



CENTER FOR
FOOD SAFETY

Docket No. APHIS-2012-0067
Regulatory Analysis and Development
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Comments to USDA/APHIS on Plant Pest Risk Assessment and Environmental Assessment for Determination of Nonregulated Status of Potatoes Genetically Engineered for Reduced Browning and Reduced Acrylamide

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The Center for Food Safety (CFS) hereby submits these comments regarding the Animal and Plant Health Inspection Service (APHIS)'s draft Plant Pest Risk Assessment (PPRA) and draft Environmental Assessment (EA) prepared in regards to the J.R. Simplot Company (Simplot) Petition (13-022-01p) for Determination of Non-regulated Status for Innate™ Potatoes with Low Acrylamide Potential and Reduced Black Spot Bruises.¹

CFS is a national nonprofit public interest and environmental advocacy organization working to protect human health and the environment by curbing the use of harmful food production technologies.² In furtherance of this mission, and on behalf of its 500,000 members, CFS uses legal actions, groundbreaking scientific and policy reports, books and other educational materials, and grassroots campaigns. CFS is a recognized national leader on the issue of genetically engineered (GE) organisms and has worked to improve GE regulation and address GE impacts continuously since the organization's inception in 1997.

I. INTRODUCTION

USDA/APHIS is evaluating a petition to deregulate potatoes genetically engineered for reduced acrylamide potential and browning. Simplot petitioned APHIS for a determination of nonregulated status for GE potatoes and APHIS has prepared a draft PPRA for public comment.

The Simplot potatoes, consisting of several common cultivars, have been genetically engineered with iRNA (interfering RNA) technology to resist browning by the silencing

¹ J.R. Simplot Company Petition (13-022-01p) for Determination of Non-regulated Status for Innate™ Potatoes with Low Acrylamide Potential and Reduced Black Spot Bruises: Events E12, 78 Fed. Reg. 25942 (May 3, 2013).

² See generally Ctr. for Food Safety, <http://www.centerforfoodsafety.org> (2014).

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(inhibition) of expression of one of five polyphenol oxidase gene (ppo5), which is normally highly expressed in potato tubers. The potato processing industry desires these GE potatoes because bruised potatoes are culled for cosmetic reasons. However, bruised potatoes have not been associated with health risks.

These potatoes are also silenced for genes affecting sugar production and the amino acid asparagine. Interaction between asparagine and sugars at high temperatures (i.e., those encountered during frying and baking) leads to the production of acrylamide. Thus, silencing these genes is expected to lead to reduced levels of acrylamide in processed potato products, and Simplot has presented data showing reduction up to about 70 percent.

Acrylamide is a neurotoxin and probable carcinogen. It is unclear in whether the observed reductions will lead to positive health outcomes, given that acrylamide remains in other foods, but reductions in consumption of acrylamide are probably desirable. On the other hand, fried potato products may have other negative health effects. If reduced acrylamide encourages increased consumption of fried potato products, it is possible that Simplot potatoes may not improve overall health outcomes. Therefore, claims of health benefits by APHIS and Simplot are premature. As noted by the American Cancer Society, eating a healthful diet high in fruits and vegetables is one way to avoid risk from acrylamide in food, and “[t]his type of diet is likely to have health benefits beyond lowering acrylamide levels.”³

If approved, Simplot’s potatoes, which utilize novel technologies, would be the only GE potato varieties on the U.S. commercial market. (The only previous GE potato, from Monsanto, was rejected by the market and subsequently discontinued.) Nevertheless, despite the unprecedented nature of this proposed action, APHIS inexplicably has not undertaken the legally required rigorous and overarching analysis of the GE potatoes’ impacts, nor of the reasonably foreseeable consequences of approving this new GE crop.

Consequently, APHIS’s EA for these GE potatoes is woefully inadequate under the National Environmental Policy Act (NEPA). In short, this EA is based on incomplete and inadequate science and analyses, lacks critical data and vital risk assessments, and ignores potential consequences and uncertainties. Moreover, the scope of the EA is unlawfully narrow, thereby ignoring the plainly foreseeable environmental and socioeconomic impacts of introducing GE potatoes, and the alternatives section is unlawfully narrow and illegally predetermined. Thus, APHIS’s EA fails to take the “hard look” at environmental impacts required by NEPA.

Now, to comply with NEPA, which requires a full Environmental Impact Statement (EIS) where an agency action may significantly impact the environment, APHIS must prepare an EIS. Under NEPA, “significantly” is defined to include both considerations of context and intensity, and includes considerations of the “degree to which the proposed action affects public health or safety” and the “degree to which the effects on the quality of the human environment are likely to be highly controversial.”⁴ Here, the effects of the proposed action (i.e., approving

³ Am. Cancer Soc’y, *Acrylamide*, <http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/acrylamide> (last revised Oct. 1, 2013).

⁴ 40 C.F.R. § 1508(b)(2), (4).

deregulation of the GE potatoes) on public health were inadequately reviewed in the EA. Thus, APHIS must generate an EIS that fully considers the potentially significant public health impacts of this proposed action. Further, this action is indeed highly controversial, because so little is known about the impacts these GE potatoes will have on human health and the environment; consequently, an EIS is called for.

Finally, APHIS must act expeditiously to comply with the mandates of the Endangered Species Act (ESA). The agency's failure to consult with the U.S. Fish and Wildlife Service is unlawful. APHIS's claim that this proposed action would have no effects on threatened or endangered species is premised on inadequate data and poorly supported assumptions.

The inadequacy of APHIS's data is specifically egregious because these GE potatoes present significant, novel issues for APHIS to analyze. Given these new issues, the assessments APHIS made in response to Simplot's petition will set important precedents and must, at a minimum, be rigorously performed and analyzed in an EIS before any decision is made.

CFS has analyzed the EA and PPRA and concluded that APHIS simply does not have enough basic information from Simplot or the scientific literature to be able to adequately assess environmental and health impacts of approving these GE potatoes, and thus cannot make a responsible and lawful determination of nonregulated status. For the many reasons discussed in these comments, APHIS's draft EA is woefully inadequate: APHIS has failed to take the requisite "hard look at the environmental consequences" of its proposed decision to approve the petition,⁵ and failed to provide a "convincing case" in support of its decision. Overall, APHIS's extremely deficient analyses and lack of basic data flouts NEPA's fundamental tenets of ensuring comprehensive, timely, and transparent environmental review of agency actions.

Specifically, approval of Simplot's potatoes presents several risks that are not fully addressed by Simplot's petition for deregulation or APHIS's EA or PPRA:

- As explained in CFS comments on the Arctic apple, APHIS underestimates the potential for unintended effects from the iRNAs on other genes in the crop, with unknown consequences for health or the environment
- APHIS underestimates the possibility of negative effects on the environment through consumption of potato crop tissues by beneficial organisms, such as pollinators or pest natural enemies, or threatened or endangered species.
- The functions of PPO genes are not adequately understood. Some of these functions may include protection of the potato crops from pathogens, and others may be unknown.
- Recent research has strongly suggested that asparagine 1 genes (*asn1*) in plants may have an important role in defense against pathogens. Simplot did not explicitly consider this in its data and testing.
- *Asn1* genes are crucial and multifunctional nitrogen metabolisms genes in plants, with multiple effects, many of which are not well understood. *Asn1* genes respond to multiple environmental and developmental cues, many of which may not be experienced in the

⁵ See, e.g., *Friends of the Payette v. Horseshoe Bend Hydroelectric Co.*, 988 F.2d 989, 993 (9th Cir. 1993); see also *Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

limited field trials conducted by Simplot, and may only be encountered after commercialization. Silencing of this gene may therefore produce undesirable agronomic effects over time.

- Simplot data showed statistically significant and substantial reductions in yield for five of ten transformation events. If these initial data proves to be accurate, commercialization could have negative agronomic, and therefore possible negative economic or environmental consequences.
- Testing of potato events showed inconsistent response to inoculation by the late blight pathogen (*Phytophthora infestans*). In some cases susceptibility was increased compared to the non-GE control, and in others decreased (and in some there was no change). It is difficult to interpret these results, but increased susceptibility could have negative environmental, economic, or health consequences.
- Contamination of non-GE potatoes could occur, and cause economic harm to organic and other non-GE potato growers

The first three bullets, *supra*, pertain to issues raised in CFS Arctic apple (AA) comments to USDA, and are hereby incorporated by reference, including all reference material therein. While there are material differences between Arctic apple and the Simplot potatoes, the same general concerns apply regarding PPO gene silencing. Silencing in the AA was applied to multiple PPO genes, while only one is silenced in the Simplot potato. However, the same concerns about possible pathogen susceptibility, off-target effects, harm through consumption by other organisms, and so on, still apply. These issues, regarding PPO gene silencing, will therefore not be discussed further in these comments, which will focus on the possible consequences of silencing of the *asn1* gene.

Based on all these concerns, APHIS should deny the petition to deregulate these GE potatoes. Alternatively the decision whether or not to deregulate these GE potatoes cannot be made until and unless, at a minimum, APHIS prepares an EIS to fully review the significant environmental, health, and socioeconomic effects of this possible deregulation, and complies with all other applicable statutory mandates.

II. LEGAL BACKGROUND

National Environmental Policy Act

NEPA requires a federal agency to prepare a detailed EIS for all “major Federal actions significantly affecting the quality of the human environment.”⁶ 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.”⁷

⁶ 42 U.S.C. § 4332(2)(C).

⁷ *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989).

