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Docket No. APHIS-2007-0016
Regulatory Analysis and Development
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Comments to USDA APHIS on Environmental Assessment for the Determination of Syngenta Seeds, Inc. Alpha-Amylase Maize Event 3272

January 20, 2009

Docket No. APHIS-2007-0016

USDA APHIS is evaluating a petition from Syngenta Seeds, Inc. (Syngenta) to deregulate a genetically engineered ("GE") corn variety (Event 3272) genetically engineered to produce a microbial enzyme that facilitates ethanol production and has issued a draft environmental assessment ("EA"). Pursuant to the USDA November 19, 2008 Federal Register notice, the Center for Food Safety ("CFS") submits the following comments concerning the inadequacy of the agency's EA accompanying petition for deregulation.

The Center for Food Safety (CFS) is a non-profit, membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture.[1] CFS represents 67,000 members throughout the country that support organic agriculture and regularly purchase organic products. In addition to the comments submitted herein, CFS is concurrently submitting 7,084 comments from CFS Food Network members opposing the deregulation of Event 3272 (Docket No. APHIS-2007-0016).[2]

[1] See generally http://www.centerforfoodsafety.org.
[2] Letter from Heather Whitehead, Submission of 7,873 comments opposing Docket No. APHIS-2007-0016 from Center for Food Safety True Food Network members, January 20, 2008 (Submitted under separate cover to Docket No. APHIS-2008-0054 with comments attached.).

SUMMARY

CFS strongly objects to APHIS proposed unconditional deregulation of Event 3272. If approved, it would become the first genetically engineered, industrial 'food for fuel' crop. Its approval is unnecessary. The only stated need and reason for this crop is to help meet US statutorily created biofuel goals, but output is already well ahead and meeting those goals without Event 3272. Ethanol production from corn surpassed the 2012 target for ethanol production (7.5 billion gallons) in 2007 (over 8 billion gallons). And with 10 billion gallons of ethanol produced in 2008, the country is well on the way to achieving the mandate for 2022 without the introduction of Event 3272 corn. (*See* pp __ *infra*).

The APHIS approval is misguided. The dramatic worldwide surge in food prices last year--which has already pushed 100 million more of the world's poor into hunger and poverty--has caused a radical rethinking of how biofuels are produced, especially the use of corn for ethanol. Food experts from academia to the World Bank have decried the massive diversion of corn from food to fuel, blaming it for at least part of the steep price increases in food staples like corn, wheat and rice. Event 3272 corn, an unprecedented industrial fuel crop, will only exacerbate this situation. (*See* pp 3-4 *infra*).

The APHIS approval will contaminate the food supply, causing economic harm to organic and conventional farmers, export markets, and endangering the public's right to choose. USDA proposes unconditional approval for Event 3272, relying on the corn's developer, Syngenta, to protect non-industrial corn from contamination. APHIS does not include any measures of its own to prevent contamination, or even analyze the efficacy of Syngenta's proposed stewardship measures. But past experience with genetically engineered StarLink corn leaves no doubt that this arrangement will result in substantial contamination of organic and conventional corn; likely cause considerable economic losses to US farmers, corn exporters and the food industry; and endanger consumers' right to choose uncontaminated corn products. If we learned anything from the StarLink episode, it is that voluntary, industry-led agreements to curtail contamination do not work in the real world. (*See* pp. 44-51 *infra*).

The APHIS approval raises serious human health and environmental risks. Event 3272 contains an exotic enzyme derived from deep sea microorganisms that has several properties characteristic of allergy-causing substances, and so might be capable of causing food allergies in people who inadvertently consume this corn. For this reason, allergy experts have requested more careful evaluation of Event 3272. Among other environmental risks, unharvested corn will deposit large amounts of this enzyme in agricultural soils, and may disrupt important soil carbon cycling processes. (*See* pp. 6-20 *infra*).

The APHIS approval is illegal because the EA fails to comply with NEPA. APHIS fails to analyze reasonable alternatives to the proposed action, only looking at two alternatives (no action or complete deregulation). In claiming it could not even consider partial deregulation alternatives such as isolation distances or geographic restrictions APHIS misconstrued the scope of its NEPA duties. (*See* pp 20-26 *infra*). APHIS also illegally

relied on Syngenta's proposed stewardship measures for Event 3272 instead of doing its own analysis of their efficacy. (*See* pp. 26-30 *infra*.) Further APHIS failed to adequately address the cumulative impacts of the approval, particularly regarding climate change, food markets, and the stacking of Event 3272 with other GE crops. (*See* pp. 44-52 *infra*.)

The APHIS approval is illegal because an EIS is required. Whether there are significant impacts requiring an EIS is determined by a number of enumerated factors (40 C.F.R. § 1508.27), any one of which requires an EIS. Many are present here including, impacts on public health (*See* pp. 6-20 *infra*), farmland (*See* pp. 30-42 *infra*) and whether impacts are cumulatively significant (*See* pp. 44-52 *infra*); the highly controversial nature of this fuel-only industrial crop; the precedent for future actions of this approval; the uncertain, unique, and unknown risks of this unprecedented type of crop and its stacked progeny; and adverse affects on endangered or threatened species.

If APHIS intends to continue to consider approving Event 3272 in any fashion, CFS urges the agency to delay such consideration until after APHIS has completed a rigorous and comprehensive EIS that analyzes and discloses to the public Event 3272's numerous significant potential health, environmental and economic impacts. Approval without an EA will be arbitrary and capricious agency action that violates NEPA and the Plant Protection Act (PPA).

COMMENTS

APHIS's Overarching Reason for the Need for Event 3272 is Mistaken

The increase in biofuel production has been largely the result of political policies which encouraged the planting of corn for ethanol. As the evidence of global warming impacts mounted with increased scientific research, biofuels were offered as a sustainable solution to combating the problem. New research has since demonstrated that biofuels, especially ethanol, do not produce environmental benefits and instead exacerbate global climate change. Regardless, government subsidies and mandates have been the driving force behind the increase in ethanol production in the United States.[3] In the draft Environmental Assessment (EA), APHIS notes the need for 3272 corn as a result of the recent political initiatives mandating biofuel production,[4] (EA at 6), and believes that the deregulation of Event 3272 corn is necessary to help the United States achieve political mandates for ethanol production. In fact, APHIS relies on this as the exclusive reason for the need for Event 3272 corn. (EA at 6). In reality, the United States has already reached

[3] In the Federal Energy Policy Act of 2005, a Renewable Fuels Standard (RFS) was established that directed a doubling of ethanol and biodiesel over the current level, amounting to 7.5 billion gallons by 2012. Two years later, the RFS was increased again in the 2007 Energy Independence and Security Act, which mandated an increase to at least 36 billion gallons of biofuel by 2022. The standard represented a nearly five fold increase over the then current level of biofuel production.

[4] "Corn-based ethanol production may be a feasible way to meet the ethanol consumption benchmark for 2012 set in the Energy Policy Act of 2005, and 2022 goals set by the Energy Independence and Security Act of 2007." They further note, "Event 3272 corn is expected to help the U.S. meet its goals for ethanol production." (EA at 6).

the level of ethanol production mandated by the Energy Policy Act of 2005 and is well on its way to achieving the mandate for 2022 *without* the introduction of Event 3272 corn.

In 2007, farmers in the United States planted and produced more corn than any year after 1944. Yet, while the majority of the United States corn crop in 1944 would have been utilized for food or animal feed, the same is not true for 2007. According to the USDA, U.S. farmers produced more than 13 billion bushels of corn in 2007, converting more than 3 billion bushels—23% of the total crop-- to ethanol production. In total, this produced more than 8.2 billion gallons of ethanol- far exceeding the 7.5 billion gallon mandate for 2012. In 2008 the United States diverted even more corn for ethanol production—3.7 billion bushels in total, representing 30.8% of the total corn crop for 2008. This produced more than 10 billion gallons of ethanol, far outpacing the 2012 mandate a full four years early.[5] The United States does not need Event 3272 corn to help meet its political mandate for ethanol production by 2012- it has already met it.

Further, while APHIS notes the 36 billion gallon ethanol mandate under the Energy Independence and Security Act of 2007, APHIS fails to mention that the ethanol mandate is not entirely for biofuels made from corn. In fact, only 15 billion gallons of the mandate are directed to come from corn.[6] Since the 2005 Energy Policy Act, corn production has increased by nearly one million bushels. At the same time, the percent of the U.S. corn supply devoted to ethanol production has doubled from nearly 15% to more than 30%.[7] If the U.S. maintains such trends they will likely produce an additional one million bushels of corn every four years until 2022, for a conservative total of a 3 million additional bushels. Devoting 2 million bushels of this extra 3 million bushels will more than meet the 15 billion gallon mandate by 2022 for ethanol. The United States is already achieving and outpacing its ethanol mandate goals for 2012 and 2022. APHIS' assumption that Event 3272 corn is necessary to help the United States achieve political mandates is not based on the reality of our current agricultural and economic system.

The following comments illustrate why the proposed deregulation should not be finalized until APHIS prepares an environmental impacts statement ("EIS") to fully review the significant environmental effects of this possible deregulation.

The National Environmental Policy Act

The National Environmental Policy Act (NEPA) requires a federal agency such as USDA APHIS to prepare a detailed EIS for all "major Federal actions significantly affecting the quality of the human environment."[8] NEPA "ensures that the agency ... will have available, and will carefully consider, detailed information concerning significant

[5] United States Department of Agriculture Economic Research Service. Data Sets: Feed Grains Database. http://www.ers.usda.gov/data/feedgrains/FeedGrainsQueriable.aspx
[6] "Doubts Grow Over Ethanol". http://thehill.com/leading-the-news/doubts-grow-over-ethanol-2008-04-30.html
[7] Id at 4.
[8] 42 U.S.C. § 4332(2)(C).

environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience."[9]

If the federal action may significantly affect the environment, APHIS must prepare an EIS.[10] 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.[11] 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.[12] "The statement of reasons is crucial to determining whether the agency took a "hard look" at the potential environmental impact of a project."[13] An EA must "provide sufficient evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact."[14] NEPA regulations require the analysis of direct and indirect, as well as cumulative, effects in NEPA documents, including EAs.[15] The assessment must be a "hard look" at the potential environmental impacts of its action.[16] APHIS's decisions in the EA must be "complete, reasoned, and adequately explained."[17]

Whether there may be a significant effect on the environment requires consideration of two broad factors: 'context and intensity. A number of factors should be considered in evaluating intensity, including, "[t]he degree to which the proposed action affects public health or safety," "[t]he degree to which the effects on the quality of the human environment are likely to be highly controversial," "[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks," "[t]he degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration," "[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts," and "[t]he degree to which the action may adversely affect an endangered or threatened species or its habitat."[18] An action may be "significant" if one of these factors is met.[19]

The Council on Environmental Quality (CEQ)

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[9] *Robertson v. Methow Valley Citizens Council,* 490 U.S. 332, 349(1989).
[10] 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).
[11] 40 C.F.R. § 1508.9.
[12] *Save the Yaak v. Block*, 840 F.2d 714, 717 (9th Cir. 1988).
[13] Id.
[14] *Id.*
[15] See 40 C.F.R. §§ 1508.8, .9, .13, .18.
[16] *Blue Mountains Biodiversity v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998). Nat'l Parks & Conservation Ass'n, 241 F.3d at 731 (quoting 40 C.F.R. § 1508.27).
[17] Northwest Coalition for Alternatives to Pesticides v. U.S. E.P.A., 544 F.3d 1043, 1052 n.7 (9th Cir. 2008).
[18] 40 C.F.R. § 1508.27(b)(2), (4), (5), (6), (7), (9).
[19] Ocean Advocates v. U.S. Army Corps of Eng'rs, 361 F.3d 1108, 1125 (9th Cir.2004); see also Nat'l Parks & Conservation Ass'n, 241 F.3d at 731 (either degree of uncertainty or controversy "may be sufficient to require preparation of an EIS in appropriate circumstances.").

NEPA also established the Council on Environmental Quality and charged CEQ with the duty of overseeing the implementation of NEPA.[20] 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."[21] CEQ's regulations are applicable to and binding on all federal agencies.[22] Among other requirements, CEQ's regulations mandate that federal agencies address all "reasonably foreseeable" environmental impacts of their proposed programs, projects, and regulations.[23]

I. Human Health: The EA is deficient because it fails to adequate analyze potential significant human health impacts of Event 3272. APHIS improperly relies on FDA's cursory review and Syngenta's own analysis rather than analyzing impacts itself. Potential significant impacts from allergenicity are not addressed. An EIS is required.

Public Health

Public health issues may be significant environmental impacts requiring the preparation of an EIS. The CEQ regulations explain what factors may be significant effects on the human environment and one such factor is "[t]he degree to which the proposed action affects public health or safety."[24] 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.[25] Accordingly, APHIS's EA 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 to be found not to be significant, there must be a convincing statement of reasons.[26]

Here there is no meaningful analysis by the agency of potential human health impacts or a convincing statement of reasons" why such impacts may not be significant. APHIS has not complied with NEPA and an EIS is required.

First APHIS attempts to disavow it must assess health impacts at all, pointing to the limits of its PPA authority. (EA at 34 (arguing that its assessment is limited to plant pest risk only)). But NEPA creates independent duties on APHIS, the procedural duties of broad and meaningful analysis, that are not circumscribed as the EA claims.[27] APHIS must comply with the Plant Protection Act, but it must independently comply with NEPA.

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[20] See 42 U.S.C. §§ 4321, 4344.
[21] 40 C.F.R. § 1500.3.
[22] 40 C.F.R. §§ 1500.3, 1507.1; see, e.g., Hodges v. Abraham, 300 F.3d 432, 438 (4th Cir. 2002).
[23] See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.
[24] 40 C.F.R. § 1508.27(b)(2).
[25] National Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722, 731 (9th Cir. 2001); Public Service Co. of Colorado v. Andrus, 825 F.Supp. 1483, 1495 (D. Idaho 1993).
[26] National Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722, 731 (9th Cir. 2001).
[27] Further, as discussed in detail in Section II *infra*, APHIS misstates the scope of its authority as overly limited. APHIS's statutory authority is much broader than mere plant pest risks, and it includes oversight of noxious weeds, which are specifically to include risks to public health. *See infra*; 7 U.S.C. § 7702(10).

APHIS does not seriously argue to the contrary: after all, the EA acknowledges that it must do its own assessment and that such impacts are cognizable under NEPA, because the EA has a section title for the issue ("Public Health") and the EA has a paragraph of summary for its conclusion that the corn will have no impacts on human or animal health (EA at 35). Moreover in the APHIS draft programmatic EIS, issued July 7, 2007, APHIS listed impacts on human health (including human allergenicity) as a category of impacts of its NEPA assessment.[28]

The problem is that the analysis is inadequate to comply with NEPA regarding these impacts. APHIS bases its conclusion on three things: Syngenta's completition of the FDA's consultation process (i.e., that FDA had "no questions"), that three other countries have found Event 3272 safe for food and feed and the data submitted by Syngenta in its petition. (EA at 35). This is not the "hard look" NEPA requires.

With regard to FDA's "analysis" from its voluntary consultation process, APHIS cannot solely rely on another agency's evaluation of environmental effects under a separate statute to adequately fulfill its own NEPA obligations.[29] As explained above, the health impacts discussed below are cognizable impacts pursuant to NEPA that require an EIS if they may significantly impact the "human environment." These impacts are interrelated to the environment because they would stem from the biological contamination of other non-Event 3272 corn (through cross-pollination and other means) and cause unknown and unwilling human exposures. Accordingly, APHIS has its own duty to comply with NEPA, including assessment of potential significant impacts to public health and safety.

There is a further reason APHIS must not merely defer in toto to FDA: FDA's voluntary consultation process is extraordinarily weak. It is based on a statement of policy, not a binding regulation.[30] GE crop developers may choose to consult with FDA, but this process is vitiated by its voluntary nature and a lack of any established testing standards; in particular, GE crop developers seldom if ever conduct animal feeding trials with GE crops for the purpose of detecting potential toxicity. FDA did not prepare any NEPA documentation (no EA nor EIS) on its policy nor provide notice and comment.[31] In its process, contrary to APHIS's mischaracterization, FDA makes no "findings" (EA at 35) for APHIS agree with, it makes no findings at all.[32] In the FDA process only "*Syngenta has concluded* that AMY797E alpha-amylase corn event 3272 is not materially different in composition, safety, or any other relevant parameter from corn now grown, marketed, and consumed."[33] The manufacturer merely sends FDA a summary of its findings. (EA at 15). Rather FDA merely had no questions with Syngenta's submission.

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[28] DEIS at 67-90.
[29] Save Our Ecosystems v. Clark, 747 F.2d 1240, 1248 (9th Cir. 1983); Oregon Envtl. Council v. Kunzman, 714 F.2d 901, 905 (9th Cir. 1983).
[30] *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166 (D.D.C.2000).
[31] *Id.* at 170.
[32] *See* http://www.cfsan.fda.gov/~rdb/bnfm095.html (throughout, "Syngenta provided"; "Syngenta examined"; "Syngenta reports"; "Syngenta determined"; and "Syngenta has concluded").
[33] *Id.* at Paragraph 8 (Conclusion).

Nor does blind reliance on other nations' assessments fulfill APHIS's NEPA duties. Further, APHIS notes that South Africa specifically did *not* approve Event 3272, but APHIS did not analyze why, saying the reasons were "unclear" and discrediting it because concerns were raised to South Africa by "opponents of genetic engineering." (EA at 35). This is not reasoned analysis. Why should one country's approval of Event 3272 be convincing and another country's disapproval be not? Such cherry-picking of evidence only when it supports the agency's conclusion is classic is arbitrary and capricious behavior.

Finally, APHIS relies on Syngenta's submitted data to it, saying its studies are "sufficient." (EA at 35). Notably APHIS does not analyze this itself but relies on Syngenta's characterization of the data (EA at 35 (Syngenta conducted.."; "Syngenta reported.."; "Syngenta assessed.."; "Syngenta maintains.."). As discussed in detail below, that data is insufficient. An EIS is required.

