anticipate will not be completed until later in 2013.<sup>141</sup> Relying on EPA's outdated analyses of glufosinate falls below the standards of NEPA; it also fails to satisfy APHIS's independent duty to analyze all reasonably foreseeable impacts of its own action pursuant to NEPA, and to consider "indirect risks" to plants and the environment under the PPA.<sup>142</sup> At a minimum, APHIS should wait for EPA to complete its process of registering glufosinate so that the agency may independently assess and incorporate EPA's analyses into its NEPA process and PPA risk assessment.

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<sup>139</sup> 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.").

<sup>140</sup> See EPA, Glufosinate Summary Document Registration Review: Initial Docket March 2008, Docket Number: EPA-HQ-OPP-2008-0190, available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0190-0003;oldLink=false>.

<sup>141</sup> See EPA, Registration Reviews; Draft Human Health and Ecological Risk Assessments: Cyromazine, Silica Silicates, Glufosinate Ammonium, Dioctyl Sodium Sulfosuccinate and Undecylenic Acid <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0190-0021> (last visited Apr. 29, 2013) (establishing a comment period on the current review of glufosinate and allowing the public to submit online comments for the record).

<sup>142</sup> See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.7 U.S.C. § 7702(10); 7 U.S.C. § 7712(a).

### *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 glufosinate to conclude that glufosinate use on 4114-containing corn hybrids would not endanger the health and safety of farm workers. *See* DEA at 101-02. However, EPA's FIFRA registration does not obviate APHIS's own independent NEPA duties.<sup>143</sup>

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 4114 corn would allow more frequent, over-the-top applications of different pesticides (the DEA notes that glyphosate and glufosinate will likely be sprayed at different times, DEA at 110, increasing opportunities for exposure), increasing workers' exposure to the toxic herbicide. APHIS also failed to consider how the introduction of other classes of herbicides that will be used on volunteer 4114-containing corn hybrids would increase workers' overall exposure to toxic chemicals.

More generally, APHIS failed to assess the harms to human health stemming from the increase in glufosinate use that will accompany the deregulation of 4114 corn. As discussed in detail in the separately submitted CFS Science Comments, numerous studies have linked exposure to glufosinate to major health risks.<sup>144</sup> *See* separately submitted CFS Science Comments for a full treatment of the health risks of synthetic herbicide use that foreseeably flows from 4114 corn deregulation.

APHIS must address the potential harms to human health in its NEPA analysis. Public health effects are 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."<sup>145</sup> Thus, an EA must address any potential human health or safety risks and determine whether they may be significant. If those impacts are found not to be significant, there must be a convincing statement of reasons. APHIS failed to do so here and an EIS is required.

### *Global Warming*

APHIS's discussion of the cumulative impacts of the new generation of 4114 corn glufosinate-resistant crop systems on global warming relies on unsupported presumptions and unsound science.

APHIS's assertion that 4114 corn will not create climate change impacts is predicated upon the DEA's erroneous conclusion that 4114-containing corn hybrids will somehow foster conservation tillage. *See* DEA at 74-75. As discussed in the CFS Science Comments and in the

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<sup>143</sup> *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).

<sup>144</sup> *See* separately submitted CFS Science Comments

<sup>145</sup> 40 C.F.R. § 1508.27(b)(2); *see, e.g., Stauber v. Shalala*, 895 F.Supp. 1178, 1195 (W.D. Wis. 1995).

section on Conservation Tillage in these comments, *supra*, the adoption of the herbicide-resistant crop system is not the cause of the increased utilization of conservation tillage practices in farming, and multiple-herbicide-resistant stacked GE hybrids will increase manual removal practices, negatively impacting conservation tillage. 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, 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.<sup>146</sup> APHIS's frequent references to conservation tillage show that the DEA was prepared without reviewing the best science available, instead relying on industry-sponsored studies and reviews.

APHIS minimizes the fact that the increased use of glufosinate in corn production, made possible by deregulation of 4114 corn, promotes global warming. APHIS inaccurately assumes that the 4114 corn crop system would not result in "any changes in corn production practices or an expansion of corn acreage." DEA at 120. Yet, the DEA recognized that 4114 corn would allow glufosinate, which was only applied to 2 to 6 percent of total corn acreage in the U.S., as well as other herbicides associated with stacked traits, to be applied to the genetically engineered corn. APHIS also readily acknowledged that 4114 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 110. More pesticide applications per season may mean more emissions of greenhouse gases from farm equipment. 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. *See, e.g.*, DEA at 119, 121, 122, 124. APHIS provides no support for the contention that the label restrictions will prevent environmental damage from the increasing and new uses of glufosinate on 4114-containing corn hybrids. Nor can the agency pass the buck on its NEPA duties to another agency, or industry submissions. APHIS must properly analyze the climate change impacts of its action in an EIS.