If the federal action *may* significantly affect the environment, APHIS *must* prepare an EIS.⁸ As a preliminary step, an agency may prepare an EA to decide whether the environmental impact of a proposed action is significant enough to warrant preparation of an EIS.⁹ 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.¹⁰ “The statement of reasons is crucial to determining whether the agency took a “hard look” at the potential environmental impact of a project.”¹¹ An EA must “provide sufficient evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact.”¹² NEPA regulations require the analysis of direct and indirect, as well as cumulative, effects in NEPA documents, including EAs.¹³ The assessment must be a “hard look” at the potential environmental impacts of its action.¹⁴ APHIS’s decisions in the EA must be “complete, reasoned, and adequately explained.”¹⁵

Whether there may be a significant effect on the environment requires consideration of two broad factors: context and intensity. “Context” means that “the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality Both short- and long-term effects are relevant.”¹⁶ In addition, a number of factors should be considered in evaluating intensity, including “[t]he degree to which the proposed action affects public health or safety,” “[t]he degree to which the effects on the quality of the human environment are likely to be highly controversial,” “[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks,” “[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts,” “[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts,” and “[t]he degree to which the action may adversely affect an endangered or threatened species or its habitat.”¹⁷ An action may be “significant” if even one of these factors is met.¹⁸

A thorough consideration of cumulative impacts is required in the preparation of an EA.¹⁹ Specifically, an EA must provide a quantified assessment of project’s environmental impacts when combined with other projects.²⁰ Notably, courts and the Council on Environmental Quality (CEQ) emphasize that a detailed cumulative impacts analysis is especially important in an EA,

⁸ *Idaho Sporting Cong. v. Thomas*, 137 F.3d 1146, 1150 (9th Cir. 1998) (citation omitted); *Steamboaters v. U.S. Fed. Energy Regulatory Comm.*, 759 F.2d 1382, 1392 (9th Cir. 1985).

⁹ 40 C.F.R. § 1508.9.

¹⁰ *Save the Yaak v. Block*, 840 F.2d 714, 717 (9th Cir. 1988).

¹¹ *Id.*

¹² *Id.*

¹³ See 40 C.F.R. §§ 1508.8, 1508.9, 1508.13, 1508.18.

¹⁴ *Nat’l Parks & Conservation Ass’n v. Babbitt*, 241 F.3d 722, 731 (9th Cir. 2001) (quoting 40 C.F.R. § 1508.27); *Blue Mountains Biodiversity v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998).

¹⁵ *Nw. Coal. for Alternatives to Pesticides v. U.S. Envtl. Prot. Agency*, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008).

¹⁶ 40 C.F.R. § 1508.27(a).

¹⁷ *Id.* § 1508.27(b)(2), (4), (5), (6), (7), (9). “Human environment shall be interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment.” *Id.* § 1508.14.

¹⁸ *Ocean Advocates v. U.S. Army Corps of Eng’rs*, 361 F.3d 1108, 1125 (9th Cir. 2004); see *Nat’l Parks & Conservation Ass’n*, 241 F.3d at 731 (either degree of uncertainty or controversy “may be sufficient to require preparation of an EIS in appropriate circumstances”).

¹⁹ See, e.g., *Kern v. Bureau of Land Mgmt.*, 284 F.3d 1062, 1075 (9th Cir. 2002).

²⁰ *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 972 (9th Cir. 2006).

because there is a much higher risk of cumulative impacts resulting from many smaller decisions for which EAs are prepared.²¹ The cumulative impact analysis must also include an assessment of potential aesthetic, historic, cultural, economic, social, and health impacts.²²

Council on Environmental Quality

NEPA established CEQ and charged the agency with overseeing implementation of this law.²³ The regulations subsequently promulgated by CEQ²⁴ 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.”²⁵ CEQ’s regulations are applicable to and binding on all federal agencies.²⁶ Among other requirements, CEQ’s regulations mandate that federal agencies address all “reasonably foreseeable” environmental impacts of their proposed programs, projects, and regulations.²⁷ Direct effects are those that are caused by the action and occur at the same time and place.²⁸ Indirect effects are those that are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable.²⁹ A cumulative impact constitutes the impact on the environment that results from the incremental impact of the action when added to past, present, and reasonably foreseeable future actions regardless of what agency or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.³⁰

CEQ’s regulations clearly lay out the purpose of an EIS: “The primary purpose of an environmental impact statement is to serve as action-forcing devices to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government.”³¹ An EIS shall provide “full and fair discussion of significant environmental impacts and shall inform decisionmakers of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment.”³² Agencies are to focus on “significant environmental issues and alternatives.”³³

²¹ See, e.g., *Native Ecosystems Council v. Dombeck*, 304 F.3d 886 (9th Cir. 2002); *Kern*, 284 F.3d at 1076, 1078 (“Given that so many more EAs are prepared than EISs, adequate consideration of cumulative effects requires that EAs address them fully. Without such individually minor, but cumulatively significant effects, it would be easy to underestimate the cumulative impacts of the action . . . and of other reasonably foreseeable future actions, on the [environment].”) (internal citation marks omitted).

²² 40 C.F.R. § 1508.8; see e.g., *id.* § 1508.14 (when “economic or social and natural or physical environmental are interrelated,” then the NEPA analysis must discuss “all of these effects on the human environment); *Wyoming v. U.S. Dep’t of Agric.*, 661 F.3d 1209, 1251 (10th Cir. 2011) (cumulative impacts analysis must consider all of the effects listed at 40 C.F.R. § 1508.8).

²³ See 42 U.S.C. §§ 4321, 4344.

²⁴ 40 C.F.R. §§ 1500–08.

²⁵ *Id.* § 1500.3.

²⁶ *Id.* §§ 1500.3, 1507.1; see, e.g., *Hodges v. Abraham*, 300 F.3d 432, 438 (4th Cir. 2002).

²⁷ See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, 1508.25.

²⁸ *Id.* § 1508.8(a).

²⁹ *Id.* § 1508.8(b).

³⁰ *Id.* § 1508.7.

³¹ *Id.* § 1502.1.

³² *Id.*

³³ *Id.*

Plant Protection Act

APHIS oversees transgenic crops pursuant to the Plant Protection Act (PPA),³⁴ which provides USDA broad authority to “prohibit or restrict . . . movement in interstate commerce of any plant” as necessary to prevent either “plant pest” or “noxious weed” harms.³⁵ The statute’s multifaceted purpose is to protect not only agriculture, but the “environment, and economy of the United States” through the “detection, control, eradication, suppression, prevention, or retardation” of these harms.³⁶

The PPA defines these harms expansively. A “noxious weed” is “any plant or plant product that can directly or indirectly injure or cause damage to crops . . . or other interests of agriculture, . . . the natural resources of the United States, the public health, or the environment.”³⁷ “Plant pest” means “any living stage [of a list of organisms] that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.”³⁸

Developers seeking to commercialize a transgenic plant must petition APHIS for deregulation,³⁹ which the agency can grant “in whole or in part.”⁴⁰ The PPA mandates that all APHIS decisions “be based on sound science.”⁴¹

Endangered Species Act

As recognized by the U.S. Supreme Court, the ESA is “the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.”⁴² The ESA’s statutory scheme “reveals a conscious decision by Congress to give endangered species priority over the ‘primary missions’ of federal agencies.”⁴³ Federal agencies are obliged “to afford first priority to the declared national policy of saving endangered species.”⁴⁴

Section 7(a)(2) of the ESA requires every federal agency to consult the appropriate federal fish and wildlife agency—FWS, in the case of land and freshwater species—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.⁴⁵ To facilitate compliance with section 7(a)(2)’s prohibitions on jeopardy and adverse modification, the ESA requires each federal agency that plans to undertake an action to request information from FWS “whether any species which is listed or proposed to be listed [as an endangered species or a

³⁴ 7 U.S.C. §§ 7701–7772.

³⁵ *Id.* § 7712(a); 7 C.F.R. §§ 2.22(a), 2.80(a)(36) (delegating to APHIS).

³⁶ 7 U.S.C. § 7701(1).

³⁷ *Id.* § 7702(10).

³⁸ *Id.* § 7702(14).

³⁹ 7 C.F.R. § 340.6.

⁴⁰ *Id.* § 340.6(d)(3)(i).

⁴¹ 7 U.S.C. § 7701(4); *see id.* § 7712(b).

⁴² *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 180 (1978).

⁴³ *Id.* at 185.

⁴⁴ *Id.*

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

threatened species] may be present in the area of such proposed action.”⁴⁶ If FWS advises the agency that listed species or species proposed to be listed may be present, the agency must then prepare a biological assessment for the purpose of identifying any such species that are likely to be affected by the proposed agency action.⁴⁷

If an agency determines that its proposed action may affect any listed species and/or their critical habitat, the agency generally must engage in formal consultation with FWS.⁴⁸ At the end of the formal consultation, FWS must provide the agency with a “biological opinion” detailing how the proposed action will affect the threatened or endangered species and/or critical habitats.⁴⁹

Migratory Bird Treaty Act

The Migratory Bird Treaty Act (MBTA) implements the obligations of the U.S. under several international treaties and conventions for the protection of migratory birds.⁵⁰ The MBTA mandates that proposed projects must avoid the take of migratory birds entirely and must minimize the loss, destruction, and degradation of migratory bird habitat.⁵¹ The vast majority of U.S. native birds are protected under the MBTA, even those that do not participate in international migrations.⁵² Under the MBTA, “[n]o person may take, possess, import, export, transport, sell, purchase, barter, or offer for sale, purchase, or barter, any migratory bird, or the parts, nests, or eggs of such bird except as may be permitted under the terms of a valid permit.”⁵³

Administrative Procedure Act

The Administrative Procedures Act (APA) sets forth standards that govern judicial review of decisions made by federal agencies.⁵⁴ The APA provides that “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved within the meaning of a relevant statute, is entitled to judicial review thereof.”⁵⁵ Under the APA, an agency decision is unlawful if it is arbitrary or capricious or fails to follow procedures required by law.⁵⁶ Agencies must “articulate a rational connection between the facts found and the choice made.”⁵⁷ An agency’s decision is unlawful if it, *inter alia*, “entirely fail[s] to consider an important aspect of the problem,” “fail[s] to offer any explanation” about an important aspect of the problem, or “offer[s] an explanation for its decision that runs counter to the evidence before the agency.”⁵⁸

⁴⁶ 16 U.S.C. § 1536(c)(1).