Allergenicity

Allergies are one of the most commonly cited health risks presented by GM crops, particularly when they express novel proteins that have never been a part of the human food supply. Food allergies are often taken less seriously than they deserve to be. First, they affect a great many people, for instance an estimated 2-2.5% of adults and 6-8% of children in the U.S.[34] (or roughly 8 million Americans). While most allergic reactions are mild or moderate, a significant number of people experience allergic reactions known as anaphylactic shock, which can be life-threatening. An estimated 29,000 episodes of anaphylaxis occur each year in the US, killing an estimated 150 people.[35] It can be difficult to determine which food component has caused an allergy sufferer's reaction. Since corn rarely causes allergies, allergists often discount it as a potential cause of allergies, and sometimes even prescribe corn-based diets to allergy-prone infants and young children. Thus, the hidden presence of an allergenic protein in GM corn would give rise to particular concern, as it would likely go undetected as the cause of an allergic reaction.

These concerns have driven the formulation of protocols for testing new GM crops for their potential to cause allergies (i.e., their allergenicity). While it remains impossible to predict with certainty whether a GM crop protein will cause allergies, one can test it for properties that are common characteristics of allergy-causing proteins (known as allergens). The likelihood that a transgenic protein is or will become allergenic increases with the number of these properties it possesses. The alpha amylase enzyme in Event 3272 (called AMY797E) possesses three of these properties: sequence similarity to a known allergen, thermostability, and some degree of acid tolerance. Two other factors also raise concern: the allergenicity of related alpha amylase enzymes derived from fungi,

[34] Sampson, H. A. (1999). "Food allergy. Part 1: Immunopathogenesis and clinical disorders," Journal of Allergy and Clinical Immunology 103 (5), pp. 717-28.
[35] Bock et al. (2001). "Fatalities due to anaphylactic reactions to foods," *Journal of Allergy and Clinical Immunology* 107 (1), pp. 191-3.

and the high expression level of AMY797E relative to other transgenic proteins in GM crops.

AMY797E has sequence similarity to an American cockroach allergen (Per a 3)

Food allergens are most often proteins, and proteins are composed of amino acids. The amino acid sequence of some allergens is known, but many other allergen remain uncharacterized. One widely recommended allergenicity test procedure is to compare the sequence of the transgenic protein (here, AMY797E) to the sequences of known allergens. If some portion of the transgenic protein is identical or highly similar to a portion of a known allergen, the transgenic protein is more likely to be allergenic. A range of procedures have been recommended for performing such comparisons. Some protocols prescribe searching for stretches of 8 contiguous amino acids that may be shared by a transgenic protein and a known allergen.[36] A more recent protocol calls for testing for matches of shorter sequences of 6 amino acids.[37] This protocol was formulated by international experts, including leading U.S. allergists, who were commissioned by the UN's Food and Agriculture Organization and World Health Organization (FAO-WHO 2001). The basis for such comparisons is the fact that allergic reactions can be triggered by certain segments of the allergen, which are known as epitopes. Epitopes vary in length, but can be as short as 6 to 8 amino acids in length. A negative result (no matches) does not rule out the possibility that a transgenic protein is allergenic, in part because many allergens have not been identified and/or characterized. On the other hand, finding matches of this sort by no means guarantees that a transgenic protein is allergenic, but rather only increases the likelihood that it may be.

Syngenta reports that AMY797E shares an identical sequence of 8 amino acids with the American cockroach allergen, Per a 3.[38] According to the FAO-WHO (2001) protocol cited above, sequence identity at the less stringent 6-amino acid level is sufficient to regard a protein as "likely allergenic."[39] Since identity at the 8-amino acid level is less likely to represent a spurious "false positive," it should be regarded as stronger evidence of potential allergenicity. For 6-amino acid matches, FAO-WHO (2001) recommends testing the putative allergen against sera from patients with known allergies to relevant source materials, if available, for possible IgE antibody binding. As discussed further below, AMY797E should be tested against sera from alpha-amylase allergic individuals.

Syngenta did not conduct any sera testing. The company also does not report the sequence of the 8 amino acid segment, but states that it does not match the epitopes of the

[36] METCALFE, D.D., ASTWOOD, J.D., TOWNSEND, R., SAMPSON, H.A., TAYLOR, S.L. AND FUCHS, R.L. (1996). Assessment of the Allergenic Potential of Foods Derived from Genetically Engineered Crop Plants. *Critical Reviews in Food Science and Nutrition* **36**(S), S165-186.
[37] FAO-WHO (2001). Evaluation of Allergenicity of Genetically Modified Foods. Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, Jan. 22-25, 2001, p. 10. ftp://ftp.fao.org/es/esn/food/allergygm.pdf.

[38] Petition, p. 115.
[39] FAO-WHO (2001), pp. 26-27.

Per a 3 allergen reported in a single paper.[40] The authors of this paper found four epitopes of the Per a 3 allergen, from 6 to 16 amino acids in length. It is not clear if this represents all of the epitopes of Per a 3, or if there are others. Since the shortest epitope is 6 amino acids long, and Syngenta only looked for matches of 8 contiguous amino acids, it is possible that the unreported 8 amino acid segment shared by AMY797E and Per a 3 contains the 6 amino acid epitope. The sequence similarity test procedure should be repeated at the 6 amino acid level. A literature search for other possible epitopes of Per a 3 should also be conducted.

AMY797E possesses great thermostability

Thermostability is resistance to inactivation and breakdown by heat. According to a leading U.S. food allergist, Dr. Hugh Sampson, thermostability is a characteristic of proteins that cause allergies.[41] Food allergist Steven Taylor agrees,[42] as does the US Environmental Protection Agency (EPA), which has formally adopted stability to heat as a criterion of potential allergenicity of transgenic proteins produced in GM crops.[43] According to Syngenta, AMY797E "was selected for development due to its increased thermostability and activity during the high temperatures required for starch hydrolysis in corn processing."[44] Hence, AMY797E has been intentionally engineered for a property regarded as one characteristic of food allergens. Unfortunately, Syngenta did not provide thermostability testing data for AMY797E.

Though we lack data specific to AMY797E, Syngenta refers us to a similar alpha-amylase enzyme that was developed for a similar purpose, and from the same three parental enzymes, as AMY797E. This enzyme, known as BD5088, is said to have 93% amino acid identity to AMY797E.[45] Syngenta cites a paper discussing the development of BD5088 and related alpha amylase enzymes. According to this paper, BD5088 retains roughly 90% of its activity after 60 minutes at 100º C., the boiling point of water, and is still able to hydrolyze starch (remain active) at 115º C.[46] Most proteins are denatured (lose their characteristic three-dimensional structure) and/or degraded into small fragments at such high temperatures. (The small fragments of a degraded protein are less likely to be allergenic than the undegraded protein.) AMY797E likely possesses a similar degree of thermostability, though data specific to this enzyme would be desireable.

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[40] C.H. et al (2003). "IgE-binding epitopes of the American cockroach Per a 3 allergen," *Allergy* 58: 986-992.

[41] Sampson, H. A. (1999). "Food allergy. Part 1: Immunopathogenesis and clinical disorders," Journal of Allergy and Clinical Immunology 103 (5), pp. 717-28.

[42] Taylor & Hefle (2001). "Will genetically modified foods be allergenic?," *Current Reviews of Allergy and Clinical Immunology* 107 (5), pp. 765-71.

[43] EPA BRAD (2001). "Biopesticides Registration Action Document: Revised Risks and Benefits Sections – Bacillus thuringiensis Plant-Pesticides," US Environmental Protection Agency, July 16, 2001, p. IIB2. It should be noted that the EPA will ***not*** review Syngenta's application for Event 3272, since the Agency is only responsible for GM crops that produce pesticidal proteins (i.e. Bt crops).

[44] Petition, p. 47.

[45] Petition, pp. 48-49.

[46] Richardson et al (2000). "A novel, high performance enzyme for starch liquefaction: discovery and optimization of a low pH, thermostable alpha-amylase," J. Biol. Chem. 277(29): 26501-507. See Figure 4 and text on p. 26505. Stability is greater in the presence of calcium (Figure 4B) than in its absence (4A).

According to one protocol for stability testing of transgenic proteins in GM crops, resistance to breakdown at a temperature of 100º C. constitutes thermostability.[47]

At present, the most widely used enzyme for conversion of corn starch to ethanol is the alpha-amylase enzyme isolated from the common soil bacterium *Bacillus licheniformis*. In the same test reported above, *B. licheniformis* alpha-amylase lost all activity after 2-4 minutes at 100º, indicating that it is rapidly denatured and/or broken into fragments at this temperature.[48] Hence, AMY797E possesses substantially greater thermostability than the alpha amylase enzyme most commonly used in conversion of corn to ethanol. This considerable thermostability is a second factor making it more likely to be allergenic.

AMY797E is engineered to be acid-tolerant

AMY797E is designed to be active under the acidic conditions obtaining in corn ethanol plants. Unfortunately, Syngenta does not provide specific data on the acid-tolerance of AMY797E. In Appendix C of the draft EA, a Syngenta consultant reports that ethanol processing of Event 3272 takes place at a constant level of 4.8, indicating robust activity at this somewhat acidic pH.[49] Richardson et al (2000) provide activity data on BD5088 (highly similar to AMY797E, see section on thermostability above) at pH values of 4.25 to 5.5. BD5088 retains 65% of its maximal activity at the moderately acidic pH = 4.25, indicating that this enzyme (and presumably AMY797E) would remain active and so structurally intact at pH values somewhat below 4.25.[50] Once again, data specific to AMY797E would be desirable, but in its absence it is reasonable to assume that AMY797E has acid tolerance similar to that of BD5088.

The acid tolerance of AMY797E is important because acid tolerance is one component of "digestive stability," another widely recommended test for potential allergenicity of a transgenic proteins in GM crops.[51] Digestive stability means resistance to breakdown in the stomach. Proteins that withstand breakdown by proteases (protein degrading enzymes) in the acidic conditions of the stomach are considered more likely to be presented to the immune system, the first step in eliciting an allergic reaction. The usual test involves measuring the rate at which a transgenic protein degrades in "simulated gastric fluid," which consists of an acidic solution that contains pepsin (a gastric protease). It should be noted that such a simple test system cannot truly simulate the varying gastric conditions of human beings, leading to calls for more complex test systems that mimic physiological conditions more closely.[52] Gastric conditions vary

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[47] Helm, Ricki M. (2001). "Stability of known allergens (digestive and heat stability)," Working Paper Biotech 01/07 for the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, January 22-25, 2001.
[48] Richardson et al (2000), op. cit., Figure 4.
[49] Draft EA, Appendix C, section II(A).
[50] Richardson et al (2000), op. cit., Figure 2.
[51] See Metcalfe et al (1996), FAO-WHO (2001), and Helm (2001), all cited above.
[52] Minekus, M. et al (1995). "A multicompartmental dynamic computer-controlled model simulating the stomach and small intestine," ALTA 23: 197-209.
http://altweb.jhsph.edu/publications/journals/atla/atla23_2/atla23_2b.htm
See also: http://www.pharma.tno.nl/Product.cfm?PShID=372&DivID=7.

greatly, depending on the individual, the person's age, the time of day, the antacid effect of recently ingested food, and other factors. For instance, the gastric environment of infants is considerably less acidic, ranging from pH values of 2.3 to 3.6, than that of adults.[53] Adult gastric pH is typically 1 to 2 under fasting conditions, but rises considerably during and directly following meals.[54]

In general, ingested proteins will be broken down more rapidly and hence rendered harmless under more acidic conditions (lower pH values) and in the presence of larger amounts of pepsin. Thus, the very same (transgenic) test protein will often exhibit a quite different degree of digestive stability depending on the test conditions that are employed for the digestive stability test.[55] It is therefore very important to have standardized test conditions to be able to interpret the meaning of the results. The authoritative FAO-WHO (2001) protocol cited above is the first such protocol to specify test conditions: simulated gastric fluid of pH = 2.0 that contains a ratio of 1.3 units pepsin to 1 unit test protein (by weight).[56] Since a pH value of 2 is more acidic than gastric conditions in infants, and in adults during and following a meal, it would also be advisable to conduct several different tests under a range of milder pH conditions. Allergist Ricki Helm recommends digestive stability tests at pH values ranging from 1.0 to 6.0 "due to the pH variation in the stomach following a meal."[57]

Unfortunately, Syngenta does not report the conditions under which it conducted its digestive stability test on AMY797E, but merely states that it was "rapidly degraded (within 5 minutes) in simulated gastric fluid containing pepsin…"[58] USDA was apparently not satisfied with this cursory description. Dr. Neil Hoffman, director of Regulatory Programs at APHIS's Biotechnology Regulatory Services, specifically requested that Syngenta provide more information on how this digestive stability test was conducted in a follow-up letter to the company dated 11/29/06. Syngenta's response (1/10/07), however, still failed to provide these two simple but crucial pieces of information – pH value and relative proportion of pepsin to AMY797E in the simulated gastric fluid.[59] These omissions, as well as USDA's failure to require submission of this information, are troubling.[60]

Syngenta's Event 3272 was also reviewed by Food Standards Australia New Zealand (FSANZ) in response to a petition submitted by Syngenta for import clearance into those

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[53] Erickson, T.B. et al (2004). "Pediatric Toxicology: Diagnosis and Management of the Poisoned Child," McGraw-Hill Professional, p. 34.
[54] Helm (2001), op. cit., p. 10.
[55] Freese, W. & Schubert, D. (2004), "Safety Testing and Regulation of Genetically Engineered Foods," *Biotechnology and Genetic Engineering Reviews,* Vol. 21, November 2004, pp. 299-324; see also: FREESE, B. (2001). A Critique of the EPA's Decision to Reregister *Bt* Crops and an Examination of the Potential Allergenicity of *Bt* Proteins. Adapted from Comments of Friends of the Earth to the EPA, Docket No. OOP-00678B, Dec. 9, 2001. www.foe.org/safefood/comments.pdf.
[56] FAO-WHO (2001), op. cit., pp. 12-13. Ratio of pepsin to test protein calculated from data presented.
[57] Helm (2001), op. cit.
[58] Petition, p. 51.
[59] Petition, introductory section, pp. 5, 7.
[60] FDA's voluntary consultation document on Event 3272 also fails to specify digestive stability test conditions.

countries. FSANZ reports a digestive stability test by Syngenta's J. de Fontes and C. Kramer.[61] This test was conducted in simulated gastric fluid containing 10 units pepsin per microgram AMY797E at pH = 1.2, under which conditions AMY797E apparently degraded within 5 minutes, much like the results reported in Syngenta's U.S. petition. Rapid digestion under these extreme conditions is not surprising, but tells us little about the fate of AMY797E under more typical human gastric conditions. The use of such extremely acidic conditions for digestive stability testing of transgenic proteins has been criticized by a leading expert in GM crop safety testing, Dr. Hubert Noteborn of Wageningen University in the Netherlands, who in the context of the StarLink investigation stated: "The continual setting of the pH value of 1.2 [for digestive stability tests] does not mimic accurately the kinetics of the physiological events in the human stomach."[62] Dr. Noteborn, like FAO-WHO (2001), favors a milder pH = 2.0 as more representative of human gastric conditions. It also appears that Syngenta's test employed considerably more pepsin than prescribed by the protocol in FAO-WHO (2001).[63] The use of an extremely acidic pH and the apparent excess of pepsin vs. AMY797E in Syngenta's digestive stability test mean that the results – rapid degradation – do not accurately simulate the fate of AMY797E in most human gastric environments, including those of infants and adults after ingestion of food.

In summary, AMY797E is stable at moderately acidic pH values, and has not been properly tested for digestive stability. At a minimum, proper testing at the pH value and pepsin/test protein ratio recommended by FAO-WHO's experts as described above should be conducted. Several tests at a range of pH values as Dr. Helm recommended above would be desirable to simulate degradation in varying gastric conditions. Until such tests are conducted, AMY797E must be regarded as stable to digestion, a third characteristic of food allergens.

Allergenicity of fungus-derived alpha-amylases

Some alpha-amylase enzymes are known to cause allergies. Fungal alpha-amylase is an important occupational allergen, and in fact is considered the most frequently reported

[61] FSANZ (2007). "Final Assessment Report Application A580: Food Derived from Amylase-Modified Corn Line 3272," Food Standards Australia New Zealand, October 3, 2007, Section 4.4 under "In vitro digestibility," pp. 36-37.

[62] Dr. Hubert Noteborn, SAP member, as quoted in the transcript to: "Assessment of Scientific Information Concerning StarLink Corn," FIFRA Scientific Advisory Panel, SAP Report No. 2000-06, December 1, 2000. p. 399.

[63] To determine this with certainty, one would need to know the specific activity of the pepsin that Syngenta used in the test reviewed by FSANZ in order to be able to convert from activity units to the weight units used by FAO-WHO (2001). Different pepsin preparations have differing "potency." Typical activities of porcine pepsin, which is often used in digestive stability tests, are 1 unit activity/microgram pepsin and 2.5 units per microgram pepsin. Syngenta used 10 units pepsin activity per microgram AMY797E. Based on the specific activities noted above, this gives either 4 or 10 micrograms pepsin per microgram AMY797E, a considerably higher pepsin to test protein ratio than the 1.3 unit pepsin to 1 unit test protein prescribed by FAO-WHO (2001).

cause of allergy.in the baking industry.[64] Fungal alpha-amylases have been demonstrated to cause respiratory allergies; it is unclear whether they have been tested as potential food allergens. But respiratory allergens can in some cases also cause food allergies. In addition, workers who process Event 3272 would be exposed to substantial amounts of AMY797E in corn dust by the inhalational route, and so could be at risk of developing allergies to it, just as bakery workers have become allergic to fungal alpha-amylase. AMY797E should be tested for IgE antibody binding (which would constitute strong evidence of allergenicity) against sera from alpha-amylase allergic individuals. Such testing should be required before USDA considers approval of Event 3272.