Furthermore, the DEA's discussion of climate change impacts falls short of a NEPA analysis. As the DEA concedes "climate change may reciprocally affect agriculture. . . [i]n response to climate change, the current range of weeds and pests of agriculture may increase." DEA at 28. But in the next paragraph the DEA only mentions what may happen in the coming century in relation to climate change. This grossly general discussion provides neither the agency nor the public with information necessary to determine the alternatives' relative responses to these massive environmental considerations. At the same time the DEA acknowledges the severe drought that greatly reduced corn output in 2012. DEA at 45, 107. The document notes that the large change in supply led to a large change in the price of corn, hence changing market forces relevant to farmers. DEA at 45. Not only does the document not address

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<sup>146</sup> *See* CFS Science Comments submitted separately.

these market forces, it also uses irrigation figures from 2010—ignoring actual climate change impacts and change in irrigated land that occurred in 2012. DEA at 26. Significantly, the DEA repeatedly discusses how 4114 corn will help farmers to avoid mycotoxin contamination by stopping insect damage that allows for such contamination (*see* DEA at 14, 43, 46, 99, 105), yet ignores the fact that mycotoxin contamination expanded to record amounts in 2012-season corn due to the drought.<sup>147</sup> Add to this omission the fact that the DEA indicates glufosinate will require more water usage, DEA at 19, and it becomes apparent that APHIS has failed to assess climate change impacts that are actually occurring and will also affect farming differently if 4114 corn is deregulated. The paucity of climate change impacts analysis demonstrates that this DEA is insufficient, and the agency should prepare an EIS to fully vet these environmental effects.

## **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.<sup>148</sup> APHIS must prove its deregulation will neither jeopardize any species, nor harm any critical habitat, anywhere the crop system may be grown.<sup>149</sup>

The initial request for information from FWS and/or NMFS is a prerequisite for further agency action and cannot be ignored.<sup>150</sup> 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 4114 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 4114 corn will have “no effect” on listed species or their critical habitats. DEA at 137, 139. APHIS violated Section 7(a)(2) of the ESA by failing to consult with FWS or NMFS—informally or formally—about the effects of 4114 corn deregulation on listed species and critical habitat.

APHIS’s decision not to initiate formal or informal consultation with FWS or NMFS is arbitrary and capricious. 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

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<sup>147</sup> Julie Ingwersen, *Grain Handlers Wary of Toxin Lingering in '12 U.S. Corn Harvest*, REUTERS, Apr. 19, 2013, available at <http://www.reuters.com/article/2013/04/19/us-usa-crops-afatoxin-idUSBRE93I11I20130419>.

<sup>148</sup> 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).

<sup>149</sup> Wash. Toxics Coal. v. EPA, 413 F.3d 1024, 1035 (9th Cir. 2005).

<sup>150</sup> Pac. Rivers Council, 30 F.3d at 1054 n.8.

whether APHIS must enter consultation. APHIS's claim in the DEA that because the agency independently reached a "no effect" determination the agency need not formally or informally consult<sup>151</sup> with FWS and/or NMFS is legal error.

### *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 4114 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."<sup>152</sup> 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.<sup>153</sup> "Indirect effects are 'those that are caused by the proposed action and are later in time, but still reasonably certain to occur.'"<sup>154</sup> Here, the DEA makes plain that the application of glufosinate and other herbicides are certain to accompany the deregulation of 4114 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.<sup>155</sup>

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 glufosinate on Pioneer 4114 [corn], including potential impacts on [threatened and endangered species] and critical habitat." DEA at 139 (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 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. *See* DEA at 139.

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<sup>151</sup> It seems that APHIS asked the Fish and Wildlife Service for lists to threatened or endangered species, but this does not rise to the level of a consultation. DEA at 134.

<sup>152</sup> 50 C.F.R. § 402.02 (emphasis added).