⁴⁷ *Id.*

⁴⁸ 50 C.F.R. § 402.14.

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

⁵⁰ 16 U.S.C. § 701.

⁵¹ *Id.* § 701–712.

⁵² *See* 50 C.F.R. § 10.13.

⁵³ *Id.* § 21.11.

⁵⁴ 5 U.S.C. § 706.

⁵⁵ *Id.* § 702.

⁵⁶ *Id.* § 706(2)(A), (D).

⁵⁷ *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43, 59 (1983).

⁵⁸ *Id.* at 43, 56.

III. COMMENTS

A. *APHIS's NEPA Analysis Is Inadequate*

NEPA is our national charter for protection of the environment.⁵⁹ It is designed to ensure that federal agencies take a hard look at the environmental consequences of their actions.⁶⁰ For the many reasons discussed in these comments, APHIS's EA is woefully inadequate under NEPA: in short, the agency has failed to take the requisite "hard look at the environmental consequences" of the proposed action to approve GE potatoes.⁶¹ NEPA's fundamental tenets include ensuring comprehensive, timely, and transparent environmental review of agency actions, and this EA fails to meet those obligations.

1. *Process and Public Participation*

NEPA "is a procedural statute intended to ensure environmentally informed decision-making by federal agencies."⁶² In taking a "hard look" at the consequences of major decisions, agencies are required to "involve the public in preparing and implementing their NEPA procedures."⁶³ Further, agencies have an obligation to afford "interested persons an opportunity to participate in the rule making."⁶⁴

The very purpose of NEPA is to "ensure that federal agencies are informed of environmental consequences before making decisions and that the information is available to the public."⁶⁵ Meaningful and effective public participation is one of the cornerstones of NEPA because it gives the public an opportunity to inform the agency of environmental consequences the agency may not have considered. For this reason, NEPA's implementing regulations require that agencies "make diligent efforts to involve the public in preparing and implementing their NEPA procedures."⁶⁶ Thus, the agency must "hold or sponsor public hearings or public meetings whenever appropriate"⁶⁷ and "provide public notice of NEPA-related hearings, public meetings, and the availability of environmental documents" so that interested persons can be informed.⁶⁸ Also, federal agencies must to the fullest extent possible "encourage and facilitate public involvement in decisions which affect the quality of the human environment."⁶⁹

Here, APHIS has failed to make an adequate effort to engage public participation in its review of this petition for the deregulation of GE potatoes. Many Americans across the country grow potatoes, and nearly all Americans consume potatoes, but most do not check the Federal Register for actions. For an action that could potentially have far reaching impacts for potato

⁵⁹ 40 C.F.R. § 1500.1(a).

⁶⁰ See, e.g., *Sierra Club v. Bosworth*, 510 F.3d 1016, 1018 (9th Cir. 2007).

⁶¹ See, e.g., *Friends of the Payette*, 988 F.2d at 993; see also *Overton Park*, 401 U.S. at 416.

⁶² *Tillamook Cnty. v. U.S. Army Corps of Eng'rs*, 288 F.3d 1140, 1142 (9th Cir. 2002).

⁶³ 40 C.F.R. § 1506.6(a).

⁶⁴ 5 U.S.C. § 553(c).

⁶⁵ *Citizens to Preserve Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 970–71 (9th Cir. 2003).

⁶⁶ 40 C.F.R. § 1506.6(a).

⁶⁷ *Id.* § 1506.6(c).

⁶⁸ *Id.* § 1506.6(b).

⁶⁹ *Id.* § 1500.2(d).

growers and consumers, APHIS should have done significantly more to solicit public comment. Appropriate actions to engage the public would include open houses, especially in areas where potato growing constitutes an important segment of the economy. APHIS has undertaken similar public outreach in the past related to the agency's assessment of other GE crops. The lack of notice of this action outside of the Federal Register makes it very difficult for most people to provide meaningful input to APHIS. For this reason, APHIS should not proceed with any action until and unless it publishes an EIS and, concurrent with a new public comment period, and provides the public with meaningful opportunities to give feedback by hosting open houses.

2. *APHIS Fails to State a Valid Purpose and Need for Approving GE Potatoes*

In preparing a NEPA document and determining the appropriate scope of analysis, the first thing an agency must define is the project's purpose.⁷⁰ The purpose and need statement is one of NEPA's threshold requirements, but in this EA, APHIS completely fails to articulate a purpose and need for this proposed action. APHIS simply states that it "must respond to petitioners that request a determination of the regulated status of GE organisms," and that in so doing it must "determine whether the regulated [GE organism] is unlikely to present a greater plant pest risk than the unmodified organism."⁷¹

APHIS thus explains why it must *consider* this petition, but the agency *entirely fails to identify a purpose and/or need for approving deregulation of the GE potatoes*. The purpose and need of a proposed action is not just the agency is considering the action; rather, the purpose and need statement must actually describe the underlying purpose and need for the proposed action. APHIS briefly describes Simplot's intent behind genetically engineering the GE potatoes, which is to reduce acrylamide potential and reduce browning,⁷² but the few sentences devoted to this in the purpose and need section do not describe why either facilitating more consumption of potatoes or reducing visible signs of damage (i.e., browning) is a compelling enough problem to necessitate such a drastic measure as approving the first GE potato in the U.S.

APHIS is contemplating a major action but provides no meaningful insight into the purpose or need for deregulating these GE potatoes. The agency cannot possibly take the requisite "hard look" where it has hardly articulated a purpose and need for the underlying action.

3. *APHIS Fails to Consider a Reasonable Range of Alternatives*

NEPA analysis "shall serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made."⁷³ APHIS appears to violate the statute's fundamental function by not even considering reasonable range of alternatives in its analysis because it does not evaluate alternatives that would minimize the environmental impacts of the proposed action. This type of resigned attitude calls into doubt

⁷⁰ See *Citizens Against Burlington, Inc. v. Busey*, 938 F.2d 190, 195–96 (D.C. Cir. 1991).

⁷¹ EA at 3.

⁷² EA at 2.

⁷³ 40 C.F.R. § 1502.02(g); see *id.* § 1500.1(c) ("NEPA's purpose is not to generate paperwork—even excellent paperwork—but to foster excellent action.").

whether it is undertaking this NEPA process to engage in informed decision making or whether this is simply a paper exercise. NEPA calls upon APHIS to fully consider the impacts revealed by its NEPA analysis. Here, however, APHIS’s alternatives analysis reveals a lackluster position toward the analysis in its entirety.

NEPA requires agencies to “[s]tudy, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources.”⁷⁴ Regardless of whether an EA or EIS is prepared, NEPA “requires that alternatives be given full and meaningful consideration.”⁷⁵ In fact, the alternatives section is considered the heart of an environmental analysis.⁷⁶ “[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.”⁷⁷ Agencies must therefore rigorously explore and objectively evaluate all reasonable alternatives, including the no action alternative.⁷⁸

First, despite the rigor required by NEPA, APHIS’s EA presents no serious analysis of potential alternatives. Instead, APHIS merely provides a review of just two options, stating, “Two alternatives are evaluated in this EA: (1) no action and (2) determination of nonregulated status of event.”⁷⁹ It is a classic NEPA violation to limit the consideration of alternatives simply to (1) action or (2) no action.⁸⁰

Second, APHIS’s alternatives analysis is fundamentally flawed because it is—like the rest of the EA—far too limited in scope. An agency’s alternatives analysis should be a function of the “purpose and need” of the action under review,⁸¹ and NEPA requires APHIS to consider and evaluate a wide range of alternatives capable of addressing the same problem.⁸² However, in its EA, APHIS inexplicably limits its alternatives. NEPA also requires that the alternatives considered must include a “range of reasonable actions which might meet the goals of the agency by using different approaches which may reduce the environmental impacts of the agency’s action.”⁸³ This necessarily includes, among other things, the following examples:

- Identify alternate ways to stop browning in potatoes.
- Selectively breeding non-GE potato varieties that naturally are not as susceptible to browning, or that have lower acrylamide potential. For example, the Food and Drug

⁷⁴ 42 U.S.C. § 4331(2)(E).

⁷⁵ *Bob Marshall Alliance v. Hodel*, 852 F.2d 1223, 1229 (9th Cir. 1988).

⁷⁶ 40 C.F.R. § 1502.14.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ EA at 41.

⁸⁰ *See, e.g., Muckleshoot Indian Tribe v. U.S. Forest Serv.*, 177 F.3d 800, 813–14 (9th Cir. 1999) (consideration of only unqualified deregulation and the no action alternative is presumptively too limited to comply with NEPA); *Am. Oceans Campaign v. Daley*, 183 F. Supp. 2d 1, 17–21 (D.D.C. 2000).

⁸¹ *See* 40 C.F.R. § 1502.13 (agency must “specify the underlying purpose and need to which the agency is responding in proposing the alternatives”); *City of Carmel-By-The-Sea v. U.S. Dep’t of Transp.*, 123 F.3d 1142, 1155 (9th Cir. 1995) (“The stated goal of a project necessarily dictates the range of ‘reasonable’ alternatives and an agency cannot define its objectives in unreasonably narrow terms.”) (citation omitted).

⁸² 40 C.F.R. § 1502.13; *see, e.g., City of Carmel-By-The-Sea*, 123 F.3d at 1155.

⁸³ *See, e.g., Soda Mountain Wilderness Council v. Norton*, 424 F. Supp. 2d 1241, 1265 (E.D. Cal. 2006).