AMY797E is expressed at high levels relative to other transgenic protein in GM crops

Allergenic proteins are often among those proteins found at relatively high levels in the allergenic food source, though this is not always true. In rare cases, exposure to billionths of a gram is sufficient to induce an allergy or allergic reaction.[65] There are reports of infants becoming sensitized through breast milk and fetuses acquiring allergies *in utero*.[66] Some people may even become allergic to a food through inhalation of trace quantities.[67]

According to Syngenta, AMY797E is expressed in corn kernels at mean levels ranging from 838 to 1627 mcg AMY797E per gram of corn (fresh weight),[68] or 0.1-0.2%. This is three orders of magnitude (roughly 1,000 times) higher than the levels of transgenic proteins found in most GM crops. For instance, most insect-resistant Bt crops express their insecticidal proteins at <1 to 2 mcg/g fresh weight.[69] Some allergists have expressed concern about the allergenicity potential of Bt insecticidal proteins in Bt crops despite their presence at such comparatively low levels.[70] The comparatively high levels of AMY797E in Syngenta 3272 means considerably greater exposure relative to transgenic proteins in most GE crops, in the event that Event 3272 is consumed. It also

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[64] Houba, R. et al (1996). "Exposure-sensitization relationship for alpha-amylase allergens in the baking industry." *Am J Respir Crit Care Med* 154(1): 130-36; Houba R. et al (1997). "Airborne levels of alpha-amylase allergens in bakeries," *J Allergy Clin Immunol* 99(3): 286-92.

[65] Businco et al. (1999). "Prevention and management of food allergy," *Acta Paediatr* Suppl 88 (430), pp. 104-9.

[66] SAP III (2000). "A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Assessment of Scientific Information Concerning StarLink Corn," FIFRA Scientific Advisory Panel, SAP Report No. 2000-06, December 1, 2000, p. 16.

[67] FDA (1994). Transcript of "Conference on Scientific Issues Related to Genetically Modified Organisms in Transgenic Food Crops," a conference sponsored by FDA, EPA and USDA, April 18-19, 1994, pp. 219-220; Urisu A. (2001). "Commonly known allergenic sources (IgE-mediated and non IgE-mediated food allergens as well as environmental allergens)," Working Paper Biotech 01/04 for the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, January 22-25, 2001.

[68] Petition, pp. 43-44.

[69] EPA BRAD (2001b). Biopesticides Registration Action Document (BRAD) --- *Bacillus thuringiensis* Plant-Incorporated Protectants: Product Characterization & Human Health Assessment, US EPA, October 15, 2001, Table A2, pp. IIA4-5. http://www.epa.gov/pesticides/biopesticides/pips/bt_brad2/2-id_health.pdf.

[70] SAP MT (2000). Mammalian Toxicity Assessment Guidelines for Protein Plant Pesticides. *FIFRA Scientific Advisory Panel.* SAP Report No. 2000-03B.

means that food-grade corn contaminated with Event 3272 even at low levels could still have levels of AMY797E sufficient to raise allergenicity concerns.

Consultation with allergists on potential allergenicity of AMY797E

CFS consulted several leading food allergists who also have extensive experience in the allergenicity assessment of transgenic proteins in GM crops to get their impressions of the allergenic potential of AMY797E. Their brief comments were given in response to summary information about the properties of AMY797E presented to them by CFS. To our knowledge, these allergists did not have the opportunity to examine Syngenta's petition or USDA's draft environmental assessment. Thus, it is possible that their thoughts on this matter might change after more thorough consideration of the relevant material.

Dr. Hugh Sampson is a leading food allergist and pediatrician at the Mount Sinai School of Medicine, and currently serves as president of the American Academy of Allergy, Asthma & Immunology. He has participated in formulation of protocols for the allergenicity assessment of transgenic proteins in GM crops, and also served on expert panels convened by the U.S. Environmental Protection Agency to examine the potential allergenicity of genetically engineered StarLink corn's insecticidal protein, Cry9C. Dr. Sampson's extensive experience with the StarLink affair made him skeptical that Event 3272 could be prevented from entering the human food chain. Dr. Sampson was not sure how to interpret AMY797E's similarity to the cockroach allergen without further investigation, but felt that "the apparent resistance to digestion of this corn variety does raise concern with respect to allergenicity." He hoped that USDA would require more testing before considering approval.[71]

Dr. Marc Rothenberg is director of the Division of Allergy and Immunology and professor of pediatrics at Cincinnati Children's Hospital Medical Center. Dr. Rothenberg is also a leading food allergist, and like Dr. Sampson served on expert panels convened by the EPA to examine the StarLink affair. In a comment he submitted to the docket, Dr. Rothenberg noted some potential concerns, including AMY797's acid stability, its relatively high concentration, and its homology to a known allergen. Dr. Rothenberg urged USDA to apply "extra caution" in considering approval of this corn variety.[72]

Dr. Heimo Breiteneder is a molecular allergologist and head of the Division of Medical Biotechnology at the Medical University of Vienna, Austria, and has written extensively on the structure of food allergens and related topics. Dr. Breiteneder's concerns centered on AMY797E's thermostability, its resistance to digestion and low pH, and its high expression level. He noted that the lack of prior human exposure to AMY797E is no guarantee that it will not act as an allergen. Dr. Breiteneder also stated that "if IgE from

[71] Email communication, January 15, 2009.
[72] Comment number APHIS-2007-0016-0114, received 1/12/09, posted 1/13/09, comment tracking number 8081bc77.

alpha-amylase allergic individuals reacts with the transgenic protein, that would be of concern."[73]

Other potential adverse health impacts

Production of AMY797E is the intended effect of the genetic engineering process used to develop Event 3272. It is well accepted that genetic engineering has a greater likelihood of producing unintended effects than traditional breeding, some of them hazardous or detrimental.[74] The "degree to which possible effects on the human environment are highly uncertain or involve unique or unknown risks" is of course key to NEPA's trigger of significance requiring an EIS.[75]

Unintended effects are rarely well-understood, but can result from extensive mutations to the organism's genes caused by the genetic engineering process,[76] or unexpected metabolic alterations. Such disruptions are sometimes evident in the form of non-viable or debilitated organisms. Others may have subtler effects that go undetected in the development process. Potential adverse effects include the unintended amplification of naturally occurring toxins that are normally present at low, unobjectionable, levels; the unintended creation of novel toxins; or reduced levels of nutrients.
For example, yeast genetically modified for altered glycolytic pathways exhibited a 30-fold increase in production of methyglyoxal,[77] a highly toxic and mutagenic compound that also causes enhanced protein glycation and oxidative stress, conditions associated with diabetes, neurodegenerative disease and a variety of autoimmune disorders.[78] The authors of the yeast study concluded that "careful thought should be given to the potential metabolic products and their safety when a genetically modified yeast is applied to food-related fermentation processes.[79]

A second example involves production of the dietary supplement tryptophan in bacteria. In the late 1980s, thousands of consumers of tryptophan contracted a rare and debilitating disease, eosinophilia myalgia syndrome, that was most likely due to the unintended creation of highly toxic metabolites when the manufacturer switched from conventional

[73] Email communication, January 13, 2009.
[74] NAS (2004). *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects, Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health*, Institute of Medicine & National Research Council, National Academy of Sciences.
[75] 40 C.F.R.§ 1508.27(b)(5).
[76] Wilson, AK, Latham, JR and RA Steinbrecher (2006). "Transformation-induced mutations in transgenic plants: Analysis and biosafety implications," *Biotechnology and Genetic Engineering Reviews*, Vol 23, Dec. 2006, 209-234.
[77] Inose, T. & Murata, K. Enhanced accumulation of toxic compound in yeast cells having high glycolytic activity: A case study on the safety of genetically engineered yeast. *Intl J Food Sci Tech* **30**, 141-146 (1995).
[78] Kurien, B.T., Hensley, K., Bachmann, M. & Scofield, R.H. Oxidatively modified autoantigens in autoimmune diseases. *Free radical biology & medicine* **41**, 549-556 (2006).
[79] Inose et al (1995), op. cit.

to genetically modified bacteria to produce the tryptophan.[80] The world's most widely planted GM crop, Roundup Ready soybeans, have been reported to have lower phytoestrogen levels,[81] and higher levels of lignin,[82] the latter effect implicated in stem-splitting at high temperatures. Other unintended effects reported in GM plants are necrotic lesions in wheat, adverse tuber tissue perturbations in GM potatoes, and unexpected carotenoid derivatives in GM rice.[83]

Current assessment procedures examine a very limited array of key nutrients and selected anti-nutrients and toxicants for potential changes in levels of expression relative to non-engineered plants. With this "targeted approach:"

"…unexpected changes are merely identified by chance. The targeted approach has severe limitations with respect to unknown anti-nutrients and natural toxins…"[84]

The inadequacies of this approach have led to calls for a "non-targeted" assessment utilizing profiling methods.

Profiling methods currently available or under development include DNA expression analysis, proteomics, two-dimensional gel electrophoresis, and chemical fingerprinting. These techniques – used singly or in combination – permit simultaneous, small-scale, quantitative analysis of a large array of plant components, including messenger RNA, proteins and metabolites. The virtue of this "non-targeted" approach is that it casts a wide net, implicitly acknowledging what genetic engineers often prefer to ignore: that genetic engineering often causes completely unintended effects, making the crude "targeted" analysis of a few cellular components ineffective as a means for detecting them. Kuiper et al (2001) urge rapid refinement and application of these profiling techniques to ensure the most complete assessment possible of unintended effects caused by any application of genetic engineering. In part because profiling techniques have not been perfected, long-term animal feeding studies with the whole GM plant are also needed to ensure that any subtle, long-term effects (such as reproductive disorders, cancers, or endocrine disruption) do not go undetected.[85]

It should be noted that neither US nor EU regulatory authorities demand either comprehensive profiling assessments or long-term animal feeding studies with the whole

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[80] Kilbourne, EM et al (1996). "Tryptophan produced by Showa Denko and epidemic eosinophilia-myalgia syndrome," *J. Rheumatol Suppl.*, 46: 81-88; Schubert, D.R. (2002). "A different perspective on GM foods," Nature Biotechnology 20: 969.

[81] Lappe, MA et al (1998). "Alterations in clinically important phytoestrogens in genetically modified, herbicide-tolerant soybeans," *Journal of Medicinal Food,* 1: 241-45.

[82] Gertz, J.M., Vencill, W.K. and Hill, N.S. (1999). Tolerance of transgenic soybean (Glycine max) to heat stress. In: Proceedings of the 1999 Brighton Crop Protection Conference: Weeds, Vol. 3. Farnham, UK: British Crop Protection Council, pp. 835-840.

[83] Kuiper, HA, Kleter, GA, Noteborn, HPJM & Kok, EJ (2001). Assessment of the food safety issues related to genetically modified foods," *The Plant Journal* 27(6): 503-528, Table 6.

[84] Kuiper et al (2001), op. cit., p. 516.

[85] Freese, W. & Schubert, D. (2004), "Safety Testing and Regulation of Genetically Engineered Foods," *Biotechnology and Genetic Engineering Reviews,* Vol. 21, November 2004, pp. 299-324.; http://www.foe.org/camps/comm/safefood/gefood/testingregbackgrounder.pdf.

GM plant. For one recommended GM crop safety testing scheme, see Freese and Schubert (2004).

The Need for additional testing of Event 3272 for unintended effects

U.S. regulators have yet to acknowledge the need for long-term animal feeding studies, despite the fact that several such studies suggest that certain GM crops may be harmful.[86] However, the need to test for unintended alterations in the levels of nutrients and naturally occurring, harmful plant compounds is better accepted. Syngenta measured the levels of a handful of antinutrients and secondary metabolites in the grain of Event 3272.[87] However, no tests were conducted for several toxins[88] that have recently been characterized in ground corncobs, fresh corn, and as well as corn tortillas in a series of seven papers published by a Baylor University team from 2002 to 2008.[89]

The presence of these toxins was first discovered by accident, when researchers observed severe disruption in the sexual behavior of laboratory rats raised on ground corncob bedding material. The endocrine-disrupting substances were eventually isolated, and were found to be tetrahydrofuran-diol (THF-diol) and leukotoxin-diol (LTX-diol) derivatives of linoleic acid, the most common fatty acid in corn. The lowest observed adverse effects levels of THF-diols and LTX-diols for blocking estrous cyclicity in female rats were found to be 0.5-1.0 ppm and 0.2-0.5 ppm, respectively, while 1-2 ppm of THF-diols block male sexual behavior. These potent compounds are therefore active at levels 200-fold lower than classical phytoestrogen endocrine disruptors. In addition to

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[86] Velmirov, A, Binter, C and J. Zentek (2008). "Biological effects of transgenic maize NK603 x MON810 fed in long term reproduction studies in mice," Federal Ministry for Health, Families and Youth, Government of Austria, October 2008; Seralini, GE, Dellier, D, de Vendomois, JS (2007). "New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity," Arch. Environ. Contam. Toxicol. 52(4): 596-602.

[87] Petition, p. 68.

[88] Like Syngenta's petition, FDA's consultation memo on Event 3272 contains no mention of any testing for these compounds, discussed below.

[89] Shoulars K, Rodriguez MA, Thompson T, Turk J, Crowley J, Markaverich BM (2008). "Regulation of the nitric oxide pathway genes by tetrahydrofurandiols: microarray analysis of MCF-7 human breast cancer cells," *Cancer Lett.* 264(2): 265-73; Markaverich BM, Crowley J, Rodriquez M, Shoulars K, Thompson T (2007). "Tetrahydrofurandiol stimulation of phospholipase A2, lipoxygenase, and cyclooxygenase gene expression and MCF-7 human breast cancer cell proliferation," *Environmental Health Perspectives* 115(12): 1727-31; Markaverich BM, Alejandro M, Thompson T, Mani S, Reyna A, Portillo W, Sharp J, Turk J, Crowley JR (2007). "Tetrahydrofurandiols (THF-diols), leukotoxindiols (LTX-diols), and endocrine disruption in rats," *Environmental Health Perspectives* 115(5): 702-8; Markaverich BM, Crowley JR, Alejandro MA, Shoulars K, Casajuna N, Mani S, Reyna A, Sharp J (2005). "Leukotoxin diols from ground corncob bedding disrupt estrous cyclicity in rats and stimulate MCF-7 breast cancer cell proliferation," *Environmental Health Perspectives* 113(12): 1698-704; Mani SK, Reyna AM, Alejandro MA, Crowley J, Markaverich BM (2005). "Disruption of male sexual behavior in rats by tetrahydrofurandiols (THF-diols)," *Steroids* 70(11): 750-754; Markaverich BM, Alejandro MA, Markaverich D, Zitzow L, Casajuna N, Camarao N, Hill J, Bhirdo K, Faith R, Turk J, Crowley JR (2002). "Identification of an endocrine disrupting agent from corn with mitogenic activity," *Biochem Biophys Res Commun* 291(3): 692-700;
Markaverich et al (2002). "A Novel Endocrine-Disrupting Agent in Corn with Mitogenic Activity in Human Breast and Prostatic Cancer Cells," *Environmental Health Perspectives*, 110(2), Feb. 2002, pp. 169-177.

their impacts on rat sexual behavior, these compounds also foster proliferation of human breast and prostrate cancer cells *in vitro*, and so may adversely affect human health.

Distillers grain and solubles derived from Event 3272 as the byproduct of ethanol production would be fed in large quantities to livestock. Event 3272 would also inevitably enter human food channels via contamination and human error; and whatever Syngenta's current marketing plans might be, the proposed deregulation would in no way prohibit the intentional routing of Event 3272 into the human food supply. At a minimum, then, Event 3272 should be thoroughly tested for the presence of these toxic compounds to protect human and animal health. Application of profiling techniques and long-term animal feeding studies with toxicological endpoints should also be conducted.

These potential significant impacts to public health require analysis in an EIS.

II. The EA Alternatives Analysis is deficient and improperly limited to only two alternatives. APHIS mischaracterizes its authority overly narrowly instead of properly analyzing reasonable alternatives to the proposed action. An EIS is required.

The EA's Alternatives Section is legally deficient and without further analysis, including more alternatives, will render APHIS's determination arbitrary and capricious. (EA at 20-23). "NEPA requires that alternatives ... be given full and meaningful consideration, whether the agency prepares an EA or an EIS, the agency must "provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact."[90] The consideration of alternatives requirement furthers NEPA's goal by guaranteeing that agency decisionmakers "[have] before [them] and take [ ] into proper account all possible approaches to a particular project (including total abandonment of the project) which would alter the environmental impact and the cost-benefit balance."[91] 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.[92] Informed and meaningful consideration of alternatives is thus an integral part of the statutory scheme.[93]

The draft EA only analyzes two alternatives: a no-action alternative and complete deregulation of Event 3272. (EA at 20). In order to comply with NEPA, APHIS must "[r]igorously explore and objectively evaluate all reasonable alternatives."[94] APHIS's determination it must only analyze two alternatives, no-action and complete deregulation,

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[90] 40 C.F.R. § 1508.9; Center for Biological Diversity v. National Highway Traffic Safety Admin. 538 F.3d 1172, 1217 -1218 (9th Cir. 2008)
[91] Calvert Cliffs' Coordinating Committee, Inc. v. United States Atomic Energy Commission, 449 F.2d 1109, 1114 (D.C. Cir.1971).
[92] Id.
[93] *See* Bob Marshall Alliance v. Hodel, 852 F.2d 1223, 1228 (9th Cir. 1988).
[94] 40 C.F.R. § 1502.14(a).

that there are no other "reasonable alternatives," is arbitrary and capricious.[95] APHIS prejudges the outcome and the scope of its assessment from the outset to exclude any partial deregulation alternatives: in the introduction of the EA, APHIS says that public comment is requested only on whether it should "grant nonregulated status in whole, or that an [EIS] of Event 3272 corn is necessary prior to the decision to grant nonregulated status." (EA at 8).