<sup>153</sup> 50 C.F.R. § 402.02; *see* *Wild Fish Conservation v. Salazar*, 628 F.3d 513, 525 (9th Cir. 2010).

<sup>154</sup> *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).

<sup>155</sup> 50 C.F.R. § 402.14(a).

The ESA prohibits the agency from deregulating 4114 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.”<sup>156</sup>

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 PPRAs 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,<sup>157</sup> 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 4114 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 141. APHIS further assumed that EPA’s label restrictions and best practice guidance provided by petitioner Pioneer will “reduce the possibility of exposure and adverse impacts to [threatened and endangered species] from application of glufosinate to Pioneer 4114 [corn].” DEA at 142. 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 143. Based on these findings, APHIS concluded, that “label use restrictions by the pesticide applicator will ensure that the use of the herbicide will not adversely affect [threatened or endangered species] or critical habitat.” DEA at 142.

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.<sup>158</sup> Contrary to APHIS’s conclusion, the DEA is littered with evidence that the use of the associated herbicides (glufosinate and glyphosate) on stacked 4114-containing corn hybrids

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<sup>156</sup> *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 185 (1978).

<sup>157</sup> 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).

<sup>158</sup> “[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).

“may affect” threatened and endangered species and their critical habitats, admissions that triggered the need to consult.

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.<sup>159</sup> APHIS must consult with FWS and NMFS regarding the specific impacts of herbicides in conjunction with the release of 4114 corn and the anticipated release of a stacked corn variety combining resistance to the herbicides associated with GE traits that will foreseeably be stacked with 4114 corn.

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.”<sup>160</sup> Nor can APHIS rely on any “mitigation” measures from Pioneer or other industry that are beyond the agency’s control.<sup>161</sup>

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 4114 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 4114 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”<sup>162</sup> 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.”<sup>163</sup>

Sound science includes objective findings, which take into account all relevant and available data, does not disregard superior data and is based on accepted scientific method, which includes peer review and methodology that is widely used and can be replicated. As discussed in detail in the separately submitted CFS Science Comments, the PPRA and DEA are largely based on Pioneer’s own studies, which are largely not peer reviewed or objective. See the CFS Science Comments for discussion of the non-biased studies that the PPRA and DEA failed to consider.

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<sup>159</sup> U.S. Fish & Wildlife Serv., Draft Biological Opinion, Roundup Ready Bentgrass (July 2009).

<sup>160</sup> 16 U.S.C. § 1536(d).

<sup>161</sup> *Ctr. For Biological Diversity v. Rumsfeld*, 198 F. Supp. 2d 1139, 1152 (D. Ariz. 2002).

<sup>162</sup> 7 U.S.C. § 7702(10) .

<sup>163</sup> 7 U.S.C. § 7701(4).

Assuming that 4114 corn will be “functionally equivalent” to GE traits on the market supposedly allows APHIS to rely on past environmental documents in assuming that this new trait is relatively safe. Such reliance on old, and themselves insufficient, documents does not rise to the level of sound science.

Finally, “sound science” would counsel that APHIS should properly inform its PPA decision, with its NEPA analysis, which was not done here. Instead, APHIS stated that the PPRA considered “plant pest risks” of 4114 corn itself and completed this analysis in barely thirteen pages of cursory discussion. Further, even if the agency *had* informed the PPA decision with its NEPA assessment, the DEA is chock full of unsound science—errors of biology, botany, agronomy, genetics, and economics—to name a few; the result of which allows APHIS to conclude, at least preliminarily, that the deregulation will have no significant impacts.

On March 9, 2009, President Obama issued a Memorandum entitled “Scientific Integrity” mandating that “[s]cience and the scientific process must inform and guide decisions of my Administration,” with the “highest level of integrity in all aspects of the executive branch’s involvement with scientific and technological issues.”<sup>164</sup> 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.”<sup>165</sup>

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

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<sup>164</sup> Barack Obama, Memo for the Heads of Departments and Agencies, Mar. 9, 2009, *available at* [http://www.whitehouse.gov/the\\_press\\_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/](http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/).

<sup>165</sup> *Id.*



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 Science Comments.

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

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

## CONCLUSION

In this 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 record shows that the unrestricted approval of Pioneer’s 4114 corn crop system will cause, among other adverse direct, indirect and cumulative impacts: massive increases in current and new herbicide use, 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