Administration (FDA) has observed that conventional breeding has “shown promise” in reducing acrylamide potential.⁸⁴

- Use products like citric acid, enzymes such as asparaginase, and amino acids that substitute for asparagine.
- Avoid use of dextrose, which increases acrylamide levels.
- “Selecting potato varieties that are low in reducing sugars, keeping in mind seasonal variation, may help reduce acrylamide.”⁸⁵
- “Optimizing potato maturity by controlling planting time, harvest time, and input management, and by removing immature tubers before processing, may help reduce acrylamide.”⁸⁶
- “Avoiding handling potatoes with excessive roughness, avoiding bruising potatoes, and sorting out or carefully trimming potatoes with defects may help reduce acrylamide.”⁸⁷
- “Avoiding cold temperatures during harvest, transport, and delivery may help reduce acrylamide.”⁸⁸
- “Managing storage conditions to control sprouting and provide ventilation may help reduce acrylamide.”⁸⁹
- “Monitoring reconditioning results and avoiding reconditioning potatoes stored for prolonged periods may help reduce acrylamide.”⁹⁰
- “Assessing reducing sugar levels in incoming potatoes, identifying target levels for incoming potatoes, or using treatments to reduce sugar levels may help reduce acrylamide.”⁹¹
- Developing training programs for conversion to higher-value organic potato production.

In fact, FDA has published an entire, thirty-seven-page draft guidance on reducing acrylamide in foods that identifies numerous, readily available alternatives to genetically engineering potatoes.⁹² Here, in its alternatives analysis, APHIS simply must consider the alternatives suggested by its sister agency, FDA.

As those unconsidered alternatives demonstrate, using genetic engineering, with its consequent potential for significant environmental and socioeconomic harms, to silence potato genes truly is not the only reasonable alternative to reducing potato browning or acrylamide potential. Indeed, as APHIS acknowledges, to comply with a California law limiting acrylamide contents, and in response to litigation from 2005, potato chip manufacturers agreed to significantly reduce the acrylamide in their products.⁹³ NEPA mandates that APHIS give meaningful consideration to alternatives.

⁸⁴ FDA at 6.

⁸⁵ *Id.* at 9.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² See Draft Guidance for Industry on Acrylamide in Foods; Availability, 78 Fed. Reg. 68,852 (Nov. 15, 2013).

⁹³ EA at 33.

Third, as a consequence of the overly narrow design of APHIS's alternatives discussion, the commercialization of these GE potatoes may become a foregone conclusion. "An agency may not define the objectives of its actions in such unreasonably narrow terms as to make consideration of alternatives a mere formality."⁹⁴ Relatedly, such a tunnel-vision focus also impermissibly accepts OSF's own biased representation of its product, ignoring that "NEPA requires an agency to 'exercise a degree of skepticism in dealing with self-serving statements from a prime beneficiary of the project and to look at the general goal of the project rather than only those alternatives by which a particular applicant can reach its own specific goals.'"⁹⁵

Fourth, APHIS's purported reliance on a separate PPRA determination underscores that in APHIS's view the entire NEPA process is a predetermined façade, because the agency is making/has made a separate decision, pursuant to which the agency's hands are otherwise purportedly tied. Under this reasoning, presumably APHIS would then have no authority to restrict or deny approval of the GE potato, even if the agency's NEPA analysis concluded it would cause irreparable environmental harm or the collapse of the U.S. potato industry. Yet this would turn the NEPA review process into a charade, and subvert the requirement that "[e]nvironmental impact statements shall serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made."⁹⁶ APHIS would violate NEPA's fundamental goal if the agency erroneously concluded that it need not or could not take into account what its NEPA analysis reveals. In fact, APHIS has the NEPA analysis process *precisely backwards*: The NEPA analysis must inform the agency's decision-making process, not the other way around.⁹⁷ NEPA requires that environmental considerations be factored into government decision-making "early enough so that it can serve practically as an important contribution to the decisionmaking process and will not be used to rationalize or justify decisions already made."⁹⁸

Here, however, APHIS summarily rejects alternatives without fully considering them on the basis that the PPA precludes those options. For example, the agency provides only cursory information about creating an isolation distance between these GE potatoes and non-GE potato varieties, or requiring testing for these GE varieties.⁹⁹ Doing so impermissibly eviscerates APHIS's NEPA responsibilities. Consequently, the agency fundamentally failed to consider reasonable alternatives in its EA.

⁹⁴ *Citizens Against Burlington, Inc.*, 938 F.2d at 196.

⁹⁵ *Env'tl. Law & Policy Ctr. v. U.S. Nuclear Regulatory Comm'n*, 470 F.3d 676, 683 (7th Cir. 2006); see *Forty Most Asked Questions Concerning CEQ's NEPA Regulations*, 48 Fed. Reg. 18,026 (Mar. 23, 1981) ("In determining the scope of alternatives to be considered, the emphasis is on what is 'reasonable' rather than on whether the proponent or applicant likes or is itself capable of carrying out the particular alternative. Reasonable alternatives include those that are practical or feasible from a technical and economic standpoint and using common sense, rather than simply desirable from the standpoint of the applicant.").

⁹⁶ 40 C.F.R. § 1502.02(g); see *id.* § 1500.1(c) ("NEPA's purpose is not to generate paperwork—even excellent paperwork—but to foster excellent action.").

⁹⁷ *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 491 (9th Cir. 2011) ("The 'hard look' must be taken objectively and in good faith, not as an exercise in form over substance, and not as a subterfuge to rationalize a decision already made.") (internal citations and quotation marks omitted).

⁹⁸ *Metcalf v. Daley*, 214 F.3d 1135, 1142 (9th Cir. 2000).

⁹⁹ EA at 43–44.

4. *APHIS Fails to Properly Consider Cumulative Impacts*

Cumulative impacts are “the 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 time.”¹⁰⁰ A thorough consideration of cumulative impacts is required in the preparation of an EA.¹⁰¹ Specifically, an EA must provide a quantified assessment of project’s environmental impacts when combined with other projects.¹⁰² Notably, courts and the CEQ emphasize that a detailed cumulative impacts analysis is especially important in an EA, because there is a much higher risk of cumulative impacts resulting from many smaller decisions for which EAs are prepared.¹⁰³

It is well-established that “a cumulative impacts analysis must include ‘some quantified or detailed information’ since without such information it is not possible for the court or the public to be sure that the agency provided the hard look that is required of its review.”¹⁰⁴ In a cumulative impact analysis, “general statements about possible effects and some risk do not constitute a hard look. . . . The cumulative impact analysis must be more than perfunctory; it must provide a ‘useful analysis of the cumulative impacts of past, present, and future projects.’”¹⁰⁵ Moreover, a cumulative impact analysis must be timely: “it is not appropriate to defer consideration of cumulative impacts to a future date when meaningful consideration can be given now.”¹⁰⁶ “If the agency did not present this detailed information and analysis it will be found to have violated NEPA unless it provides a convincing justification as to why more information could not be provided.”¹⁰⁷

In order to address the cumulative impact requirement, APHIS must examine and evaluate the cumulative impacts of reasonably foreseeable actions. Here, however, APHIS’s brief, perfunctory cumulative impacts analysis omits a number of reasonably foreseeable actions.¹⁰⁸ For example, the agency does not account for the fact that Simplot has stated its intention to cross these GE potatoes with other varieties, and to introduce other GE potatoes. If there are harms related to the RNAi process, APHIS can assume that the harms will be similar in the additional GE varieties. As discussed above, harms from the RNAi may take a particularly significant toll on pollinators, including bees, which are already under significant environmental stress and therefore are especially vulnerable. But APHIS entirely failed to consider such cumulative impacts on pollinators.

¹⁰⁰ 40 C.F.R. § 1508.7.

¹⁰¹ See, e.g., *Kern*, 284 F.3d at 1075.

¹⁰² *Great Basin Mine Watch*, 456 F.3d at 972.

¹⁰³ See, e.g., *Native Ecosystems Council*, 304 F.3d 886; *Kern*, 284 F.3d. at 1076, 1078.

¹⁰⁴ *Soda Mountain Wilderness Council*, 424 F. Supp. 2d 1241.

¹⁰⁵ *Muckleshoot Indian Tribe*, 177 F.3d at 810.

¹⁰⁶ *Neighbors of Cuddy Mountain*.

¹⁰⁷ *Id.* The cumulative impact analysis is wholly distinct from the scope requirements and analysis discussed above. See *Earth Island Inst. v. U.S. Forest Serv.*, 351 F.3d 1291, 1306 (9th Cir. 2003) (“Even if a single, comprehensive EIS is not required, the agency must still adequately analyze the cumulative effects of the projects within each individual EIS.”).

¹⁰⁸ EA at 52–54.

Similarly, the agency failed to adequately consider cumulative impacts on the potato market. The cumulative impact analysis must include an assessment of potential aesthetic, historic, cultural, economic, social, and health impacts.¹⁰⁹ Here, however, APHIS's cumulative impacts analysis lacks the requisite detail. For example, APHIS acknowledges that the Simplot GE potato "could have cumulative economic impacts" on both the domestic potato market and the potato export market.¹¹⁰ But the agency completely omits any discussion of the cumulative impacts deregulation of these GE potatoes will have on consumer preferences, and thus on potato growers. Markets for potatoes and potatoes products are likely to be—and have historically been—cautious about GE technologies. Accordingly, APHIS must assess both contamination routes (e.g., mixing after harvest during transport) and also the likely significant adverse socioeconomic impacts of approval of the Simplot GE potatoes. Further, APHIS must consider the effects that the very potential for such contamination may have on consumers, who may avoid potatoes to prevent unintended contact with the GE varieties.