Partial Deregulation Arbitrarily and Capriciously Defined

APHIS admits as it must that it has at least one other option, approval of the petition "in part." (EA 20). The regulations expressly state that APHIS may deny deregulation petitions, grant them in whole or in part.[96] However APHIS claims that no partial deregulation needed to be analyzed in this case, that no analysis of any third alternative need be included. First APHIS claims "in part" would be applicable in cases where deregulation was requested for more than one line of crop and one line had a plant pest risk while the others did not. (EA at 20). Another "type" of "in part" approval the agency acknowledges is an approval with geographic restrictions, if there is a "geographic variation in plant pest risk." (EA at 20). The EA concludes that neither of these "types" of "in part" approvals are applicable to Event 3272, because there is only one line and because there are no geographic differences in plant pest risk for Event 3272. Therefore according to APHIS only two alternatives need be considered in the EA: no-action and deregulation in whole. (EA at 20).

There are several problems with APHIS's reasoning. First, even under APHIS's flawed and overly constrained interpretation of its authority, there are geographic differences with Event 3272 that would counsel in favor an alternative including geographic restrictions. For example, Event 3272 is likely to be grown more frequently near ethanol plants, increasing the probability for biological contamination to other non-fuel crops in those areas. Geography is certainly relevant: for example, APHIS itself limited its effects analysis to only those states that grew corn AND had an existing or under construction corn ethanol facility. (EA at 24). APHIS further limited its analysis to only those 26 states and the counties within them. Similarly, counties that have existing GE crop bans were left out of APHIS analysis. (EA at 25). Further, APHIS points out that Syngenta contracts for Event 3272 will be for that crop grown "only within the geographic footprint of an ethanol plant." (EA at 26). Finally, APHIS expressly states that "because Event 3272 corn will be marketed for use in ethanol production, *this corn variety will be limited to production areas that surround ethanol production facilities*." (EA at 28). Thus, geographic proximity to ethanol production facilities is clearly a relevant "geographic variation" to the risk of contamination of other crops from Event 3272, as potential contamination exposures will be much higher in those areas where it is anticipated to be grown. Such a "reasonable" alternative should have been included in the EA and "rigorously analyzed" in order to comply with NEPA.[97]

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[95] *See, e.g.*, *Curry v. U.S. Forest Service*, 988 F. Supp. 541, 553-554 (W.D. Pa. 1997) (failure of the Forest Service to consider more than two alternatives in connection to forest project was arbitrary and capricious).
[96] 7 C.F.R. § 340.6(d)(3)(i).
[97] 40 C.F.R. § 1502.14(a).

Second and more fundamentally, APHIS's determination in the EA of the scope of its "in part" deregulation authority is arbitrary and capricious.[98] In the draft EA APHIS limits when it can approve a petition "in part" to two cases only: when more than one line is applied for in a petition and geographic restrictions. (EA at 20). *Nothing in the Plant Protection Act or its implementing regulations so constricts APHIS's authority to only those two applications of a partial deregulation*. In the EA, APHIS gives no citation for its arbitrarily constrained conclusion. Agencies cannot define the project so narrowly that it foreclosed a reasonable consideration of alternatives;"[99] they "cannot define its purpose and need so as to winnow down the alternatives until only the desired one survives."[100] "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.'[101] Partial deregulation is logically interpreted to encompass a range of alternatives stretching from a regulated article or prohibiting release to complete deregulation. There is no rational basis (or explanation given) for APHIS conclusion in the EA that its authority is limited to these two types partial deregulations only. For example, at least one court has held that APHIS can and should consider in an EIS measures that would inform a judgment of a partial deregulation such as isolation distances.[102] In *Geertson* APHIS conceded that "one option that APHIS has is to approve Monsanto's 'petition with a geographic limitation stipulating that the Roundup Ready could only be grown without APHIS authorization in certain geographic areas.'"[103] APHIS did not appeal this ruling and is in the process of completing the EIS analyzing, among other things, the efficacy of any such isolation distance measures. This would be one other "Type" of partial deregulation separate from those that the EA limits itself too.

Fails to Rigorously Analyze Other Reasonable Alternatives

Next APHIS has a brief discussion of "considered but rejected" alternatives list. (EA at 21). The draft EA lists four: "prohibit any Event 3272 corn from being released"; "Isolation distance between Event 3272 corn and non-GE corn production"; "Geographic restrictions"; and "Requirement of testing for Event 3272 corn." (EA at 21-22). The paucity of discussion on these rejected alternatives is insufficient to comply with NEPA. In order to comply with NEPA, APHIS must "[r]igorously explore and objectively evaluate all reasonable alternatives."[104] Such cursory (1 ½ pages) rejection is not

[98] 7 C.F.R. § 340.6(d)(3)(i).
[99] *Davis*, 302 F.3d at 1119; *Klamath-Siskiyou Wildlands Center v. U.S. Forest Service*, 373 F. Supp. 2d 1069 (E.D. Cal. 2004)
[100] *Klamath-Siskiyou Wildlands Center v. U.S. Forest Service*, 373 F. Supp. 2d 1069 (E.D. Cal. 2004).
[101] *Center for Biological Diversity v. National Highway Traffic Safety Admin*, 538 F.3d 1172, 1213 - 1214 (9th Cir. 2008).
[102] Geertson Seed, 2007 WL 518624 at *6.
[103] *Id.* (citing and quoting APHIS in the administrative record documents, AR 5504).
[104] 40 C.F.R. § 1502.14(a).

"rigorous" analysis. As discussed above, geographic restrictions as well as isolation distances are certainly reasonable alternatives for GE crops, including Event 3272. [105]

Improper Reliance on Earlier Plant Pest Assessment

The EA rejects each of these reasonable alternatives without analysis, in a few sentences each, relying on the exact same pro forma language in each case: "*Because Event 3272 corn is unlikely to pose a plant pest risk (USDA-APHIS 2008), APHIS has no regulatory authority over Event 3272 corn and is unable to* [require/impose the alternatives such as isolation distances or geographic restrictions.]" (EA at 21). Similarly at the outset of the Alternative Section APHIS states its earlier conclusion that it found Event 3272 unlikely to pose a plant pest risk and thus, it has no regulatory authority over Event 3272 corn and that the GE corn variety is eligible for nonregulated status. (EA at 20). This gets to the crux of APHIS's misconception of NEPA and mischaracterization of its authority under the Plant Protection Act. Essentially, APHIS refuses to assess any further alternatives than a "no-action" alternative and a complete deregulation alternative, not because other alternatives like isolation distances would not work or because such measures might not be needed, *but just because APHIS claims that it is unable to impose any such restrictions* based on its authority, because it already previously decided, in a separate document that Event 3272 is not a plant pest.

APHIS essentially argues that the scope of its NEPA obligations is very narrow, limited to whether or not Event 3272 is a plant pest under the PPA. Further, since APHIS has already made its decision that Event 3272 is NOT a plant pest in an earlier document that pre-dates the draft EA, it need not look at any impacts that might be associated with plant pest risk, because in its judgment Event 3272 is not a plant pest. This doesn't leave very much at all that APHIS must then address in the EA.

The agency's reasoning is conclusory and circular: the EA need not a hard look at risks related to whether or not Event 3272 may impact the environment or other crops as a plant pest because Event 3272 is not a plant pest. APHIS has the analysis process precisely backwards: the EA *should inform the agency's decision-making process*, not the other way around (i.e., have the agency's forgone conclusion limit and prejudge the NEPA analysis). The policy behind NEPA is "to ensure that an agency has at its disposal all relevant information about environmental impacts *before* the agency embarks on the project."[106] Under the agency's reasoning the actual deregulation decision and EA accompanying it is just a formality: the only thing that matters is the seven-page plant pest assessment. If the agency doesn't have to look at any alternatives because it has already previously determined Event 3272 is not a plant pest (and that is the extent of its authority and required analysis), then why any analysis at all? It would seem the agency views the NEPA process as nothing more than a formality dance to complete in order to deregulate, rather than a searching process that should inform the agency regarding its decisions.

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[105] Geertson Seed, 2007 WL 518624 at *6.
[106] *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1356 (9th Cir.1994).

Improper Scope of APHIS's NEPA Obligations

Second, APHIS's cannot evade any meaningful NEPA review by simply pointing to its earlier plant pest assessment because APHIS's statutory authority is much broader than just "plant pest." APHIS itself recognizes this in the EA (EA at 21) (quoting risks from "plant pests *or noxious weeds*"). NEPA review can be limited by statutory authority, not by individual regulation. And APHIS's claim that its authority is limited to plant pests only is erroneous. The PPA gives APHIS broad power to prohibit or regulate not only plant pests, but "noxious weeds":

> The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.[107]

The statutory definition of "noxious weed" is very broad:

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

Thus APHIS has much more authority over Event 3272 than the EA acknowledges. It clearly has the statutory authority to "prevent" and "restrict" any plant if necessary to prevent the dissemination of a plant pest *or noxious weed*. What is a noxious weed is defined to include many of the harms noted in these comments from biological contamination to other crops from Event 3272: public health risks, damage to crops, the environment, and the interests of agriculture, for example. The NEPA assessment APHIS must do, including what alternatives are "reasonable," therefore is not cabined to merely the question of plant pest; but rather includes these broader types of impacts it is defined to include. As such, other alternatives that would explore these risks must be considered and cannot be disregarded simply because of APHIS's plant pest finding, without any further analysis.[109]

Further, APHIS claims it has no authority to mandate isolation distances and so it does not have to analyze an alternative with isolation distances, but the 2008 Farm Bill,

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

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

[109] APHIS claims it has no authority to mandate isolation distances and so it does not have to analyze an alternative with isolation distances, but the 2008 Farm Bill, Section 10204(b)(7), requires the Secretary to take actions that enhance "the use of the latest scientific techniques for isolation and confinement distances." Farm Bill Section 10204(c)(1)(C) requires the Secretary to consider establishing "standards for isolation and containment distances."

Section 10204(b)(7), requires the Secretary to take actions that enhance "the use of the latest scientific techniques for isolation and confinement distances." Farm Bill Section 10204(c)(1)(C) requires the Secretary to consider establishing "standards for isolation and containment distances." Congress clearly understands APHIS's existing oversight to include the power to establish isolation distances, else the agency could not comply with this particular directive in the Farm Bill.

APHIS has also acknowledged that its statutory authority is broader than it claims in this EA in its new proposed regulations. In the new proposed regulations APHIS points out:

> The PPA grants the Secretary authority to regulate … noxious weeds.
>
> …In order to best evaluate the risks associated with these GE organisms and regulate them when necessary, APHIS needs to exercise its authorities regarding noxious weeds and biological control organisms, in addition to its authority regarding plant pests.
>
> …
> We propose to better align the regulations with the PPA authorities in order to ensure that the environmental release, importation, or interstate movement of GE organisms does not pose a risk of introducing or disseminating plant pests or noxious weeds. … [T]echnological advances have led to the possibility of developing GE organisms that do not fit within the plant pest definition, but may cause environmental or other types of physical harm or damage covered by the definition of noxious weed in the PPA. Therefore, we consider that it is appropriate to align the regulations with both the plant pest and noxious weed authorities of the PPA.[110]

Finally, under the current regulations, no existing regulation prohibits APHIS from regulating GE crops that do not pose a plant pest risk, nor does any regulation demand that APHIS deregulate organisms that are not plant pests. APHIS's statutory authority aside, as noted above it has discretion whether to grant a petition under its plant pest regulatory authority, and may exercise that discretion to grant a petition "in whole," "in part," or not at all.[111] And partial deregulation could include isolation distances, geographic restrictions, or agronomic practices, for example, the EA's unsupported claim that "in part" is limited to only circumstances of geographic restrictions or crop line restrictions notwithstanding.

The EA is arbitrary and capricious in its disregard for reasonable alternatives and failure to assess any alternatives except the "no action" alternative and the complete deregulation. An EIS is required.

[110] 73 Fed. Reg. 60008, 60011 (Oct. 9, 2008) (emphasis added).
[111] 7 C.F.R. § 340.6(3)(i).

III. APHIS's analysis of environmental effects is inadequate and an EIS is required. APHIS improperly relies on mitigation measures that it does not require or fully analyze. APHIS fails to adequately assess biological contamination from Event 3272 and the concomitant socioeconomic impacts on organic and conventional farmers as well as export markets. APHIS fails to adequately analyze the effects on biodiversity and consumers from the loss of choice. APHIS fails to adequately analyze impacts to soil biology.

Geertson Seed Farms v. Johanns

In the recent federal court decision *Geertson Seed Farms v. Johanns,* the United States District Court held, and the United States Court of Appeals for the Ninth Circuit affirmed, that where biological contamination of a non-GE crop by is made possible by the deregulation of its GE counterpart, APHIS must prepare an EIS to disclose and analyze the contamination as well as the interrelated adverse economic effects.[112] These effects include impacts to conventional and organic farmers, exports and consumers' right to choose. There is ample evidence from the deregulation of Event 3272 that such adverse impacts are not only possible, but highly likely.

APHIS improperly relies on voluntary mitigation measures proposed by Syngenta that are not required or analyzed by APHIS.

APHIS concedes upfront that: "The environmental effect analysis is greatly dependent on assumptions used for estimating effects."[113] In general, APHIS has relied excessively on assumptions[114] and failed to collect the empirical evidence needed to make an informed decision. Many of APHIS's assumptions are based on the marketing plans, contractual arrangements, and stewardship agreements that Event 3272's developer, Syngenta, has proposed to employ. APHIS's proposed deregulation, however, is not conditioned on Syngenta's current plans, arrangements or agreements. It is improper for APHIS to conduct its environmental assessment and make a finding of no significant impact on the assumption that growers of Event 3272 will only cultivate it subject to the provisions of a stewardship agreement with Syngenta. The stewardship agreement discussed by Syngenta and APHIS merely represents the company's current marketing plans with respect to this corn variety, plans which could change at any time at the company's discretion in the event of the unconditional deregulation proposed by APHIS. Further,

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[112] 2007 WL 518624 (N.D. Cal. Feb. 13, 2007) *aff'd*, 541 F.3d 938 (9th Cir. 2008).
[113] EA, p. 24.
[114] In places, APHIS is not even clear on the assumptions it is making. (EA at 24-25). For instance, APHIS first states that it "will limit the environmental analysis to those areas that currently support corn production," and even lists the 49 states where corn is grown. Immediately afterwards, however, we learn that the environmental analysis will be restricted to the 26 states that both grow corn and have an active corn ethanol facility or one under construction. On the very next page, the environmental analysis is restricted still further, to ***the counties*** in those 26 states that have a corn ethanol plant or one under construction. Clearly, the first assumption is the most justifiable: in the absence of any APHIS-imposed geographic prohibitions on where Event 3272 may be grown, it is clearly reasonable to assume that it will be grown, like any other corn variety, wherever corn is normally cultivated.

since APHIS will have no authority to enforce these arrangements, its assessment cannot assume they will be carried out.

Syngenta's stewardship program is a form of mitigation, relied on by Syngenta and APHIS to mitigate potential gene flow and the impacts that flow from biological contamination. CEQ has warned that "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.[115] APHIS should heed this guidance and prepare an EIS analyzing, among other things, the efficacy of Syngenta's proposed stewardship measures.

CEQ has indicated that "Mitigation 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."[116] Here, Syngenta's proposal is not required by APHIS in the deregulation. In fact it is not even necessarily required by Syngenta, as the language of the EA is that Syngenta "*anticipates* that Event 3272 corn will be commercialized with the use of the [stewardship system.]" (EA at 25) (emphasis added).[117] APHIS relies on the Syngenta methods repeatedly in the EA to support its conclusion that the preferred alternative of complete deregulation does not require an EIS to address potential significant environmental impacts. (EA at 25-26; 31-32; 33; 39).

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."[118] APHIS has not undertaken any of its own analysis regarding whether Syngenta's stewardship measures will work or not as an "adequate buffer" from contamination. As is discussed in detail below, there is significant evidence that contamination will happen and that any measures proffered by Syngenta will not prevent it. *See* pp. 26-39.

Further, in an EA and FONSI if mitigation is relied upon the agency is obliged to prepare a reasonably complete discussion of the mitigation measures;[119] the mitigation analysis cannot be merely "perfunctory."[120] Here APHIS merely repeats Syngenta's measures without doing any of its own analysis of the measures. The closest that APHIS comes is merely to note that "*Sygenta's analysis* [not its own] [merely] *suggests*" that the 12 border rows of non-Event 3272 will stop contamination. (EA at 26). The grand total of APHIS's "analysis" of Syngenta's so-called "closed-loop" system is 1 ¼ pages. (EA at 25-26).

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[115] Council on Environmental Quality, "Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations," Question 40, 46 Fed. Reg. 18026, 18037 (1981).
[116] Council on Environmental Quality, "Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations," Question 40, 46 Fed. Reg. 18026, 18037 (1981).
[117] Later in the EA, APHIS relies on the measures, calling them "mandatory", in concluding they will facilitate co-existence. (EA at 31). Later still the EA calls the Syngenta measures "best management guidelines" but that they are "required." EA at 39.
[118] National Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722 (9th Cir. 2001).
[119] Vermont Pub. Interest Research Group v. USFWS, 247 F.Supp.2d (D. Vt. 2002).
[120] Neighbors of Cuddy Mountain v. USFS, 137 F.3d 1372 (9th Cir. 1998).