In addition, APHIS must consider the cumulative effects of possible increased pesticide use as a result of the GE potatoes. However, APHIS failed to adequately consider the potentially reduced pathogen resistance in these GE potatoes, instead evaluating them only under unrealistically limited and highly controlled circumstances. Thus, in order to assess the cumulative effects of increased pesticide use on these GE potatoes, as it must, APHIS needs to perform the initial step of adequately investigating the pathogen-resistance effects of Simplot's genetic engineering, which the agency has not done in its EA and PPRA.

As indicated in the record and public comments, the potential significant socioeconomic, cultural and other foreseeable impacts are considerable. The cumulative socioeconomic analysis APHIS must perform should include an analysis of both the economic and cultural importance of potatoes, demographics of the communities that would be impacted, an analysis of potential impacts to commercial potato industries, and an analysis of the market impacts of this product's commercialization.

Thus, APHIS must prepare an EIS to evaluate the cumulative impacts related to the deregulation of these GE potatoes.

5. *APHIS Fails to Adequately Consider Socioeconomic Impacts*

APHIS fails to adequately address potential adverse socio-economic effects from the deregulation of these GE potatoes. Potentially significant adverse socio-economic impacts trigger the need for APHIS to prepare an EIS.

NEPA requires that economic effects are relevant and must be examined "when they are interrelated with natural or physical environmental effects." As the court explained in *Geertson Seed Farms*: "The economic effects on the organic and conventional farmers of the

¹⁰⁹ 40 C.F.R. § 1508.8; *see, e.g., id.* § 1508.14 (when "economic or social and natural or physical environmental are interrelated," then the NEPA analysis must discuss "all of these effects on the human environment"); *Wyoming*, 661 F.3d at 1251 (cumulative impacts analysis must consider all of the effects listed at 40 C.F.R. § 1508.8).

¹¹⁰ EA at 69–70.

government's deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment; namely, the alteration of a plant species' DNA through the transmission of the genetically engineered gene to organic and conventional alfalfa."¹¹¹ The court continued, "APHIS was required to consider those effects in assessing whether the impact of its proposed action is 'significant.'"¹¹²

Past contamination episodes from GE crops provide cautionary tales for why contamination is an important potential socioeconomic impact that must be considered here. For example, of particular interest is the recent contamination of rice by the unapproved GE LL601 "Liberty Link" rice. This type of GE rice was grown only in limited-acreage field tests, rather than on a commercial scale, and under the regulatory auspices of APHIS, which includes confinement recommendations. It had not been grown at all for several years, but contamination of the US rice supply was detected several years later at low levels that have nonetheless caused economic harm to the US rice industry. At least one identified source of contamination by LL601 occurred at Louisiana State University LSU, where one of the scientists in charge has claimed that they exceeded APHIS confinement recommendation considerably, but still experienced contamination.

By one estimate, rice farmers lost \$150 million due to rejection of LL601-contaminated rice shipments by countries in Europe and elsewhere, and the consequent sharp drops in rice prices. 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. At least one identified source of contamination by LL601 occurred at Louisiana State University, where LL601 had been grown in small-scale field trials. One of the scientists in charge of the field-testing stated that LSU had grown LL601 under conditions that met and exceeded APHIS confinement recommendations considerably, but still experienced contamination. 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 (i.e., Clearfield 131).

APHIS responded by issuing several emergency action notifications to distributors of Clearfield 131 to halt sales of the contaminated seed rice. As a result, rice farmers in the South experienced a severe shortage of seed rice for the 2007 season. APHIS conducted an investigation into the contamination episodes, but was unable to determine precisely how they occurred.

Here, the potato market potentially impacted by contamination from GE potatoes is significant. As APHIS reports, potatoes, which are America's "leading vegetable crop,"¹¹³ are grown across much of the continental U.S., and annual U.S. potato harvests range between 1 million and 1.5 million acres.¹¹⁴ In 2012, U.S. potatoes were valued at \$3.9 billion,¹¹⁵ and in

¹¹¹ *Geertson Seed Farms v. Johanns*, No. C-06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

¹¹² *Id.*

¹¹³ EA at 36.

¹¹⁴ *Id.* at 10.

2012/2013, U.S. exports of potatoes totaled nearly \$1.6 billion.¹¹⁶ Given that many other countries reject GE products, contamination from these GE potatoes could be catastrophic for U.S. potato growers. Further, consumers within the U.S. increasingly reject GE products, so a contamination event with GE potatoes would have substantial domestic effects as well.

Despite the potential for contamination, APHIS failed to address the socioeconomic effects such contamination would have. APHIS should have thoroughly considered the impacts of GE potatoes on communities where potato growing is a significant source of income, amongst other socioeconomic impacts. In this case, as in *Geertson*, “APHIS’s reasons for concluding that the potential for the transmission of the genetically engineered gene is not significant are not ‘convincing’ and do not demonstrate the ‘hard look’ that NEPA requires.” Thus, APHIS must prepare an EIS to disclose and analyze the potential for biological contamination prior to deregulating these GE potatoes.

6. APHIS Fails to Adequately Consider Trans-Boundary Impacts

APHIS failed to adequately consider the impacts of approving GE potatoes on other nations. CEQ regulations explicitly state an agency must assess the cumulative impacts of the project when added to “all other past, present and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions.”¹¹⁷ A 1997 CEQ guidance clarifies that “NEPA law directs federal agencies to analyze the effects of proposed actions to the extent they are reasonably foreseeable consequences of the proposed action, *regardless of where those impacts might occur.*”¹¹⁸ CEQ concluded that “agencies must include analysis of *reasonably foreseeable transboundary effects* of proposed actions in their analysis of proposed actions in the United States.”¹¹⁹

In this EA, APHIS only briefly considers the market impacts of GE potatoes to foreign trade,¹²⁰ but does not consider the full range of potential trans-boundary environmental impacts. APHIS also states that it considered international implications pursuant to Executive Order 12114,¹²¹ but its analysis here is lacking in that it simply recites its obligations under various treaties without actually considering potential impacts. Much of the U.S. potato industry is in northern states, in relatively close proximity to Canada, so APHIS should consider reasonably foreseeable trans-boundary impacts in accordance with CEQ’s guidance.

¹¹⁵ *Id.* at 36.

¹¹⁶ *Id.* at 39.

¹¹⁷ 40 C.F.R. §1508.7.

¹¹⁸ Council on Environmental Quality Guidance on NEPA Analyses for Transboundary Impacts, July 1, 1997, available at <http://ceq.hss.doe.gov/nepa/regs/transguide.html> (last visited June 30, 2014).

¹¹⁹ *Id.* ¶ 6 (emphasis added).

¹²⁰ EA at 38.

¹²¹ EA at 63.

7. *APHIS Relies on Unenforceable Simplot Assurances in Lieu of Actual Mitigation Measures*

Under NEPA, mitigation must be enforceable, which includes the duty of on-going monitoring to ensure compliance.¹²² “Monitoring is essential in those important cases where the mitigation is necessary to support a FONSI and thus is part of the justification for the agency’s determination not to prepare an EIS.”¹²³ APHIS fails to adequately explain or analyze how it will monitor compliance with the OSF mitigation measures upon which it depends. Mitigation measures cannot substitute for actually analyzing environmental impacts.¹²⁴ This is precisely what APHIS has improperly done here, relying solely on OSF’s measures and failing to analyze the potential impacts.

CEQ defines “mitigation” to include

- (a) Avoiding the impact altogether by not taking a certain action or parts of an action.
- (b) Minimizing impacts by limiting the degree or magnitude of the action and its implementation.
- (c) Rectifying the impact by repairing, rehabilitating, or restoring the affected environment.
- (d) Reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action.
- (e) Compensating for the impact by replacing or providing substitute resources or environments.¹²⁵

Courts examine mitigated FONSI to see whether such measures keep impacts below the EIS threshold, which is the “low standard” of whether a project “may have a significant effect.”¹²⁶ APHIS’s reliance here does not comply with NEPA.

In its EA, APHIS’s discussion of mitigation measures is entirely inadequate. The agency recognizes the concern that Simplot’s GE potatoes may contaminate organic growers but simply observes that such growers may impose their own isolation distances:

individuals might choose on their own to geographically isolate their non-GE potato production systems from potato or to use isolation distances and other management practices to minimize gene movement between potato fields. Information to assist growers in making informed management decision for Simplot Innate™ Potato is available from Association of Official Certifying Agencies.¹²⁷

¹²² Council on Env’tl. Quality, *Appropriate Use of Mitigation and Monitoring and Clarifying the Appropriate Use of Mitigated Findings of No Significant Impact* 7 n.18 (2011); *id.* at 2 (explaining that when agencies do not “monitor mitigation commitments to determine if mitigation was implemented or effective, the use of mitigation may fail to advance NEPA’s purpose of ensuring informed and transparent environmental decisionmaking”).

¹²³ *Id.* at 10.

¹²⁴ *See, e.g., N. Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1085–86 (9th Cir. 2011).

¹²⁵ 40 C.F.R. § 1508.20.

¹²⁶ *See, e.g., Klamath Siskiyou Wildlands Ctr. v. Boody*, 468 F.3d 549, 562 (9th Cir. 2006).

¹²⁷ EA at 43–44.

But such voluntary measures, which do not even involve Simplot, are entirely unreliable, and APHIS cannot lawfully rely on such voluntary mitigation measures to avoid a finding of significance and the requirement to prepare an EIS.

Simplot acknowledges that “[r]isks to organic growers would be most likely to occur with accidental mixing of planting material or of potatoes in farming, transportation, or processing channels,” and that domestic and export markets mandate that GE and non-GE varieties be tracked.¹²⁸ However, Simplot simply makes vague, unfounded assertions that “international approvals will be pursued from key trading partner countries before the Innate™ varieties are launched commercially,” and that the GE potatoes “will be controlled within existing processing channels to ensure that potatoes enter only the intended markets.”¹²⁹ According to the company, this supply chain and system of separation from non-GE potato varieties “will be well controlled by grower and processor agreements.”¹³⁰ However, voluntary measures as part of technology use agreements are not reliable. More importantly, APHIS cannot rely on such voluntary mitigation measures to avoid a finding of significance and the requirement to prepare an EIS.