Courts have emphasized that "substantial evidence" is needed in support of mitigation measures, assurance that the mitigation measure is effective. [121] Certainly APHIS has not shown what data if any supports Syngenta's stewardship system, let alone that the measures are supported by substantial evidence. Mitigation analysis is inadequate if there is a paucity of or no supporting of analytical data, or if the agency failed to conduct a study on the anticipated effects or efficacy of the mitigation measures, or provide criteria for an ongoing examination of them or for taking needed corrective actions.[122] The EA does not include any of APHIS's own studies regarding Syngenta's stewardship proposals for Event 3272, or provide any criteria for an ongoing examination of it or for taking corrective actions. (EA at 25-26). Courts have struck down as arbitrary and capricious EAs relying on mitigation measures in which the agency did not conduct a study of its likely effects, did not propose monitoring, and did not consider alternatives. [123] Nor has APHIS considered reasonable alternatives to the proposed action (see above Section II) or propose any monitoring.

Syngenta also claims that the stewardship measures it offers to "facilitate coexistence" and the "suite of industry practices in the U.S. grain market system" make *Geertson Seed Farms* inapposite, because the diversity of corn is "closely guarded." (Appendix G at 126).[124] To the contrary, in *Geertson* APHIS similarly relied on "good stewardship" with regard to the development of weed resistance in particular, 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.[125] Similarly, in placing an injunction in place until APHIS completes the GE alfalfa EIS, the court recognized that the threat of harm absent the injunction was sufficiently likely because contamination had occurred *despite Monsanto's contractual stewardship provisions being in place*.[126] The court held APHIS's proposal for relief inadequate to protect from contamination harm in part because they were substantially similar to Monsanto's already existing contractual provisions.[127] The Court of Appeals affirmed: "Here, the agency's proposed interim measures [found to be substantially similar to the contract stewardship provisions] would perpetuate a system that was found by the district court to have caused environmental harm in the past."[128] As in this case, in *Geertson* Monsanto and Forage Genetics represented their contractual provisions as more than sufficient to prevent contamination, a misrepresentation belied by the real world events.

Biological Contamination from Gene flow

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[121] National Audubon Soc'y v. Hoffman, 132 F.3d 7 (2d Cir. 1997)
[122] Id. at 734; Western Land Exch. Project v BLM, 315 F. Supp. 2d 1068 (D. Nev. 2004).
[123] National Audubon Soc'y v. Hoffman, 132 F.3d 7 (2d Cir. 1997)
[124] Syngenta also claims that *Geertson* is not precedential because it was an unpublished opinion. Appendix G at 126. This is not the case. *Geertson* was affirmed on appeal in a published decision of the Ninth Circuit. 2007 WL 518624 (N.D. Cal. Feb. 13, 2007) *aff'd*, 541 F.3d 938 (9th Cir. 2008).
[125] *Geertson*, 2007 WL 5186624, at *10.
[126] *Geertson*, 2007 WL 1302981, at *5.
[127] *Id.*
[128] 541 F.3d at 946.

The potential for biological contamination, through pollen flow and uncontrolled seed movement of Event 3272, triggers the requirement that APHIS prepare an EIS for this deregulation. The term "biological contamination" refers to the unintended comingling of GE crops with non-GE crops. "Biological 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."[129] As the *Geertson* Court noted: "Once the gene transmission occurs and a farmer's seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread."[130]

As the *Geertson* Court found, once a GE crop is deregulated "the government will not be able to impose isolation distances on the growers of [the GE crop]; in other words, it cannot ensure that farmers using genetically engineered seed will be more than two miles away from seed farmers who do not wish to grow [the GE crop]."[131] In this case, there is ample evidence that contamination is not only possible but highly likely where Event 3272 is allowed to be grown without restriction.

However, even if one assumes that Event 3272 will be grown in the context of some sort of stewardship agreement, neither the petition nor APHIS's EA provide sufficient information to judge its adequacy for the crucial task of preventing gene flow from Event 3272 corn to other varieties of corn grown in the area. First, we should but do not have access to a copy of the stewardship agreement itself, and so are unable to judge the adequacy of its provisions. Second, we find no reference in the petition or the EA suggesting that growers in a stewardship agreement with Syngenta to grow Event 3272 will observe any particular isolation distance between Event 3272 and other corn fields. APHIS refers to "the requirement that growers include 12 rows of non-Event 3272 corn as a pollen trap to reduce the amount of Event 3272 pollen that may leave the corn field," referring to the analysis provided by Syngenta in Appendix D to the EA.[132]

Appendix D, entitled "Pollen-mediated gene flow report submitted by Syngenta: Minimization of pollen-mediated gene flow from corn amylase corn [sic] through planting border rows,"[133] likewise contains no statement that growers of Event 3272 will be requested or required to observe any particular isolation distance. Syngenta states: "As previously communicated to APHIS BRS on September 6, 2007, Syngenta, post-commercialization, will instruct growers to plant 12 border rows around each CA [corn amylase] field." This statement, the title of the appendix, and the absence of any affirmative statements on this point, suggest that the stewardship agreement will not stipulate that growers observe any particular isolation distance. It is true that the two scenarios portrayed in Figures 1 and 2 of the appendix involve isolation distances of 200 meters. But these scenarios are presented merely to illustrate any pollen-mediated gene

[129] Id. at 5.
[130] Id.
[131] Id.
[132] EA, p. 26.
[133] EA, pp. 113-117.

flow analysis by Ma (2005) as applied to Event 3272. There is no affirmative statement that 200 meters will be stipulated as the required isolation distance in the stewardship agreeement. APHIS further states that: "Best management guidelines for Event 3272 corn (Appendix D and Appendix G) require the use of 12 border rows of non-Event 3272 corn to reduce the likelihood of gene movement between Event 3272 corn and other corn fields."[134] One would surely expect an isolation distance to be stated here if it were in fact part of the "best management guidelines" or stewardship agreement. Appendix G to the draft EA, which contains a section IV entitled: Syngenta Stewardship Program for Event 3272 Corn, also fails to cite any isolation distance, and in fact fails to provide any detailed information on its provisions. In short, based on the information provided in the petition and the draft EA, we must assume that Syngenta's stewardship agreement includes the planting of border rows, but no minimum isolation distance.

However, for the sake of argument for the following discussion, we will make the twin assumptions that Event 3272 will only be grown subject to the provisions of a stewardship agreement, and that this stewardship agreement stipulates that growers utilize the isolation distance analyzed in Appendix D – that is, 200 meters (roughly 660 feet). Even under these assumptions, however, the evidence is overwhelming that Event 3272 corn will contaminate other corn.

First, it must be emphasized that there are a huge number of corn pollen flow studies, and that the results of various studies with respect to the distance corn pollen can travel vary dramatically depending upon the conditions under which they are conducted. For instance, though corn pollen normally remains viable for only 1 to 2 hours, under milder temperatures and higher humidity it can remain viable longer, up to several days, increasing the potential for cross-fertilization of neighboring corn fields. Individual corn plants produce four to five million pollen grains, each of which is responsible for the fertilization of a single kernel. "Therefore, even 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."[135]

According to Emerson Nafziger, Professor of Agronomy at the University of Illinois: "*…it is possible for corn pollen to move on the wind for more than a mile*. Even under low wind conditions, some corn plants on the edge of a field are normally pollinated by pollen from outside the field. ... producers 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."[136] The importance of wind speed during pollen shed is difficult to overemphasize.

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[134] EA, p. 39.
[135] Thomison, P. "Managing 'Pollen Drift' to Minimize Contamination of Non-GMO Corn, AGF-153," Ohio State University Extension Fact Sheet, undated. http://ohioline.osu.edu/agf-fact/0153.html.
[136] "How are 'GMO-free soybeans and corn labeled?" by Emerson Nafziger, Professor of Agronomy, Extension Service, University of Illinois-Urbana-Champaign, undated. http://faq.aces.uiuc.edu/faq.pdl?project_id=28&faq_id=590. Last accessed 1/20/09.

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]."[137] Discussing the difficulties of preventing contamination of organic by GE corn, Iowa State Univeristy 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."[138]

A report commissioned by the European Environment Agency that reviewed numerous corn pollen flow studies found that: "Maize pollen has been shown, by the action of wind, to cross with other cultivars of maize at up to 800 m [2625 ft.] away. It is estimated that small quantities of pollen are likely to travel much further under suitable atmospheric conditions."[139]

The Ohio State University Extension Service reports that "research has indicated that cross-pollination between corn fields could be limited to 1% or less on a whole field basis by a separation distance of 660 ft., and limited to 0.5% or less on a whole field basis by a separation distance of 984 ft. *However, cross-pollination could not be limited to 0.1% consistently even with isolation distances of 1640 ft.*"[140]

Clearly, there is no pat answer to the question of how far corn pollen can flow to fertilize neighboring corn fields, which can vary dramatically depending on conditions. What is clear is that even if Syngenta were to stipulate an isolation distance of 660 feet (for which we have no evidence, as discussed above), Event 3272 would inevitably contaminate neighboring corn fields at levels that would vary dramatically depending on the particular conditions.

The setting of isolation distances in any particular case depends upon the degree of purity that one wishes to achieve, and the adverse impacts of not achieving this goal. APHIS's discussion of the potential for Event 3272 to contaminate surrounding corn is vitiated by its failure to discuss these important matters. This failure is still more striking in view of the fact that APHIS does have considerable experience in the reproductive isolation (e.g. isolation distances and other measures to prevent contamination) of corn varieties that have been genetically engineered to produce experimental pharmaceuticals or industrial compounds (henceforth, "pharma/industrial corn" or simply "pharma corn"). Pharma/industrial corn has been genetically engineered to serve as a "biofactory" for the production of these substances.

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[137] Nielsen, R.L. (2001, rev. 2007). "Tassel Emergence & Pollen Shed," Purdue University Extension Service. http://www.agry.purdue.edu/ext/corn/news/timeless/Tassels.html.

[138] As quoted in: Perkins, J. "Genetically modified mystery," Des Moines Register, August 10, 2003.

[139] Eastham, K. and Sweet, J. (2002). Genetically modified organisms (GMOs): the significance of gene flow through pollen transfer. *Environmental Issue Report 28*. Copenhagen: European Environment Agency.

[140] Thomison, P. "Managing 'Pollen Drift' to Minimize Contamination of Non-GMO Corn, AGF-153," Ohio State University Extension Fact Sheet, undated, emphasis added. http://ohioline.osu.edu/agf-fact/0153.html.

An expert committee of the National Academy of Sciences reviewed APHIS's performance at regulating genetically engineered crops, releasing a book-length report on their assessment in 2002.[141] Among the issues addressed by the committee was gene flow with respect to pharma/industrial corn. Among the issues addressed by the committee was gene flow with respect to GE pharmaceutical-producing corn varieties (henceforth, "pharma corn"). As part of its assessment, the NAS committee reviewed a field trial permit for pharma corn production, noting that the field trial applicant was employing a 1320 foot isolation distance. Noting that a 660-foot isolation distance allows a contamination level of 0.1%, the expert NAS committee states:

> "There is no reason to assume that absolute isolation should be attained at twice that distance. It is likely there would be some very low level of contamination of any corn grown at or near the 1,320-foot isolation distance from the test plots."[142]

Dr. Norman Ellstrand, a geneticist who is a leading expert in gene flow between plants and also served on the NAS (2002) committee, says that long-distance pollen flow is poorly understood. With respect to the increased isolation distance for pharma corn noted above, he stated: "It's just not clear that setting a double distance is going to solve everything."[143] Some of the many factors that make it so difficult to predict how far corn pollen will flow to fertilize other fields of corn include, crucially, wind speed at the time the corn is pollinating; climatic conditions such as humidity that affect the length of time the corn pollen is viable; geographic features of the area where the corn field is planted, which help determine convection currents; and many others.

In 2002, APHIS set new requirements for reproductive isolation of pharma corn field trials. Previously, APHIS had merely recommended an isolation distance of 660 feet. The 2002 rule required greater isolation distances, depending on the circumstances: 0.25 miles (1,320 feet) applied to pharma corn planted *with border rows* to capture/impede pollen flow; 0.5 miles (2640 feet) for pharma corn planted *without* border rows; while an isolation distance of fully one mile (5,280 feet) was established between GE pharma corn and any corn grown for seed production, whether breeders', foundation, certified or registered seed.[144] In 2003, APHIS strengthened permit requirements still more. The new rules required a one-mile (5,280 foot) isolation distance around field trials of GE pharma corn, except when corn tassels were covered by bags to control pollination, in which case an isolation distance of one-half mile (2,640 feet) was permitted.[145]

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[141] NAS (2002). *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*. Committee on Environmental Impacts associated with Commercialization of Transgenic Plants, National Research Council, National Academy of Sciences, Washington, DC: National Academy Press. http://books.nap.edu/catalog/10258.html.

[142] NAS (2002), p. 124-125.

[143] As quoted in: Pollack, A. "New ventures aim to put farms in vanguard of drug production," *New York Times*, May 14, 2000.

[144] USDA APHIS, untitled document dated May 21, 2002 outlining the cited changes, among others. Formerly available at: http://www.aphis.usda.gov/ppq/biotech/pdf/pharm-2002.pdf. This rule is also discussed in: Brasher, P. "USDA toughens rules on biotech crops," Des Moines Register, 6/14/02.

[145] FR notice dated March 10, 2003, Vol. 68, No. 46: 11337-40. "Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds."

The 2003 rulemaking represents APHIS's judgement that an isolation distance of 5,280 feet is required to prevent GE pharma corn from contaminating corn grown nearby. *This isolation distance is fully eight times the 660 foot isolation distance that Syngenta assumes in its analysis of pollen-mediated gene flow in Appendix D.* We note further that APHIS's 2003 rulemaking prohibited the use of border rows – as proposed by Syngenta – as a means to reduce these isolation distances, as it had previously allowed (i.e. the 2002 rules discussed above). APHIS stated that:

> "other methods are available and do not pose the difficulties inherent in using border rows. For example, by eliminating the use of border rows/buffer strips, there will be a reduction in the amount of plant material that must be disposed of after the field test is terminated (border rows are handled the same as the regulated article, as their proximity to the plots make them possible pollen recipients). This should reduce the possibility of inadvertent mixing of regulated articles with nonregulated plant material."[146]

It is indeed remarkable that APHIS does not discuss, or even refer to, the rationale for the various reproductive isolation measures that it deemed necessary to mandate in order to prevent experimental GE pharma corn from contaminating other corn fields. These reproductive isolation measures represent APHIS's best judgements with respect to mitigation of gene flow in corn, and so obviously have great relevance to the discussion of this phenomenon with respect to Event 3272. APHIS's stipulation of a 5,280-foot isolation distance for pharma corn implicitly acknowledges the potential for gene flow at lesser distances.

APHIS's failure to discuss the gene flow mitigation measures it required for pharma corn field trials is still more puzzling when one recalls that Event 3272 is, properly speaking, an industrial GE crop. In 2003, APHIS issued a rule requiring that GE crops engineered to produce industrial compounds be subject to its more rigorous permitting system, similar to existing provisions already in place for pharma corn. According to APHIS:

> "For purposes of this rule, plants engineered to produce industrial compounds include those plants that meet the following three criteria: (1) The plants are engineered to produce compounds that are new to the plant; (2) the new compound has not been commonly used in food or feed; and (3) the new compound is being expressed for non-food, non-feed industrial uses."[147]

Under this definition, Event 3272 is in fact a plant engineered to produce an industrial compound. Contrary to APHIS's repeated claims of its "ubiquitous" nature, the alpha-amylase enzyme derived from marine archaeal microorganisms of the order Thermoccocus are new to corn, has not been commonly used in food

[146] FR notice March 10, 2003 cited above, p. 11338.
[147] FR notice entitled "Introduction of Plants Genetically Engineered to Produce Industrial Compounds," interim rule (effective August 6, 2003 to Dec. 31, 2004) and request for comments. I'm not sure what the status is now. Vol 68, No. 51, pp. 46434-36, August 6, 2003.

or feed, and is being expressed for the non-food, non-feed industrial use of ethanol production.

In discussing APHIS's reproductive isolation rules with respect to pharma crops, we are not arguing that they should necessarily apply as a condition of deregulation of Event 3272, for instance. Our point is that these rules reflect APHIS's experience with and judgements re: gene flow and the measures needed to mitigate gene flow with respect to corn; that this experience and these judgements are at great variance with the gene flow discussion presented by Syngenta in the petition and by APHIS in the draft EA; and that an EA which makes no attempt to deal with the huge discrepancies must be regarded as cursory, biased and incomplete, and cannot be considered NEPA-compliant.

For instance, Syngenta, referring to a single pollen-mediated gene flow [PMGF] report, states that: "Dr. Ma's exponential decline model indicates essentially a zero probability of detecting PMGF beyond six hundred and sixty-six feet (200 meters)..."[148] This may or may not be true of Dr. Ma's model, but what is clear is that Dr. Ma's model does not begin to capture the probability of pollen-mediated gene flow at any distance under the majority of corn-growing environments. As noted above, wind speed at the time of pollination is an obviously important factor in determining how far corn pollen will travel to fertilize other plants. However, the article by Dr. Ma cited by Syngenta in Appendix D[149] in support of the statement quoted above provides no information whatsoever on wind speed. The study was based on data collected over three years in Ottawa, Canada (not even in the U.S.). Dr. Ma concedes that: "Seasonal weather conditions affected the level of cross-fertilization" and further that: *"The level of cross-fertilizations across site-years fluctuated greatly because of wind speed and directions"* (emphasis added). The large fluctuations in cross-fertilization in the different years of Dr. Ma's experiments obviously call for presentation of detailed data for each year, and the wind speeds and directions obtaining during the period of pollen shed in each of those years. These data are not presented; rather, Dr. Ma appears to have averaged the data over the three years, which has the the effect of flattening out (by averaging) the large fluctuations from season to season. Without such data, it is impossible to make an informed assessment of the value or applicability of Dr. Ma's "exponential decline model" to the many different corn production environments in the 49 states of the U.S. where roughly 90 million acres of corn are grown.[150] If wind speeds during pollen shed happened to be low in those years, one would expect pollen to travel lesser distances than in higher wind conditions. Even if this is not the case, the model would tell us little or nothing about corn pollen flow and cross-fertilization distances in areas of the U.S. that normally experience higher winds than Ottawa, Canada.

When dealing with natural phenomena with such huge variability as wind speed, the sort of analysis that is needed is an analysis of these large variabilities. This approach is (or

[148] EA, Appendix D, p. 113.
[149] Cited at EA, p. 113: Ma, B.L. "Frequency of Pollen Drift in Genetically Engineered Corn," Feb. 2005. http://www.isb.vt.edu/articles/feb0502.htm.
[150] As suggested above, we will choose to go with APHIS's first assumption as to where Event 3272 corn may be planted.

should be) used, for example, in judging how close to a river's edge one should build or farm. One does not rationally base such decisions on data on the river's high stage in just three, arbitrarily chosen years. Rather, one examines the 50- to 100-year history of high-water levels to avoid being washed out in the exceptional year. In short, Dr. Ma's model is worth no more than the extremely limited data it is based on, and has little applicability to more exceptional conditions that are nonetheless encountered frequenty enough to merit consideration. Though APHIS does not provide a rationale for its 5,280 foot isolation distance for pharma corn, it is almost certainly based on a desire to avoid contamination under more exceptional conditions.

Similarly, APHIS's cursory and biased discussion of gene flow in corn references very few studies overall, and rests heavily on a review article (Sanvido et al 2008) which "recommended 50 meters (approximately 164 feet) as the distance needed to isolate GE corn and non-GE corn...," purporting to find that "the cross-fertilization rate in non-GE corn typically remained below 0.5% at this distance..."[151] APHIS does not state that contamination levels below 0.5% are acceptable, but seems to imply that they represent no concern. If this is indeed APHIS's assumption, it should explain why this is so. It is not explained why this particular study or the contamination level of "typically below 0.5%" is relevant to the assessment of Event 3272, particularly given APHIS's no action alternative for "gene movement," which notes that: "Under regulated releases, GE corn is typically separated from non-regulated corn by a distance of 660 feet, based on distances set for seed production (AOSCA 2004), if distance is the only method used to prevent movement of pollen or genes."[152] There is absolutely no discussion of the efficacy of the no action alternative in preventing or mitigating contamination of organic or conventional corn by Event 3272, and any interrelated economic impacts, versus the preferred alternative, which would allow cultivation of Event 3272 without any APHIS oversight and without any mandatory isolation distance between plantings of Event 3272 and organic or conventional varieties grown nearby.

APHIS does discuss one study – Jones and Brooks (1950) – that "found successful gene movement to be as high as 2.5% at 660 feet."[153] This level of gene flow at 660 feet would seem to be more in line with APHIS's setting of a 5,280-foot isolation distance for pharma corn. However, APHIS mentions this study not in support of its own prior rulemaking – but rather only to dismiss it as irrelevant because it investigated the appropriate isolation distance for seed production in *open-pollinated varieties*, which it states *may* be more receptive to pollen for a longer period of time than hybrids; if so, the study *may* be an overestimation of cross-fertilization potential for hybrid corn events.[154] It is not explained why only hybrid corn is of concern re: contamination, or why the higher likelihood of contamination of open-pollinated varieties by Event 3272 is not problematic. Neither does APHIS's uncertainty in this matter ("may") support the conclusion that it has taken a hard look at this matter. APHIS may or may not be aware that many organic varieties of corn are open-pollinated. In either case – whether APHIS

[151] EA, p. 15.
[152] EA, p. 38.
[153] EA, p. 38.
[154] EA, p. 38.

is ignorant or biased against organic or open-pollinated corn – the analysis is clearly inadequate.

Other Modes of Contamination

APHIS's discussion of "gene movement" is just three paragraphs in length, and considers only cross-pollination, one of several potential modes of gene movement. There are many possible modes of contamination from seed purchase through field to table: seed spillage; residues of contaminating seeds in farm equipment; volunteer growth; cross-pollination by wind, insect or animal; and post-harvest mixing in the grain-handling system. These issues are not addressed in a meaningful way in the EA. APHIS seems to rely on Syngenta's stewardship measures here as well, but as discussed above, this reliance alone, without substantial evidence in support and APHIS's own assessment of these measures is insufficient to comply with NEPA. *See supra* pp. 26-30.

In the Union of Concerned Scientist ("UCS") report, "Gone to Seed," UCS found that about 50% or more of the certified non-GE corn, canola, and soybean seed has been contaminated with transgenes.[155] The level of contamination was typically 0.05%-1.0%, far greater than the minimum levels that can be detected. "Gone to Seed" demonstrated that the frequency and levels of contamination of soybean seed was found to be about as high as for corn. Soybeans are largely self-pollinating (do not pollinate other soybean flowers very often), while corn is highly out-crossing. Therefore, the contamination of soybean seed is likely to be largely from causes other than cross-pollination. Such causes could include seed mixing or human error, and suggests that these sources may be at least as important as cross-pollination.

Another report, "A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops," UCS enlisted the assistance of several academic experts in agricultural sciences to determine whether GE pharmaceutical-producing crops could be kept out of food. This report demonstrates how difficult this is, even for pharmaceutical crops that would be grown on small acreage and under stringent confinement, to avoid contaminating food. The authors of this report examined confinement methods, such as field separation, cleaning of farm equipment, segregation of seed, and others, and found that it would still be difficult to ensure the absence of contamination.[156] The experts felt that contamination might be prevented by taking heroic means, such as geographical isolation from food crops. Union of Concerned Scientists concluded that even though it may be theoretically possible to prevent contamination, it would not be economically feasible.

Another route of contamination that is unpredictable, but likely over time, is human error. Two academic ecologists address this in a peer-reviewed paper, and conclude that contamination by GE crops due to human error or other means has occurred numerous

[155] M. Mellon and J. Rissler, Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply, Union of Concerned Scientists, 2004.
[156] David Andow, et al., A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops Union of Concerned Scientists, December 2004.

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.[157] Thus, biological contamination through human error and human behavior, such as composting and exchanging seeds, must be addressed in an EIS.

Past Contamination Episodes

StarLink is a variety of corn genetically engineered to produce the Cry9C insecticidal toxin to kill certain corn pests.[158] Due to the concerns of leading allergists advising the EPA that this toxin might cause food allergies, the EPA approved StarLink in 1998 only for animal feed and industrial uses such as ethanol production, but not for human consumption. The EPA had a binding agreement with the developer of StarLink, Aventis CropScience. According to this agreement, all Aventis-affiliated seed dealers would sell StarLink corn seed to farmers only if the farmers would agree to the following conditions: 1) Plant a buffer strip 660 feet wide around StarLink corn plots to mitigate cross-fertilization of neighboring corn fields; and 2) Segregate StarLink corn and buffer strip corn for distribution only to non-food channels.[159] Aventis CropScience assured the EPA that with these measures it could keep StarLink out of the human food supply.

StarLink corn was grown for only three years, from 1998 to 2000, on at most 341,000 acres, or 0.43% of total U.S. corn acreage (year 2000).[160] Despite the limited acreage planted to StarLink, and the conditions attaching to its cultivation, testing initiated by public interest groups and subsequently conducted by the U.S. Food and Drug Administration (FDA) found that over 300 corn products in grocery stores around the country were contaminated with StarLink. The USDA found StarLink contaminating 9-22% of grain samples.[161]

The estimated number of people who consumed contaminated supermarket products (e.g. taco shells, bags of corn meal, etc.) is in the tens of millions, and hundreds of people reported allergic reactions that they believed might be linked to StarLink-contaminated corn products, yet only a handful were ever tested.[162] A few of the reported cases involved life-threatening anaphylactic reactions. The FDA and Centers for Disease Control (CDC) conducted an investigation into potential allergic reactions to StarLink

[157] M. Marvier and R. Van Acker, "Can crop transgenes be kept on a leash?" Front. Ecol. Environ., 2005, vol.3, p.95-100.
[158] For the following discussion of StarLink, see Freese, B. (2001). "The StarLink Affair," Friends of the Earth, July 2001. www.foe.org/safefood/starlink.pdf.
[159] EPA Cry9C Fact Sheet (2000). "Biopesticide Fact Sheet: *Bacillus thuringiensis* subspecies *tolworthi* Cry9C Protein and the Genetic Material Necessary for Its Production in Corn (006466)," Issued November 2000.
[160] SAP StarLink (2001). "Assessment of Additional Scientific Information Concerning StarLink Corn," FIFRA Scientific Advisory Panel to the EPA, SAP Report No. 2001-09, from meeting on July 17/18, 2001.
[161] Shadid, A. "Genetically engineered corn appears in one-tenth of grain tests," Boston Globe, May 3, 2001. Shadid, A. "Testing shows unapproved, altered corn more prevalent than thought," Boston Globe, May 17, 2001.
[162] Freese, B. (2001). "The StarLink Affair," Friends of the Earth, July 2001, pp. 14-15, 22.

that was severely hampered by the difficulty of determining after the fact whether suspect food items were contaminated by StarLink, a faulty allergy test developed by FDA, and numerous other uncertainties. Though the FDA and CDC thought it was unlikely that StarLink corn's toxin had caused the reported allergic reactions, their conclusions were called into question by leading U.S. food allergists who served on a Scientific Advisory Panel convened by the EPA to investigate the matter. Regarding the FDA-developed allergy test, the Panel reported: "The test, as conducted, does not eliminate StarLink Cry9C protein as a potential cause of allergic symptoms."[163] In the end, this Scientific Advisory Panel advised against approving an extremely low "tolerance" (i.e. maximum permitted level) for the StarLink corn toxin (Cry9C) in the food supply, a tolerance of just 20 parts per billion, stating:

> "… the Panel concluded that based on reasonable scientific certainty, there is no identifiable maximum level of Cry9C protein that can be suggested that would not provoke an allergic response and thus would not be harmful to the public."[164]

The EPA accepted the SAP's advice and rejected Aventis's petition of a Cry9C tolerance. StarLink corn is no longer grown.

This massive contamination of the food supply with StarLink corn also had serious economic repercussions, triggering numerous costly recalls of corn-based food products by Kraft Foods, Mission Foods, and numerous other domestic food companies, costing tens of millions of dollars. StarLink-contaminated corn exports were rejected by Japan and many other companies, resulting in lower corn prices and losses to corn farmers. Seventeen state attorneys general successfully sued Aventis to recover at least some of the losses suffered by all corn farmers, whether or not they grew StarLink, from the depression in corn prices and inability to sell corn harvests triggered by the episode.

The extent of the contamination is startling when one considers that StarLink never represented more than 0.43% of U.S. corn acreage. While most of the contamination was probably due to post-harvest mixing of StarLink with conventional corn, another important contributing factor was that some farmers were not informed of the planting and sales restrictions. In fact, there is evidence that some farmers were positively misled by Aventis's seed dealers, and told that StarLink was in fact acceptable for human consumption. According to Iowa Attorney General Tom Milller, dozens of farmers who called his office told him that they had not been informed about the restrictions attaching to StarLink cultivation; one reported that the seed tag on the bag of StarLink corn stated that: "You are licensed upon purchase of this product only to produce forage or grain for food, feed or grain processing." Miller said the complicated restrictions associated with StarLink raise a common-sense question: Why would farmers buy the seed if they knew there were so many conditions attached to growing the crop? "I just don't think if the restrictions were disclosed many farmers would have bought the grain."[165]

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[163] SAP StarLink (2001), op. cit., p. 29.
[164] SAP StarLink (2001), op. cit., p. 35.
[165] As quoted in: Ryberg, W. "Growers of biotech corn say they weren't warned: StarLink tags appear to indicate it's suitable for human food products," Des Moines Register, 10/25/00.

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.[166] These latter findings strongly suggest that StarLink pollen blown by the wind fertilized conventional corn, despite the 660-foot border strip requirement. In fact, the a USDA-sponsored testing program for seed companies that had never been licensed to grow StarLink found that nearly one-fourth of these seed firms (71 of 288) had some corn lines that tested positive for StarLink. USDA had to buy back nearly 450,000 units of StarLink-contaminated seed corn at a cost of several million dollars to prevent further spread of StarLink in future years. Tainted seed dated anywhere from production year 1997 to 2001.[167]

APHIS provided absolutely no discussion of the StarLink affair in its inadequate EA, despite the similarities to Event 3272. Like StarLink, Event 3272 is not intended for human consumption. Like StarLink, Event 3272 contains a transgenic protein that leading allergists believes should be more thoroughly investigated for potential allergenicity. The FDA's inadequate investigation of potential allergic reactions to StarLink corn – as evidenced by the criticisms of its conduct of the investigation by leading U.S. food allergists – casts great doubt on FDA's cursory voluntary consultation document on Event 3272. Like StarLink, contamination of approved corn varieties or corn products with Event 3272 (whether organic, conventional or even GE) could trigger substantial marketplace rejection, including in important export markets like Japan. This latter potential is strengthened by the lack of import clearance for Event 3272 in all of our major corn export markets. Finally, the StarLink affair makes it perfectly clear that a seed company like Syngenta cannot be trusted to adequately inform growers of restrictions attaching to the cultivation of Event 3272, or enforcing those restrictions, for the simple reason that farmers will be less likely to purchase Event 3272 seed if they are aware of the "complicated restrictions" they will have to follow in order to grow it. This is a classic conflict of interest situation that goes completely unexamined by USDA in its inadequate EA.

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

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

[167] Freese, B. (2001). "The StarLink Affair," Friends of the Earth, July 2001, p. 12.

one of the scientists in charge has claimed that they exceeded APHIS confinement recommendation considerably, but still experienced contamination.[168]

Furthermore, there is substantial variation in the results from different experiments when measuring biological contamination through pollen transfer. This has been seen for virtually every crop studied. Many factors affect gene flow frequencies, including weather conditions (precipitation, wind, temperature, humidity), which will affect bee behavior, pollination levels, and the duration of pollen viability. The relative size of the pollen recipient and pollen production fields also has a very big impact on the distances and frequencies of gene flow. As one example, a field trial of creeping bentgrass containing 286 plants revealed contamination at up to about 1400 feet, while one of 400 acres had cross-pollination at 13 miles.[169] Small canola field trials (a bee pollinated crop) often have significant cross pollination at several hundred to several thousand feet, while a study in Australia at the commercial scale observed contamination at up to about 3 kilometers.[170]

Despite evidence of potential widespread contamination, APHIS failed to address in its EA the potential for biological contamination once Event 3272 is deregulated in this case. 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."[171] Thus, APHIS must prepare an EIS to disclose and analyze the potential for biological contamination prior to deregulating the GE variety at issue here.

Interrelated Socioeconomic Impacts

APHIS completely fails to address potential adverse socio-economic effects from the deregulation of Event 3272. NEPA requires that economic effects are relevant and must be examined "when they are interrelated with natural or physical environmental effects."[172] As the court explained in *Geertson Seed Farms*: "The economic effects on the organic and conventional farmers of the government's deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment; namely, the alteration of a plant species' DNA through the transmission of the genetically engineered gene to organic and conventional alfalfa."[173] The court continued, "APHIS was required to consider those effects in assessing whether the impact of its proposed action is 'significant.'"[174]

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[168] G. Vogel, "Tracing the transatlantic spread of GM rice," Science, 2006, vol. 313, p. 1714.
[169] (JK. Wipff and C. Fricker, "Gene flow from transgenic creeping bentgrass (Agrostis stolonifera L.) in the Willamette Valley, Oregon," International Turfgrass Society Research Journal, 2001, vol. 9, p. 224;LS Watrud et al., "Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker," 2004, PNAS.
[170] MA Rieger et al., "Pollen-mediated movement of herbicide resistance between commercial canola fields," Science, 2002, vol. 296, p. 2386-2388.
[171] 2007 WL 518624 at 6.
[172] *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 944 (9th Cir. 2005) (quoting 40 C.F.R. §1508.14).
[173] 2007 WL 518624 at 8.
[174] Id.

APHIS is similarly required to consider such economic effects in this case as well. APHIS acknowledges the sensitivity of markets to contamination (EA at 27) but does not analyze any alternatives that might help alleviate risk of contamination. In addressing potential impacts on commercial use, APHIS admits that foreign markets, such as the South African market, do not accept Event 3272. (EA at 35). Export rejection from contamination is an issue APHIS must analyze. The potential for the contamination to organic and conventional food corn crops from contamination also triggers the need for APHIS to prepare an EIS.

Impacts from Contamination: Organic and Food Corn

Regarding organics, the EA simply places the burden on organic farmers to "fence out" potential contamination from Event 3272, noting "practices growers may use to exclude genetically engineered products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic field and the fields of neighbors to minimize the chance that pollen will be carried between the fields." (EA at 11). Later the EA again dismisses any responsibility to assess the risks of contamination to organics by pointing to language in the organic standard and plan requiring non-GE methods. (EA at 27). The EA attempts to downplay the importance of organic by noting that it is a small percentage of overall corn production but it concedes that the market is growing by 30% annually. (Id.) APHIS dismisses effects to organic corn based on the notion that organic producers protect themselves under a variety of measures, placing the burden of organic growers to protect themselves from contamination. (EA at 27, 31). However such stewardship measures alone cannot alleviate APHIS from its NEPA duties.[175] The *Geertson* court dismissed stewardship practices as a guarantee of against harms because once deregulated, the agency has no way to ensure the measures are followed.[176]

During the implementation of the Organic Food Production Act, the 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.*"[177]

Further, APHIS only considers the effect on organic crops in so far as they "fall under the USDA National organic Program definition of organic farming." (EA at 11). Yet as the *Geertson* court held, it is not just whether a crop can be certified under USDA's program – "many farmers and consumers have higher standards than what the federal government

[175] *Geertson*, 2007 WL 518624 at *10.
[176] *Id.*
[177] 65 Fed. Reg. 13534-35 (Mar. 13, 2000) (emphasis added).