Vague references to the mere concept that some hypothetical measures may prevent contamination are insufficient to absolve APHIS of its NEPA duties. As CEQ has warned, “as a general rule . . . agencies should use a broad approach in defining significance and should not rely on the possibility of mitigation [of adverse environmental consequences] as an excuse to avoid the EIS requirement.”¹³¹ APHIS should heed this guidance and prepare an EIS analyzing, among other things, concrete stewardship measures such as quantitative isolation distances that actually prevent biological contamination.

That APHIS merely relies on the vague notion of grower and processor agreements is clearly insufficient. CEQ has indicated that “[m]itigation measures may be relied upon to make a finding of no significant impact only if they are imposed by statute or regulation, or submitted by an applicant or agency as part of the original proposal.”¹³² Here, no stewardship measure is required, never mind concretely explained. Nor has APHIS considered reasonable alternatives to the proposed action or propose any monitoring. The sufficiency of mitigation measures has been stated as whether they constitute “an adequate buffer against the negative impacts that may result from the authorized activity.”¹³³ While APHIS admits that contamination is a major public concern, the agency has not undertaken any of its own analysis regarding whether Simplot’s proposed voluntary measures might prevent such contamination.¹³⁴

¹²⁸ Simplot Petition at 61, 63.

¹²⁹ *Id.* at 63.

¹³⁰ *Id.*

¹³¹ Forty Most Asked Questions Concerning CEQ’s National Environmental Policy Act Regulations, 46 Fed. Reg. 18026, 18037 (1981).

¹³² *Id.*

¹³³ *Nat’l Parks & Conservation Ass’n*, 241 F.3d 722.

¹³⁴ In *Geertson*, APHIS similarly relied on “good stewardship” with regard to the development of weed resistance, without APHIS’s own investigation and analysis of if that stewardship was effective or not, a reliance the court held arbitrary and capricious without APHIS own analysis, which it agreed to do in the alfalfa EIS. 2007 WL 5186624, at *10.

This, combined with all the other inadequacies described above, shows that APHIS's EA fails to comply with NEPA's mandates.

B. *APHIS Fails to Consider Critical Issues, Rendering This EA Inadequate Because the Environmental Effects of GE Potatoes Remain Highly Uncertain*

APHIS's decision to not complete a comprehensive EIS is arbitrary, capricious, and contrary to NEPA, in large part because it has violated the basic principle that NEPA—at its core—contemplates high-quality information and accurate scientific analysis.¹³⁵ Public scrutiny is essential to implementing NEPA.¹³⁶ The draft EA is inadequate because it does not contain actual analysis or real data supporting APHIS's decision; it primarily contains narratives of OSF's background information, much of which is quite dated.

“In the absence of such fundamental information, it would seem that any alleged ‘finding’ that the project will not significantly affect the species is the purest sophistry.”¹³⁷ Accepting APHIS's failure to study the potential harms here “would turn NEPA on its head, making ignorance into a powerful factor in favor of immediate action where the agency lacks sufficient data to conclusively show not only that the proposed action would harm an endangered species, but that the harm would prove to be ‘significant.’”¹³⁸ At the very least, APHIS is required to disclose uncertainties, explain their relevance, and has the burden to show why the necessary information could not be obtained.¹³⁹

Underlying all discussion in the following section is one basic premise of NEPA. At its core, NEPA demands high-quality information and accurate scientific analysis.¹⁴⁰ As this section makes plain, this EA is severely lacking in both. In sum, APHIS's failure to conduct the proper analyses and account for the many potential risks and uncertainties implicit in this petition is plain evidence that the agency did not take the requisite “hard look” at the environmental consequences of this application, and is overtly arbitrary, capricious, and contrary to law.

Specifically, here, in its petition, Simplot relies primarily on several years of field trials to determine whether its potatoes present any characteristics that could cause environmental harm, and APHIS accepts the resulting data as demonstration of safety under the relevant statutes. But the *asn1* gene is important to many aspects of plant nitrogen metabolism, often in response to particular environmental conditions, which do not occur in all years or sites. For example, *asn1* is involved in both biotic (pathogen) and abiotic stress response.¹⁴¹

¹³⁵ 40 C.F.R. § 1500.1(b).

¹³⁶ *Id.* §1500.1.

¹³⁷ *Sierra Club v. Norton*, 207 F. Supp. 2d 1310, 1331 (S.D. Ala. 2002) (finding agency's FONSI arbitrary and capricious because it failed to address lack of certainty).

¹³⁸ *Id.* at 1335.

¹³⁹ 40 C.F.R. § 1502.22; see *Env'tl. Prot. Info. Ctr. v. Blackwell*, 389 F. Supp. 2d 1174, 1188 (N.D. Cal. 2004) (recognizing that 40 C.F.R. § 1502.22 guides the court in determining “whether an agency can be charged with having failed to take a hard look” because information is incomplete or unavailable).

¹⁴⁰ 40 C.F.R. § 1500.1(b).

¹⁴¹ L. Gaufichon et al., *Biological Function of Asparagine Synthetase in Plants*, 1279 *Plant Sci.* 141, 141–53 (2010).

Simplot provided limited information about environmental conditions in its plots and little about the presence of many pests and pathogens. Pests, and plant diseases in particular, are dependent not only on presence and populations of pests, but also on weather, which can drastically influence crop susceptibility or pest reproduction and growth. The lack of adequate field trial site information, and the likelihood that many potentially relevant conditions would not have occurred during these field trials, or not occurred frequently enough to provide statistically meaningful data, mean that there is not sufficient data for APHIS to have provided a “hard look” as required by NEPA.

Preparation of an EIS is mandated where uncertainty may be resolved by further collection of data, or where the collection of such data may prevent speculation on potential effects. “The purpose of the EIS is to obviate the need for speculation by insuring that available data are gathered and analyzed prior to the implementation of the proposed action.”¹⁴² “Where an EA lacks certainty on one or more issues, it is the responsibility of the agency to provide a ‘justification regarding why more definitive information could not be provided.’”¹⁴³ “Lack of knowledge does not excuse the preparation of an EIS; rather it requires the [agency] to do the necessary work to obtain it.”¹⁴⁴ Here, APHIS lacks crucial information about Simplot’s GE potatoes, so an EIS is required.

1. Possible Increase in Susceptibility to Plant Pathogens

In its petition for deregulation, Simplot acknowledged possible concern that reduction of *asn1* expression in leaves may, in theory, adversely affect important aspects of asparagine metabolism. In response, they claim that the promoter used to express the *asn1* gene, the potato ADP-glucose pyrophosphorylase gene (AGP) is only poorly expressed in tissues other than the tuber and stolon. Therefore, Simplot argues, there should be minimal silencing of *asn1* in potato tissues other than the tuber and stolons.

Simplot presents data in its petition for de-regulation in Appendix 5, Figure 9, from a Northern blot of *asn1* mRNA from potato leaf tissue. The company claims this shows that *asn1* is not appreciably silenced in leaf tissue. Simplot does acknowledge that one event does show some silencing in leaves. However, this figure shows apparently low expression of *asn1* in control leaves—as is expected for constitutive *asn1* expression in uninduced leaves—as well as in transgenic leaves. The bands representing *asn1* expression are too faint to reasonably quantify and compare for expression levels. Simplot should have presented better data on silencing, for example, using several dilutions of leaf mRNA and optical scanning to better quantify the RNA in the bands, or using other methods such as quantitative PCR

Additionally, silencing in uninduced leaf tissues is not an adequate test. Hwang et al. demonstrate strong induction of *asn1* transcription in pepper leaves in response to pathogen challenge.¹⁴⁵ This would have been a more meaningful test for silencing in Simplot potato

¹⁴² *Nat'l Parks*, 241 F.3d at 732.

¹⁴³ *Blue Mountain*, 161 F.3d at 1213.

¹⁴⁴ *Id.*

¹⁴⁵ S. Hwang et al., *Pepper Asparagine Synthetase I (CaAS1) Is Required for Plant Nitrogen Assimilation and Defense Response to Microbial Pathogens*, 67 *The Plant J.* 749, 749–62 (2011).

leaves, since possibly increased pathogen susceptibility has been demonstrated by the Hwang et al. research.

However, even if Simplot is accurate in its assessment that leaf expression of *asn1* is not silenced, this could still allow possible unintended harmful phenotypes. For example, important potato pathogens including scab, soft rot, ring rot, and several nematodes, infect the tuber. So if reduced expression did increase pathogen susceptibility, silencing of *asn1* only in the tuber and stolons may not avoid increased disease severity.

Second, it is not clear whether low expression of the transgenic iRNA in leaves or other tissues would avoid impeding the proper expression of *asn1* in the leaves or elsewhere in the potato plant. Low levels of expression of iRNA may sometimes be effective in silencing gene expression.

Simplot seems also to have misread the literature on AGP expression. One reference cited by Simplot, Visser et al (1991), did report low levels of expression of a reporter gene linked to the AGP promoter. However, the later paper cited by Simplot, Nakata et al. (1994) reported that transcription from the AGP promoter was high in leaves (highest in tubers), as shown in a northern blot in figure 6. Nakata et al. also, like Visser et al., found lower expression of a reporter gene in leaves. But this is apparently due to post-transcriptional regulation (based on the northern blot data). *Asn1* iRNA may not be subject to post-transcriptional regulation, which may depend on specific transcribed RNA sequence of the AGP gene, or characteristics of the AGP protein.

If, as suggested by Simplot data, silencing is incomplete in leaves, an intermediate susceptible phenotype might occur, with intermediate increase in disease. For any of these reasons, Simplot's suggestion that *asn1* is not silenced in transgenic potato leaves is not sufficient.

Recent data, not cited by APHIS or Simplot (although published in 2011) provides strong evidence that silencing of the *asn1* gene in pepper—like potato in the Solanaceae family—increases susceptibility to at least some diseases. Hwang et al. show by silencing in pepper, and overexpression in the model plant *Arabidopsis*, that silencing increases disease susceptibility, while overexpression decreases disease in the latter plant species. They also show that expression of *asn1* is up-regulated in response to avirulent (incompatible) pathogens, and is associated with the expression of genes involved in pathogen defense. Together, these data are convincing regarding the importance of *asn1* in resistance to plant disease. While not confirmed in potato, other research in another member of the Solanaceae, tomato, also showed increased expression of *asn1* in response to a bacterial pathogen.¹⁴⁶ In combination, these data suggest that there is a good chance that *asn1* is also involved in disease resistance in potato, and that silencing may make potatoes more susceptible to plant diseases.

¹⁴⁶ F. Olea et al., *Up-regulation and Localization of Asparagine Synthetase in Tomato Leaves Infected by the Bacterial Pathogen Pseudomonas syringae*, 45 *Plant Cell Physiol.* 770, 770–80 (2004).

Both APHIS and Simplot assert that field trial data and inoculations with the late-blight and soft rot pathogens demonstrate that there is no increased disease susceptibility in the transgenic potatoes. Inoculations were expressly intended to test whether silencing of *ppo5* led to increased disease susceptibility, but presumably silencing of *asn1* would be tested as well in these experiments.

Field trial data are inconclusive for the reasons discussed above. Inoculation data showed mixed and inconsistent results. In addition, review of Simplot data show low incidence for most diseases although Simplot's disease rating system is difficult to interpret, and not detailed. Typically, disease severity is provided as well as incidence, because both parameters are needed to evaluate disease susceptibility. Simplot provides only incidence data.

The low incidence of disease may be due to a number of factors such as non-conducive weather for disease development, absence of the pathogens, or masking by treatment with fungicides. Therefore, the field trials cannot be relied upon to be an adequate test of possible increased susceptibility of Simplot potatoes to some pathogens.

It is also possible that susceptibility is not increased to all diseases. Therefore results from inoculations of two diseases cannot be relied upon to determine susceptibility to other diseases. Not enough is known about possible mechanisms associated with the Hwang et al. research to understand whether all pathogens are equally affected. Additional data would be needed to develop confidence that susceptibility is not increased to some pathogens, given the conflicting data from the literature and limitations of the Simplot data.

Increased disease susceptibility could lead to increased pesticide (fungicide or nematicide) application, with possible harm to farmers, farm workers, consumers, or the environment, and possibly increased costs.

2. Not Enough Is Known About the Role of *asn1* to Have Confidence that Silencing Will Not Cause Harm

Asn1 has multiple roles in nitrogen metabolism, including response to multiple environmental cues, such as abiotic stresses that occur sporadically, but are nonetheless important. *Asn1* is important in nitrogen cycling and partitioning in the plant, changes in nitrogen status over the season, and undoubtedly other unrecognized roles.¹⁴⁷

Simplot provided very limited data on the conditions at the test sites in its petition—not enough to evaluate whether they are adequate for concluding that there is no harm from silencing. As with the presence of pests, there is a reasonable likelihood that some of these environmental cues would not occur during the limited field trials conducted by Simplot, and could lead to adverse agronomic effects after widespread commercialization increased the likelihood that environmental triggers would be encountered.

¹⁴⁷ Gaufichon et al. (2010); H.M. Lea et al., *Asparagine in Plants*, 150 Ann. Appl. Biol. 1, 1–26 (2007).

Both Simplot and APHIS assume that no adverse agronomic effects will occur based on limited data and incomplete knowledge of the roles of *asn1* in potatoes. This is an arbitrary and capricious interpretation of the data, and does not qualify as a “hard look” at the possibilities.

3. Yield Data for Half of the Transformation Events Were Significantly Lower than the Non-Transformed Control

Based on Simplot data, yields were often lower than controls by roughly 10 percent. In the other five events, yields showed no significant difference. The directionality (yield differences in engineered events were always lower, never higher, than controls), and number of events with lower yields suggests that it represents a real effect.

Simplot and APHIS inexplicably dismiss these results as not significant agronomically. To the contrary, high yield is typically one of the most important characteristics of crop varieties that farmers look for, because it tends to result in higher profits. APHIS’s and Simplots’ dismissal of the yield data is therefore arbitrary and capricious.

More troubling is that no cause of the lower yields has been discovered. It is possible that lower yield is associated with the transformation process, such as insertion site mutations or interference with the expression of potato genes, mutations or epigenetic effects due to tissue culture, or pleiotropic effects of the transgenes (such as off-target silencing).

In sexually propagated crops, scientists can usually eliminate unlinked mutations due to tissue culture by backcrossing for several generations into untransformed elite cultivars. But this is not generally an option for clonally propagated potatoes.

Alternatively, the yield decrease may be due to diminished stress response or undetected pathogen effects due to reduced expression of one of the target genes such as *asn1* (although yield declines of this magnitude would generally be expected to produce observable signs of disease).

In any case, without understanding the cause of the lower yields, it is not possible to say whether they might result in harm or economic impact to farmers. For example, if it turned out to be the result of plant disease, farmers may respond with higher pesticide use. If it was caused by imbalance in nitrogen metabolism, that might result in increased nitrogen fertilizer use, which is associated with nitrate leaching and water pollution. These examples are speculative, and are merely intended to illustrate how lower yield could translate into environmental harm. Without knowing the actual cause, it is not possible to rule out environmentally harmful results.

4. Incomplete and Inadequate Scientific Analysis and Data

As discussed above, APHIS’s analyses are incomplete and inadequate in numerous ways. In the face of scientific uncertainty, 40 C.F.R. § 1502.22 imposes three mandatory obligations on APHIS: (1) a duty to disclose the scientific uncertainty; (2) a duty to complete independent research and gather information if no adequate information exists (unless the costs are exorbitant

or the means of obtaining the information are not known); and (3) a duty to evaluate the potential, reasonably foreseeable impacts in the absence of relevant information.

Underlying these scientific points is the basic principle that NEPA—at its core—contemplates high-quality information and accurate scientific analysis. Public scrutiny is essential to implementing NEPA. The PPA similarly requires that APHIS’s decisions be based on “sound science.” Here, APHIS’s EA and PPRA are inadequate because they do not disclose the scientific uncertainty surrounding GE crops, and especially use of iRNA technologies. Relatedly, and also contrary to NEPA, APHIS failed to gather information on its own to supplement the gaps in the information provided by Simplot concerning, *inter alia*, nutritional composition and iRNA effects.

Environmental information must be available to the public before decisions are made. One of NEPA’s major goals is to guarantee that relevant information is made available to the public. Without this information, it is extremely difficult, if not impossible for the public, including scientists with the proper expertise, to provide meaningful opinions. This deficiency defeats a primary purpose of NEPA, and is therefore contrary to that law.

C. APHIS Fails to Adequately Consider Impacts to Public Health

Simplot’s GE potatoes, which were designed for human consumption, have the potential to significantly impact human health, and public health issues may be significant environmental impacts requiring the preparation of an EIS. CEQ regulations explain what factors may be significant effects on the human environment and one such factor is “[t]he degree to which the proposed action affects public health or safety.”¹⁴⁸ The presence of one or more of the factors in 40 C.F.R. § 1508.27 may be sufficient to require the preparation of an EIS.¹⁴⁹ Accordingly, APHIS’s analysis must address any potential human health or safety risks and determine whether those human health and safety impacts may be significant. If those impacts are found not to be significant, there must be a convincing statement of reasons.¹⁵⁰

Instead, here, APHIS passes the buck to FDA, under the Federal Food, Drug, and Cosmetic Act,¹⁵¹ but APHIS cannot solely rely on another agency’s evaluation of impacts under a separate statute to adequately fulfill APHIS’s own NEPA obligations. Health impacts are cognizable impacts pursuant to NEPA that require analysis in an EIS if they may significantly impact the “human environment.” Accordingly, APHIS has its own duty to comply with NEPA, including assessment of potential significant impacts to public health and safety.

In addition to being contrary to NEPA, there is a second reason APHIS should not defer completely to FDA: FDA’s GE consultation process, which is merely voluntary, is extraordinarily weak and therefore fails to adequately assess human health impacts. That consultation process is based on a statement of policy, not a binding regulation. GE crop

¹⁴⁸ 40 C.F.R. § 1508.27(b)(2).

¹⁴⁹ *Nat’l Parks & Conservation Ass’n*, 241 F.3d at 731; *Pub. Serv. Co. of Colo. v. Andrus*, 825 F.Supp. 1483, 1495 (D. Idaho 1993).

¹⁵⁰ *Nat’l Parks & Conservation Ass’n*, 241 F.3d at 731.

¹⁵¹ EA at 30.

developers may choose to consult with FDA, but this process is vitiated by its voluntary nature and a lack of any established testing standards; in particular, GE crop developers seldom if ever conduct animal feeding trials with GE crops for the purpose of detecting potential toxicity. The manufacturer merely sends FDA a summary of its findings. FDA makes no findings of safety.

It is well accepted that genetic engineering has a greater likelihood of producing unintended effects than traditional breeding, some of them hazardous or detrimental. Unintended effects are rarely well understood, but can result from extensive mutations to an organism's genes caused by the genetic engineering process. Such disruptions are sometimes evident in the form of non-viable or debilitated organisms. However, subtler effects often are not detected in the development process. Potential adverse effects include the unintended amplification of naturally occurring toxins that are normally present at low, unobjectionable, levels; the unintended creation of novel toxins; and reduced levels of nutrients.