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."[178]

Similarly the EA places the burden of avoiding contamination squarely on the growers of specialty corn, based on their existing markets and contracts. (EA at 12). The EA acknowledges the risk to specialty corn from "misdirection" of Event 3272 in the transportation stream and that Event 3272 may have "undesirable effects" in food products. (EA at 32). APHIS assumes that genetically engineered Event 3272 can be treated as equivalent to conventional "specialty corn" varieties such as waxy corn, white corn, blue corn, and organic corn for the purpose of identity preservation. (EA at 32-33). This is not the case. Such potential contamination, and the resulting harm to organic farmers' choice to grow non-GE, biofuel corn, constitutes a significant environmental impact to the human environment that AHIS must review in an EIS.[179]

APHIS concludes that organic corn growers have not been harmed by contamination from GE varieties based on the increased acreage of both organic (up 35%) and GE corn (up 50%) from 2001 to 2005, and the lack of mandated measures to minimize gene flow between the two during that period.[180] This cursory statement is completely illogical and in no way constitutes an assessment of this important matter. Obviously, the extent to which organic corn production has (or has not) been hampered by contamination from GE varieties is not a matter that can be decided by reference to the growth in acreage of each. Such an assessment would require consultation with organic corn farmers, organic seed growers, representatives of organic farming groups, and dealers in organic grains. For instance, APHIS could have easily found grain dealers who specialize in organic and other specialty grains, such as the Illinois-based Clarkson Grain Company. Clarkson Grain is contracted, for example, by organic food companies to supply organic grains such as corn. President Lynn Clarkson is also a board member of the national Organic Trade Association. In a 2007 article on the dramatically increasing demand for organic dairy products,[181] Clarkson was cited as estimating that demand for organic feeds such as organic corn is growing 20 percent each year, while U.S. production of organic row crops, such as corn and other feed, is growing only by as much as 4 percent. Significantly, he also stated that the "ethanol tsunami" that is encouraging more farmers to grow corn for biofuel rather than feed ensures that the shortage will likely continue for a long time. In the same article, Shannon Andrews, a Portland, Ore., feed ingredient trader for San Francisco-based agricultural commodities distributor Wilbur-Ellis Co., said she, too, can't meet demand. "I have customers that are looking for six railcars a month of [organic] corn, and I can't get that quantity coming from anywhere in the U.S."

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[178] 2007 WL 518624 at *6.
[179] *Geertson Seed Farms*, 2007 WL 518624 at 8 ("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:")
[180] EA, p. 39.
[181] Dininny, S. "Organic Dairies Test Supply of Feed," Associated Press, Dec. 20, 2007.

This indicates that demand for organic corn to meet the sharply rising demand for organic dairy products is not being met in the U.S. One important reason for this is the difficulty of growing organic corn free of contamination from GE varieties.

Laura Krouse of Mt. Vernon, Iowa would also find APHIS's analysis inadequate. Krause operates a seed company called Abbe Hills Open Pollinated Seed Corn. In 2001, she found that her 1903 world champion line of open-pollinated corn had been contaminated by engineered traits, despite the fact that she practiced both spatial and temporal isolation of her corn from neigbhboring GE corn fields. She suffered a 50-75% drop in sales due to this contamination.[182] Iowa State University (ISU) plant breeder Kendall Lamkey said organic corn farmers like Krouse have a tough problem because "GMO genes are already widespread" and: "She can't control what her neighbors do, so she's only got a couple of options and they aren't enough. Organic corn in Iowa is going to be really hard to do because of the pollen issue."[183] In the same article, ISU plant physiologist Mark Westgate said: "Six hundred feet of isolation doesn't mean a thing if the wind is blowing your way at 20 miles an hour."

In the same article, Krouse noted that most of her customers were organic corn farmers, but that she was seeking organic certifiction by 2005 because by then every organic farmer would have to plant certified organic seed. "But if I test positive for genetically modified corn, what's going to happen? Most of my customers will stop buying from me, and I'd have to go look for a different kind of customer."

These are examples of the real-world threats posed by Event 3272 to organic corn growers that APHIS completely failed to analyze in its inadequate EA.

Impacts from Contamination: Exports

It is not only organic corn farmers who are threatened by Event 3272. In the draft EA, APHIS refuses to acknowledge, much less discuss, the fact that Event 3272 poses special threats to farmers who grow any variety of corn that is acceptable and/or approved for food uses – whether that corn is organic, conventional, or even genetically engineered. According to the draft EA, Event 3272 has been approved for import into only four countries – Canada, Australia, New Zealand, and the Philippines – which collectively comprised less than 6% of U.S. corn exports in 2007. Moreover, Syngenta filed submissions for import clearance to several major corn export markets, including Japan, Korea, and Taiwan – in early to mid-2006, and apparently has still not obtained clearance nearly three years later.[184]

As APHIS notes in its draft EA, South Africa rejected Syngenta's application for import clearance.[185] While APHIS professes ignorance as to the reasons for this rejection, South

[182] Lucas, M. "Seed producer fears biotech corn may contaminate genes," Cedar Rapids Gazette, January 29, 2001; personal communication.
[183] As quoted in: Perkins, J. "Genetically modified mystery," Des Moines Register, August 10, 2003.
[184] EA, Table 1, p. 7
[185] EA, p. 35.

African authorities have clearly stated that the rejection was based in large part on potential adverse human health impacts, such as allergenicity, that had not been adequately addressed in Syngenta's petition. As discussed above in these comments, leading U.S. allergists have also expressed concerns about the potential allergenicity of the AMY797E enzyme expressed in Event 3272 corn, and suggested additional testing to confirm or rule out these concerns.

The fact that Event 3272 remains unapproved for export to markets that comprise up to 94% of US corn exports has extremely serious implications for U.S. corn farmers as well as the US grain and food industries. First, one must understand that Syngenta's representations as part of its stewardship agreement that it will "ensure the domestic consumption of DDGS prior to export market approvals"[186] does not even begin to address the adverse impacts that cultivation of this corn would have on the US agricultural economy. This is because any at all appreciable acreage planted to Event 3272 will inevitably result in widespread contamination of U.S. corn; and this in turn will likely lead to massive export market rejection of shipments contaminated with this first ever GE industrial corn in the large majority of countries that have not approved it for import. . History shows that corn exports contaminated with varieties unapproved in the respective markets are often rejected, triggering rejection that can have substantial adverse economic consequences. The GE StarLink corn debacle of 2000-01 (noted above) is an important cautionary tale in this regard.

Impacts on Biodiversity and Choice

In discussing potential impacts on biodiversity (EA at 44) APHIS gives an extremely cursory review of effects to biodiversity. For example, it does not address the possibility of reducing or eliminating non-GE varieties. As *Geertson Seed Farms v. Johanns* explained, "one of Congress's express goals in adopting NEPA was to attain 'the widest range of beneficial uses of the environment without degradation, risk to health and safety, *or other undesirable and unintended consequences*.'"[187] Specifically, NEPA aims to "maintain, wherever possible, an environment which supports diversity and variety of individual choice."[188] Accordingly, "[a] federal action that eliminates a farmer's choice to grow non-genetically engineered crops, of a consumer's choice to eat non-genetically engineered food, is an undesirable consequence."[189] Furthermore, "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.[190]

Here, APHIS completely failed to address the possibility that biological contamination may eliminate the choice of farmers to grow non-GE organic or conventional corn varieties. Thus, APHIS must prepare an EIS and do so.

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[186] EA, p. 26.
[187] *Geertson Seed Farms*, 2007 WL 518624 at 8 (emphasis in original) (quoting 42 U.S.C. § 4331(b)(3)).
[188] Id. (quoting 42 U.S.C. § 4331(b)(4)).
[189] Id.
[190] Id. at 9.

Impacts on Soil Biology

A major question that remains unanwered in APHIS's draft EA is the potential effects of Event 3272-derived thermostable alpha amylase on soil biology, including carbon cycling, in fields where Event 3272 is grown. Wolt and Karaman (2007) undertook a detailed estimate of the environmental load of Event 3272-derived thermostable alpha-amylase (AMY797E) that would be expected with production of Event 3272.[191] This estimate is based on: 1) previous work showing that roughly 1% of harvestable corn is left in the field under typical harvesting conditions; 2) typical expression levels of AMY797E in kernals, stover and roots of Event 3272 corn plants; 3) typical corn yields; and 4) uniform distribution of AMY797E in the top 7.5 cm of soil. The authors also assume that AMY797E has a specific activity of 1,000 µmol/minute reducing sugar production per mg of enzyme, based on the typical activity of thermostable alpha amylase enzymes derived, like AMY797E, from *Thermococcus*. The authors conclude that the enzymatic activity of AMY797E deposited in the soil through production of Event 3272 would be roughly one order of magnitude (10 times) greater than the enzymatic activity of alpha-amylase enzymes naturally found in the soil. The authors note that:

> "if this enzyme were to persist, accumulate, and retain activity in the soil environment there is the possibility for indirect effects to be manifested with respect to carbon cycling within agroecosystems where Event 3272 is cultivated."

Whether or not a potential ten-fold increase in alpha-amylase activity in soils through cultivation and harvesting of Event 3272 would have such indirect effects is unknown. As suggested above, much depends on whether AMY797E would persist in the soil. Most proteins are degraded by protein-degrading enzymes (proteases) that are abundant in nature, including soils. However, alpha amylases in general, like other bioactive proteins, can retain at least some of their activity through adherence to soil particles, which partially shield the enzyme from normal degradation processes. Significantly, Wolt and Karaman (2007) note that proteins derived from thermophilic organisms, such as AMY797E, generally have enhanced stability relative to proteins from non-thermophilic (mesophilic) organisms. "Therefore, thermostable AMY797E may be expected to cycle differently in the soil environment than will native amylase." Wolt and Karaman conclude that:

> "An understanding of the degradation, persistence, accumulation, and activity of thermostable alpha-amylase introduced from transgenic high-amylase maize will be necessary in order to effectively manage transgenic crop systems intended for biofeedstock production."

In short, it appears that cultivation of Event 3272 will add roughly 10-fold more starch-degrading, alpha-amylase activity to the soil than it naturally possesses. The available

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[191] Wolt, J. D. and S. Karaman. 2007. Estimated environmental loads of alpha-amylase from
transgenic high-amylase maize. Biomass and Bioenergy. **31**:831-835.

scientific evidence relating to the proteins of thermophilic organisms suggests that AMY797E may well persist, accumulate, and retain activity in the soil to a greater degree than native alpha-amylases naturally present in the soil. Adding such a massive amount of stable, starch-degrading enzyme to agricultural soils may have profound impacts on soil biology, for instance increasing the rate at which alpha-amylase substrates are degraded. More rapid degradation of starch-containing materials in the soil could have numerous consequences, such as accelerated depletion of soil organic matter. Soil with high organic matter content provides numerous benefits vs. soil with little organic matter: increased water retention (and hence superior drought-tolerance of plants grown in such soil), improved root aeration, increased nutrient uptake, and reduced soil erosion, to name a few. Thus, production of Event 3272 could degrade soil quality by reducing the level of organic matter of soil in which it is grown.

Despite these concerns, APHIS fails to collect any empirical data whatsoever to investigate the concerns raised by Wolt and Karaman. Syngenta too states that: "No studies have addressed specifically the stability of AMY797E or PMI in soil,"[192] but provides no explanation of why it didn't collect these data. APHIS states that "Wolt and Karman (2007) did not present any empirical evidence to suggest that AMY797E would persist,"[193] ignoring the plain fact that the study did have this purpose, but rather was designed to provide an estimate of possible "environmental loads" of AMY797E in the soil. APHIS tries to dismiss persistence concerns with reference to "digestibility data" presented to APHIS and FDA on degradation of AMY797E in simulated gastric fluid containing pepsin, a gastric enzyme. This response is entirely inadequate. First, the testing APHIS refers to was done to test whether AMY797E was likely to survive digestion in the stomach and thus present heightened food allergy concerns,[194] *not* determine whether or how fast AMY797E degrades in the very different soil environment. APHIS itself admits that "pepsin is not normally found in soils…" but fails to observe that the digestive stability test it refers to was conducted at the extremely acidic pH of 1.2, under which conditions proteins will degrade much more rapidly than under the more neutral pH values (6-7) obtaining in agricultural soils. APHIS's entire discussion of this matter is purely speculative, and fails completely to answer the legitimate questions raised by Wolt and Karaman in their study.

APHIS must collect empirical data on the fate, persistence and potential activity of AMY797E in soil conditions in the context of an environmental impact statement in order to answer the important questions about Event 3272's potential impacts on soil carbon cycling and important soil processes.

IV. APHIS failed to adequately analyze Cumulative Impacts and an EIS is required.

[192] Petition, p. 88.
[193] EA, pp. 45-46.
[194] As argued in the allergenicity section of these comments, the test as conducted was not adequate to answer this question.

The potential cumulative impacts associated with Syngenta's Event 3272 Corn must be disclosed and analyzed in an EIS. NEPA requires an agency to consider the possible cumulative impacts of deregulating a regulated article.[195]

"A cumulative impact is defined as '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 ... or person undertakes such other actions. Individually minor, but collectively significant actions, taking place over time, can generate cumulative impacts.[196]

The EA is generally inadequate with respect to the cumulative impacts discussion as well as specifically lacking in addressing the cumulative impacts associated with climate change, food markets and stacking.

Conclusory and Generally Inadequate

Cumulative impacts must be fully considered in an EA. "Given that so many more EAs are prepared than EISs, *adequate consideration of cumulative effects requires that EAs address them fully*."[197] NEPA requires agencies to consider the cumulative impacts of their proposed actions.[198] Specifically, an EA must provide a quantified assessment of project's environmental impacts when combined with other projects.[199] The EA cannot simply discuss the direct effect of the project and conclude that there are no cumulative impacts.[200] Instead, cumulative effects must be evaluated along with the direct and indirect effects of a project and its alternatives. A meaningful cumulative impacts analysis, according to the D.C. Circuit, must identify:

> (1) the area in which the effects of the proposed project will be felt; (2) the impacts that are expected in that area from the proposed project; (3) other actions-past, present, and proposed, and reasonably foreseeable-that have had or are expected to have impacts in the same area; (4) the impacts or expected impacts from these other actions; and (5) the overall impact that can be expected if the individual impacts are allowed to accumulate.[201]

Each section of the Event 3272 EA contains a short paragraph on "Cumulative Effects." Many of these discussions provide cursory review at best and are grossly inadequate. For

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[195] Geertson Seed Farm v. Johanns, 2007 WL 518624, *10 (N.D. Cal. 2007).
[196] Id.
[197] Kern v. United States Bureau of Land Mgmt., 284 F.3d 1062, 1076 (9th Cir. 2002) ("We have held that an EA may be deficient if it fails to include a cumulative impact analysis or to tier to an EIS that has conducted such an analysis.")
[198] 40 C.F.R. § 1508.27(b)(7); Utahns for Better Transp. v. United States Dep't of Transp., 305 F.3d 1152, 1172 (10th Cir. 2002); [198] Kern v. United States Bureau of Land Mgmt., 284 F.3d at 1076; Vill. Of Grand View v. Skinner, 947 F.2d 651, 659 (2nd Cir. 1991).
[199] Great Basin Mine Watch v. Hankins, 456 F.3d 955, 972 (9th Cir. 2006) (quoting Klamath-Siskiyou Wildlands Center v. Bureau of Land Management, 387 F.3d 989, 994 (9th Cir. 2004).
[200] Id.
[201] Grand Canyon Trust v. F.A.A., 290 F.3d 399, 345 (D.C. Cir. 2002).

instance, the assessment discusses the "cumulative effects" on specialty corn and concludes, "[t]he availability of methods used to separate specialty products from corn used as grain would be the same as currently used in production systems, and no changes are foreseeable."[202] APHIS clearly misses the point of a cumulative impacts discussion. The potential *direct effects* of Event 3272 on specialty corn are raised, but not the potential indirect effects or cumulative impacts of Event 3272 and other actions. What of questions regarding market impacts, for example, to specialty corn markets from increases in biofuel corns, increases incrementally impacted by Event 3272's potential deregulation? Are their other future reasonably foreseeable shifts in the market impacts from GE corn used for biofuels? What is the impact if they are allowed to accumulate? What about past GE deregulations? Past biofuel initiatives?