Here, APHIS lacks evidence to support its conclusions about nutritional composition and entirely failed to consider possible changes to pathogen resistance. For example, although Simplot identifies a number of unexpected but "significant" nutritional differences between GE and non-GE potatoes beyond effects on the target traits,¹⁵² and admitted that "[u]nintentional changes in, e.g., certain amino acid levels were "inconsistent among [GE] varieties,"¹⁵³ APHIS bafflingly concluded that the GE potatoes "are no different compositionally compared to untransformed controls, except for the intended traits." Consequently, the agency concluded that allergenicity is not a concern.¹⁵⁴ But APHIS's nutritional analysis cannot possibly be accurate, since the agency simply disregarded and failed to investigate even the compositional differences Simplot admitted, let alone potentially many other compositional aspects that were not tested.

Further, APHIS completely failed to evaluate the direct and indirect potential side effects from changes in pathogen resistance likely caused by reducing browning. Those side effects might include human health effects from additional pesticide use necessary to compensate for reduced pathogen resistance. Accordingly, APHIS's conclusions about nutritional composition and human safety are arbitrary and capricious, as well as entirely inconsistent with the agency's NEPA obligations.

D. APHIS Fails to Consult with Tribes

Native American tribes occupy a unique legal status, with certain rights established in the U.S. Constitution, treaties, Executive Orders, and by the judiciary. The federal government's trust obligation to tribes requires it to act in the best interest of Native American tribes and individuals. In addition, tribes have the right to government-to-government consultation with the federal government. This requirement is set forth in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments (EO 13175).¹⁵⁵ Section 5(a) of EO 13175 states

¹⁵² Petition at 51, 53–54.

¹⁵³ *Id.* at 56.

¹⁵⁴ EA at 62.

¹⁵⁵ Executive Order No. 13,175, 65 Fed. Reg. 67249 (Nov. 9, 2000). EO 13175 expanded the breadth of tribal consultation to "ensure the meaningful and timely input by tribal officials in the development of regulatory policies [rules, policies, and guidance] that have tribal implications." Tribal implications are defined as having substantial

that “[e]ach agency shall have an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.”

APHIS has made no showing in this EA to indicate that it has considered the potential impacts of this action upon tribes or whether it has sought out any input from tribal officials.

E. APHIS Failed to Properly Consider and Disclose Its Obligations to Migratory Birds

APHIS also fails to properly consider and disclose its obligations to migratory birds. The EA notes that Executive Order 13186, “Responsibilities of Federal Agencies to Protect Migratory Birds,” requires federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations to develop and implement, within two years, a Memorandum of Understanding with FWS to promote the conservation of migratory bird populations.¹⁵⁶ Rather than properly studying this matter to determine whether deregulation of the GE potatoes would have measurable negative effects on migratory bird populations, APHIS summarily dismisses potential impacts. It finds that the Simplot potato is “expected to have the same interactions with migratory birds as conventional potatoes.”¹⁵⁷

This finding is fundamentally flawed because it wrongly assumes that if impacts to migratory birds were to exist, they would be spelled out in the data submitted by the applicant. APHIS’s reliance on the lack of data and its expectations for no impacts is improper because NEPA requires it to take a hard look at environmental impacts itself, not assume that if any impacts were to exist they would be disclosed by the applicant.

Further, USDA’s finding is based on Simplot’s data purportedly showing that the GE potatoes will not increase pesticide use.¹⁵⁸ However, as discussed above, APHIS entirely failed to evaluate whether the GE potatoes will have increased pathogen resistance and therefore invite additional pesticide application. Consequently, the conclusion that GE potatoes will not increase pesticide use is arbitrary and capricious. For these reasons, APHIS’s no effects conclusion constitutes a failure to take the hard look mandated by NEPA.

Finally, while APHIS at least gave a cursory glance at impacts to migratory birds in consideration of its obligations under Executive Order 13186, it utterly failed to consider its obligations under the MBTA. The MBTA allows entities to obtain take permits in a limited number of situations if they adhere to narrowly proscribed requirements. Available permits include those for import and export,¹⁵⁹ banding or marking,¹⁶⁰ scientific collection,¹⁶¹

direct effects on one or more tribes, on the relationship between the federal government and tribes, or on the distribution of power and responsibilities between the federal government and tribes. Among other things, EO 13175 requires federal agencies to respect tribal self-government and sovereignty, honor tribal treaty and other rights, and strive to meet responsibilities arising from the unique relationship between the federal government and tribes.

¹⁵⁶ EA at 79.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ 50 C.F.R. § 21.2.

¹⁶⁰ *Id.* § 21.22.

¹⁶¹ *Id.* § 21.23.

taxidermists,¹⁶² waterfowl sale and disposal,¹⁶³ Canada geese,¹⁶⁴ falconry,¹⁶⁵ raptor propagation,¹⁶⁶ rehabilitation,¹⁶⁷ depredation,¹⁶⁸ and special purposes.¹⁶⁹ The activity discussed in this EA is not covered by any of these permitting area, thus under the MBTA, this activity may not “take” even a single migratory bird. APHIS fails to properly consider whether migratory birds may be taken as a consequence of it deregulating Simplot’s GE potatoes. All of the issues raised regarding Executive Order 13186 also apply to the MBTA.

APHIS failed to provide data or consider all of the possibilities that would allow a determination of risks to migratory birds. This constitutes a failure to take the required hard look at impacts to migratory birds and could potentially lead to take under the MBTA.

F. APHIS Fails to Adequately Assess Impacts on Threatened and Endangered Species

These GE potatoes may significantly affect threatened and endangered species (TES), but APHIS failed to consider those effects or consult with the expert wildlife agencies regarding these risks, as the ESA requires. The ESA requires APHIS to consult with FWS and/or NMFS to determine “whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action.”¹⁷⁰ If APHIS learns from FWS or NMFS that threatened or endangered species may be present, a biological assessment must be prepared to identify any endangered species or threatened species that are likely to be affected by such action.¹⁷¹ The initial request for information from FWS and/or NMFS is a predicate to further agency action and cannot be ignored.¹⁷²

Accordingly, prior to a completion of the deregulation, APHIS must demonstrate that, at the very least, it has consulted with FWS and/or NMFS and taken the first step in considering the impacts of an APHIS deregulation of these GE potatoes on threatened or endangered species. However, APHIS failed to take even the first step of consultation.¹⁷³ APHIS has already once been previously found to have violated the ESA when it skipped this initial, mandatory step of obtaining information about listed species and critical habitats from FWS and/or NMFS.¹⁷⁴ The court emphasized that regardless of whether there is any evidence that species or habitat may be harmed in any way, “an agency violates the ESA when it fails to follow the procedures mandated by Congress, and an agency will not escape scrutiny based on the fortunate outcome that no listed plant, animal, or habitat was harmed.”¹⁷⁵

¹⁶² *Id.* § 21.24.

¹⁶³ *Id.* § 21.25.

¹⁶⁴ *Id.* § 21.26.

¹⁶⁵ *Id.* § 21.29.

¹⁶⁶ *Id.* § 21.30.

¹⁶⁷ *Id.* § 21.31.

¹⁶⁸ *Id.* § 21.41.

¹⁶⁹ *Id.* § 21.27.

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

¹⁷¹ 16 U.S.C. § 1536(c)(1).

¹⁷² *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).

¹⁷³ *Ctr. for Food Safety v. Johanns*, 451 F. Supp. 2d 1165, 1182 (D. Haw. 2006).

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

Here, however, as explained above, *APHIS does not have enough information to assess any of those factors for the GE potatoes*. Without these data, APHIS cannot assess impacts on TES of deregulating Simplot's GE potatoes. Thus, APHIS lacks evidence to support its conclusion that Simplot's GE potatoes will not adversely affect TES. This failing violates NEPA, the ESA, and the APA.

IV. CONCLUSION

For the above reasons, and additionally based on the body of evidence submitted in this administrative record, it is CFS's position that APHIS's proposed approval and draft assessment is substantively, procedurally, scientifically, and legally inadequate. Specifically, APHIS has failed to take a hard look at the Simplot petition, but has instead interpreted incomplete, ambiguous, or troubling data as insignificant. A science-based evaluation of the data instead shows that there are significant gaps in our understanding of the possible impacts of Simplot potatoes. Coupled with the science literature, these gaps show reasonably foreseeable impacts.

APHIS should deny Simplot's petition for deregulation of these GE potatoes because approval would violate the mandates of NEPA, the PPA, the ESA, the MBTA, and the APA. In addition, or in the alternative, APHIS must prepare an EIS before considering any approval; analyze and fully disclose the impacts of the GE potatoes on the environment and agricultural economy—including requirements that Simplot test its potatoes more thoroughly and directly for possible adverse reactions due to reductions in expression of the silenced genes, especially *asn1*; make attempts to understand the observed yield depression before deregulation can occur—and make findings regarding those impacts pursuant to its entire PPA statutory authority; comply with the ESA and MBTA; and avoid taking action that is arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law.

Respectfully submitted,

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SCIENCE REFERENCES

Gaufichon, L. et al. 2010. Biological function of asparagine synthetase in plants. *Plant Science* 1279: 141–153

Hwang, S. et al. 2011. Pepper asparagine synthetase 1 (CaAS1) is required for plant nitrogen assimilation and defense response to microbial pathogens. *The Plant Journal* 67: 749–762

Lea, H.M. et al. 2007. Asparagine in plants. *Ann. Appl. Biol.* 150: 1–26

Olea, F. et al. 2004. Up-regulation and localization of asparagine synthetase in tomato leaves infected by the bacterial pathogen *Pseudomonas syringae*. *Plant Cell Physiol.* 45: 770–780.