Also lacking from this specialty corn section is a discussion of the "overall impacts that can be felt if incremental impacts are allowed to accumulate."[203] APHIS fails to consider how adding an additional GE corn variety to the many existing GE corn varieties increases the likelihood of contamination of specialty corn through failure of the closed loop system. Not only is it reasonably foreseeable that adding Event 3272 to the list of GE corn varieties will have an effect, but it is also foreseeable that more GE corn varieties will be approved in the future, thereby further increasing the risk for contamination. This is just one example of how APHIS fails to provide a proper cumulative impacts discussion. Throughout the EA, APHIS consistently concludes that no cumulative effects have been identified without providing an "objective quantification of the impacts."[204]

Impacts on Climate Change

APHIS also completely fails to address the cumulative impacts of certain key issues, such as global warming and the potential impacts of biofuels. "NEPA requires an agency to consider the environmental impact that results from the incremental impact of the action when added to other past, present and reasonably foreseeable actions."[205] APHIS does not address the incremental effect that deregulating Event 3272 may have on global warming even though the intent of Event 3272 is to help meet biofuel mandates. "With over 161 ethanol plants in operation in 26 different states, and more than 40 more under construction, corn-based ethanol production may be a feasible way to meet the ethanol consumption benchmark for 2012 set in the Energy Policy Act of 2005, and 2022 goals set by the Energy Independence and Security act of 2007."[206] The EA lacks consideration of the effect increasing production of biofuels will have on global warming, specifically the *incremental impact* of the deregulation of Event 3272 *when added to* the production of other biofuels. While APHIS urges the need for Event 3272 corn as a

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[202] EA at 33.
[203] Grand Canyon Trust, 290 F.3d at 345.
[204] Great Basin Mine Watch, 456 F.3d at 972.
[205] National Resources Defense Council v. U.S. Forest Service, 421 F.3d 797, 814 (9th Cir. 2005) (quoting 40 C.F.R. § 1508.7).
[206] EA at 6.

result of US mandated biofuel production, it completely ignores the potential cumulative effects of increasing biofuel production and its impact on climate change.[207]

Global warming is undoubtedly an environmental concern, one which is directly linked to the production of biofuels. An intended effect of biofuels is to fight climate change and reduce global warming. Yet, many argue that biofuels will actually have a negative effect and exacerbate global warming.[208] Increasing and significant scientific research in the past year has demonstrated the overall environmental burden that biofuel production, in particular ethanol, has had throughout the world. Research published in the prestigious journal *Science* in January 2008 effectively demonstrated the significant environmental downfall of ethanol and biofuel production. While earlier research had suggested that biofuel production could offer marginal reductions in greenhouse gas emissions, research had failed to consider the effect of land clearing on biofuel production. Taking this into consideration, the authors concluded that "biofuels, if produced on converted land, could, for long periods of time, be much greater net emitters of greenhouse gases than the fossil fuels that they typically displace."[209] According to their research, corn ethanol grown on converted US grassland would create a "carbon debt" of 93 years. Even ethanol produced on abandoned cropland would create a carbon debt of 48 years.[210]

Additional research published in the same edition of *Science*, further examined the effect of land-use changes throughout the world. The research found that corn-based ethanol nearly doubled greenhouse gas emissions over 30 years and continued to increase greenhouse gases for 167 years.[211] While APHIS argues that this corn will not increase corn acreage in the United States but rather displace other varieties of corn, it is vital to consider the international effect of event 3272 corn. Syngenta already has applications for event 3272 corn in 9 countries and may apply for additional permits. While corn acreage in the United States may seem saturated, such is not the case in other countries throughout the world. Virgin land, forest or grassland transformed into agricultural land for ethanol cultivation would have a devastating impact on international greenhouse gas emissions, as demonstrated by the research published in *Science*.

Research published in 2008 in *Atmospheric Chemistry and Physics*, continued to break down the assumption that biofuels were better for the climate. Crutzen et. al looked specifically at the extra nitrous oxide emissions associated with biofuel production, transforming the emissions into CO2 equivalents. "The outcome is that the production of commonly used biofuels, such as biodiesel from rapeseed and bioethanol from corn (maize), depending on N fertilizer uptake efficiency by the plants, can contribute as much

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[207] EA at 6. "Event 3272 corn is expected to help the U.S. meet its goals for ethanol production."
[208] Crutzen PJ., Moiser AR., Smith KA., Winiwarter W. (2008) *Atmospheric Chemistry and Physics*. 8:389-195.
[209] Fargione J., Hill J., Tilman D., Polasky S., Hawthorne P., (2008) *Science*. Land Clearing and the Biofuel Carbon Debt. 319: 1235-1237.
[210] Ibid, at 1236.
[211] Searchinger T., Heimlich R., Houghton R.A., Dong F., Elobeid A., Fabiosa J., Tokgoz S., Hayes D., Yu TH., (2008). Use of U.S. Croplands for Biofuels Increases Greenhouse Gases Through Emissions from Land-Use Change. *Science*. 319: 1238-1240.

or more to global warming by N2O emissions than cooling by fossil fuel savings."[212] Further research published in the *Proceedings of the National Academies of Science* further demonstrated the negative environmental components of ethanol production by suggesting that increased corn production would create a 10-34% increase in nitrogen influx to the Mississippi River.[213]

Syngenta's application for event 3272 corn not only fails to acknowledge the devastating effects of ethanol production on the environment and food prices, but bases the need for their product on completely irrelevant situations. The food crisis and the best science on climate change has radically changed the biofuels debate and provoked widespread calls for eliminating political targets as disastrous for both the environment and the welfare of the world's poor. Regardless, the United States has already achieved the 2012 mandate of 7.5 billion gallons of ethanol and is well on its way to achieve the 2022 mandate. Event 3272 corn is not necessary to achieve these results and is thus not necessary.

There is strong evidence that biofuels hinder instead of help the fight against climate change. Regardless of whether the effect is positive or negative, however, the cumulative impacts of deregulating must be assessed. It is reasonably foreseeable that deregulating Event 3272, as an incremental part of the biofuels growth, as the first "food for fuel" crop, specifically engineered to create biofuels, purportedly with an efficiency increase, will have *an effect* on global warming. NEPA requires assessment of impacts both beneficial and adverse.[214] If Event 3272 is deregulated it will be the first of potentially many new biofuel crops. NEPA considers the "degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration."[215] It is foreseeable that many more GE biofuel crops will be introduced to help meet the biofuel mandates and growing energy demands. A "meaningful" cumulative impact analysis must be completed that addresses "the overall impact [on global warming] that can be expected if the individual impacts are allowed to accumulate."[216] The EA does not discuss the "*actual* environmental effects" resulting from the planting of Event 3272 or place those effects in the context of other events.[217]

Impacts on Food Markets

APHIS also fails to address the potential effect deregulating Event 3272 could have on worldwide food pricing. APHIS readily admits that raising corn for ethanol has increased the price of corn.[218] However, APHIS addresses this only in the subsection of the EA on crop-rotation, and does not look at the issue of food pricing independently. When

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[212] Crutzen PJ., Moiser AR., Smith KA., Winiwarter W. (2008) N2O release from agro-biofuel production negates global warming reduction by replacing fossil fuels. *Atmospheric Chemistry and Physics.* 8: 389-395.
[213] Donner SD and Kucharik CJ. (2008). Corn-based ethanol production compromises goal of reducing nitrogen export by the Mississippi River. *Proceedings of the National Academies of Science*. 105:4513-4518.
[214] 40 C.F.R.§ 1508.27(b)(1).
[215] 40 C.F.R.§ 1508.27(b)(6).
[216] Grand Canyon Trust at 345.
[217] *Center for Biological Diversity*, 538 F.3d at 1216.
[218] EA at 29. "These [increased corn] prices are driven by a demand for corn products in ethanol and for feed."

addressing cumulative effects of crop rotation, APHIS argues, "[g]ranting non-regulated status to Event 3272 corn will not change the cumulative effects found under the "no action" alternative, because the use of corn-to-corn rotation is based on economic decisions by the farmer and is not dependent on the corn varieties (GE or conventional) available on the market."[219] Again, APHIS totally misses the point of a cumulative impacts analysis. The economic decisions of the farmers are impacted by the products available to them on the market, one of which, if deregulated, will be Event 3272. The farmers' decision to use this product, and other GE crops for biofuels, could reasonably affect worldwide food pricing. Despite this fact, the only mention of this is hidden in a section on crop rotation.

It is significant to note the already apparent effects of the increased use of biofuels throughout the world. In 2008, U.S. farmers actually planted more than 4 million fewer acres of corn, but turned nearly 700 million bushels more into ethanol. As a result, more than 30% of the U.S. corn crop was transformed into ethanol in the year 2008.[220] In 2008, not only did the corn crop acreage reduce, the amount of ethanol increased-meaning fewer acres for food to begin with and a greater portion of potential food turned into fuel.

In 2007 the Consumer Price Index (CPI) for food in the United States increased by 4 percent. In 2008, the CPI for food is expected to increase by equal or greater amounts according to the United States Department of Agriculture Economic Research Service.[221] Such phenomenon has not been unique to the United States. Food prices throughout the world skyrocketed in 2008 and a world food crisis of epidemic portions ensued. Riots in dozens of countries around the world demonstrated the urgent situation of the economic and food crisis. While the causes of the food crisis of 2008 were diverse, overwhelming public and government opinion has noted the significant impact that biofuel production had on the situation. As the world's farmers switched from growing food to growing fuel, an international crisis ensued, the effects of which are still being felt today.

The impact of this reality has been apparent as biofuels have been pushed throughout the world. The disastrous effect that biofuels would have on hunger and food prices was apparent even early in 2007. In the May/June 2007 edition of *Foreign Affairs*, authors analyzed the effect of biofuels on world hunger and food prices. "The International Food Policy Research Institute, in Washington, D.C., has produced sobering estimates of the potential global impact of the rising demand for biofuels." The IFPRI report indicated that world food prices would increase significantly in the coming years and decades, rising as much as 135% for certain staple crops. As a result, it was estimated that 1.2 billion people could be chronically hungry by 2025 -- 600 million more than previously predicted.[222] Just a month later, Jean Ziegler, a U.N. special rapporteur on the right to food, expressed grave concern about the impact of biofuel production throughout the

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[219] EA at 29.
[220] Ibid.
[221] http://www.usda.gov/oce/newsroom/archives/testimony/2008/FoodPriceTestimony.pdf
[222] C. Ford Runge and Benjamine Senauer. How Biofuels Could Starve the Poor. *Foreign Affairs*. May/June 2007. http://www.foreignaffairs.org/20070501faessay86305/c-ford-runge-benjamin-senauer/how-biofuels-could-starve-the-poor.html

world. "There is a great danger for the right to food by the development of biofuels…It (the price) will be paid perhaps by hundreds of thousands of people who will die from hunger."[223]

Nearly a year later, the effect of biofuels on the food crisis became glaringly apparent in the United States and abroad. In May 2008, the Joint Economic Committee of the U.S. Congress held a hearing to reexamine the issue of biofuels, particularly ethanol, in light of the increasing food crisis. Dozens of members of Congress, including Democrats and Republicans, voiced growing concern over the effect of biofuel production on world food prices and climate change. Republican George Voinovich requested a Government Accountability Office report to study the effects behind rising food prices, specifically asking for research on the effect of ethanol. Joseph Glauber, chief economist at the USDA, noted in his testimony, "The growth in biofuels production has coincided with rising prices for corn…From 2005/2006 to 2007/2008, the farm price of corn more than doubled. While much of the increase in the farm prices for corn and soybeans can be attributed to increased biofuels production, other factors have also contributed…"[224] So while the rise in food prices was the result of a variety of factors, biofuels, particularly corn and soy, had a significant impact.

The United Nations Food and Agriculture Organization went one step further. Dedicating their annual report, *The State of Food and Agriculture,* to biofuels, they called for a review of biofuel subsidies and policies, tying biofuels to the rise in food prices and worldwide hunger. Significantly, they noted, "Rapidly growing demand for biofuel feedstocks has contributed to higher food prices, threatening the food security of poor net food buyers in both urban and rural areas."[225] The food crisis makes painfully clear what should have been obvious all along: that diverting stupendous quantities of staple food crops (e.g. 30% of U.S. corn) to feed automobiles has dramatically increased the price of not only corn, but all primary staple crops, and is driving hunger throughout the world. As food prices continued to climb throughout 2008, increasing evidence was also demonstrating the supposed environmental benefits offered by biofuel production were completely erroneous.

NEPA clearly requires APHIS to consider the environmental impact that results from the incremental impact of deregulating Event 3272 when added to other past, present and reasonably foreseeable actions. Despite a wealth of information on the effects biofuels have on the global food market, the EA ignores this issue entirely. APHIS must consider the incremental effect deregulating Event 3272 may have on global food pricing when added to other reasonably foreseeable impacts from, for instance, biofuel production, the global commodities market, an unsteady national economy and drought.

Stacking

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[223] http://www.reuters.com/article/environmentNews/idUSL1490977120070614

[224] Statement of Joseph Glauber, Chief Economist. Joint Economic Committee Biofuel Hearing. May 1, 2008. http://www.usda.gov/oce/newsroom/archives/testimony/2008/FoodPriceTestimony.pdf

[225] The State of Food and Agriculture. Biofuels: prospects, risks and opportunities, Executive Summary. Food and Agriculture Organization. United Nations. October 2008. ftp://ftp.fao.org/docrep/fao/011/i0100e/i0290e.pdf

APHIS provides an anorexic discussion of the cumulative impacts of stacking various corn varieties in a section entitled "Other Cumulative Effects" at the end of the EA.[226] APHIS readily admits that "[i]f granted nonregulated status, Event 3272 corn may be combined with other GE corn varieties by traditional breeding technologies, resulting in amylase corn that, for example, may also be resistant to herbicides and pesticides." This combination is known as "stacking." There are at least three deregulated Syngenta corn varieties Event 3272 can be stacked with, two that have an insect resistance trait (Bt11 and Mir604) and one variety with an herbicide tolerance trait (GA 21), and there is yet another insect resistant variety (Mir162) awaiting deregulation.[227]

APHIS no longer has regulatory authority over the varieties of GE-corn previously granted non-regulated status such as these[228] and they may be bred with other conventional varieties or other GE varieties as determined by the applicant or developer."[229] Therefore, no additional environmental review of the potential impacts of these varieties is required or will be done before stacking occurs. If this is the last review of the potential impacts of stacking Event 3272 with other varieties of corn, a thorough analysis of the potential environmental impacts is required under NEPA.

Nevertheless, APHIS reasons that, due to the many potential combinations of stacked varieties, it does not have to analyze the cumulative impacts, because predicting all possible combinations is "too hypothetical and speculative."[230] This lack of a thorough cumulative impacts analysis regarding the potential combinations of Syngenta's stacked corn varieties is a direct violation of NEPA. The Ninth Circuit explains, "[s]ometimes the total impact from a set of actions may be greater than the sum of the parts."[231] If there are so many "hypothetical" combinations of corn varieties, then potentially, there are foreseeable risks and consequences from stacking these varieties that are not being considered. For instance, it is reasonably foreseeable that when stacked with herbicide tolerant varieties, such as Syngenta's GA21, Event 3272 could contribute to the development of herbicide tolerant weeds.[232] "While the deregulation of one crop in and of itself might not pose a significant risk for the development of [herbicide tolerant] weeds, when all crops are considered cumulatively such a risk may become apparent." [233] APHIS should at a minimum examine the most foreseeable of these stacked varieties, such as Event 3272 stacked with other Syngenta crops.

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[226] EA at 47.
[227] EA at 7.
[228] EA at 47.
[229] EA at 7.
[230] EA at 47.
[231] CBD, 538 F.3d at 1215.
[232] Tom Sellen, "Herbicide-Resistant Weeds Force Change In Agriculture." Dow Jones, February 7, 2007, online at http://www.cattlenetwork.com/content.asp?contentid=104080. "Herbicide Resistance Isn't New: Dandelions and wild carrot bio-types were some of the first species to be reported back in the 1950s as resistant to 2,4-D. Globally, there are 183 weed species resistant to at least one family of herbicides, according to the www.weedscience.org Web site."
[233] Geertson Seed Farm v. Johanns, 2007 WL 518624, *10 (N.D. Cal. Feb. 13, 2007).

The discussion of stacked varieties is also void of any discussion on how these varieties could impact organic and conventional farmers and consumers. Any number of the many potential combinations of stacked varieties could have an effect on farmers and consumers, especially as more varieties inevitably enter the market place. For instance, it is reasonably foreseeable that these stacked varieties could increase the possibility of contamination of organic, specialty, or conventional non-GE corn varieties.

The cumulative effects of stacking several varieties of GE-corn can also reasonably impact soil biology, increase groundwater contamination, decrease bio-diversity and otherwise harm the environment. At numerous places APHIS disavows the need to analyze any cumulative impacts from increase herbicide use, for example, because Event 3272 is not engineered to be tolerate to a herbicide. (EA at 44). But APHIS also acknowledges that Event 3272 is possible to be stacked with herbicide resistant strains, including those of Syngenta. (EA at 47). *If APHIS does not assess the combined impacts of foreseeable stacked combinations in this deregulation, they will not be assessed.*

Without a more rigorous look at the cumulative effects of deregulating Event 3272 alongside other deregulated varieties of GE corn, and the potential for stacking these varieties, the possible impacts on the environment will go un-tested. Therefore, a full EIS which takes into account the above cumulative impacts is required.

V. APHIS fails to Adequately Assess Impacts on Endangered and Threatened Species and Comply with the ESA.

APHIS did not comply with the Endangered Species Act (ESA), failing to adequately consider effects on threatened or endangered species. 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."[234] Then if APHIS learns from FWS and/or NMFS that threatened or endangered species may be present, a biological assessment must be prepared to identify any endangered species or threatened species which are likely to be affected by such action.[235] The initial request for information from FWS and/or NMFS is a predicate to further agency action and cannot be ignored.[236]
Accordingly, prior to a completion of the deregulation, APHIS must demonstrate that at the very least, it has consulted with the United States Fish and Wildlife Service ("FWS") and/or the National Marine Fisheries Service ("NMFS") and taken the first step in considering the impacts of an APHIS deregulation of Event 3272 on threatened or endangered species. As has become APHIS' pattern, it once again failed to take even the first step by doing any consultation with any other agency regarding endangered species.[237] 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

[234] 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).
[235] Id.
[236] *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).
[237] *Center for Food Safety v. Johanns*, 451 F.Supp.2d 1165, 1182 (D. Hawaii 2006).

and critical habitats from FWS and/or NMFS.[238] 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."[239]

Instead, APHIS concludes that "there is no difference in compositional and nutritional quality of Event 3272 corn compared to conventional corn, apart from the presence of AMY797E and PMI," and "not biologically different than conventional corn." (EA at 48). Based on this, it concluded that it "has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing" and "would have no effect on federally listed threatened or endangered species or species for lisiting." (EA at 50). Its noteworthy that in its cursory analysis, APHIS acknowledged that "some of the variables measured by the applicant showed statistically significant differences between Event 3272 corn and the non-transgenic hybrid controls," it found the differences within acceptable standards and therefore concluded that no further analysis was necessary. (EA at 48).

Here, there is no evidence in the EA that APHIS took the first steps of consultation with FWS and/or NMFS to determine whether the deregulation of Event 3272 may harm listed species or habitat. Thus, prior to deregulation, APHIS must at the very least consult with FWS and/or NMFS prior to approving this deregulation.

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[238] *Center for Food Safety v. Johanns*, 451 F.Supp.2d 1165, 1182 (D. Hawaii 2006).
[239] Id.