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Regulatory Analysis and Development
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To whom it may concern:

The Center for Food Safety (CFS) submits the following comments on the draft environmental assessment (EA) conducted by USDA's Animal and Plant Health Inspection Service (APHIS) on its determination of nonregulated status for the Monsanto soybean event designated as MON 89788, which has been genetically engineered for tolerance to the herbicide glyphosate, and any progeny derived from crosses of MON 89788 with other non-regulated soybean lines.

CFS is a non-profit public interest and environmental advocacy membership organization established in 1997 by its sister organization, International Center for Technology Assessment, for the purpose of challenging harmful food production technologies and promoting sustainable alternatives. CFS combines multiple tools and strategies in pursuing its goals, including litigation and legal petitions for rulemaking, legal support for various sustainable agriculture and food safety constituencies, as well as public education, grassroots organizing and media outreach.

CFS strongly opposes the cultivation and commercial use of genetically engineered food crops due to unexplored risks to the environment, biodiversity, specific protected species, and potential risks to human health that could result. Genetic engineering is a novel technology that fundamentally alters agriculture, our food supply, and the environment.

Neither standard corporate testing practices for, nor U.S. government oversight of, genetically engineered (GE) crops is sufficiently stringent to rule out, with reasonable scientific certainty, unintended adverse impacts to human health or the environment.[1] CFS therefore supports a moratorium on GE crops until the U.S. government establishes a strict, science-based regulatory system.

Short of such a blanket moratorium on GE crop commercialization, the deregulation and commercialization of this GE soy (MON 89788) and progeny derived from it requires the preparation of an EIS under the National Environmental Policy Act ("NEPA"), because the EA contains unanswered or inadequately answered health and safety questions. Specifically, CFS requests that APHIS institute a moratorium on the commercial introduction, dissemination, interstate movement or conveyance of MON 89788, including but not limited to all food products containing any ingredients or material derived from this genetically engineered soy, until the USDA, as mandated under §102 of NEPA, fully evaluates the environmental, human health and socio-economic impacts caused by the commercialization of MON 89788. Such action and analysis should include completion of an environmental impact statement analyzing the effects on the human environment resulting from any USDA actions deregulating (or other action allowing commercial distribution, sale and planting) MON 89788.

We have numerous serious concerns about this deregulation, as discussed in detail below.

BACKGROUND

On June 27, 2006 APHIS received a petition seeking a determination of nonregulated status from Monsanto for GE soybean MON 89788. (APHIS Petition # 06-178-01p). In the February 5, 2007 *Federal Register*, USDA APHIS announced a public comment period on a draft environmental assessment (EA). 72 Fed. Reg. 5262 (Feb. 5, 2007).

CFS COMMENTS

Summary

The draft EA is wholly inadequate and defective because APHIS failed to take the "hard look" required by NEPA. An EIS must be prepared for the deregulation of MON 89788 to properly address the significant environmental impacts that may result from APHIS' approval. The draft EA fails to adequately discuss numerous significant environmental and agronomic impacts, such as potentially reduced micronutrient uptake, increased susceptibility to plant disease, harm to agriculturally important soil life, glyphosate-resistant weeds, and harm to wildlife from the Roundup Ready soybean system. The

[1] Freese, W. and D. Schubert (2004). "Safety Testing and Regulation of Genetically Engineered Foods," *Biotechnology and Genetic Engineering Reviews*, Volume 21, November 2004. http://www.foe.org/camps/comm/safefood/gefood/testingregbackgrounder.pdf

draft EA fails to adequately discuss cumulative impacts on the environment, such as the dramatic increase in the use of glyphosate associated with Roundup Ready (RR) soybeans and other RR crop systems. APHIS' abysmal history of failing to contain genetically engineered crops illustrates that APHIS' standards and operating procedures are inadequate to protect organic agriculture. The draft EA is arbitrary and capricious. These comments request that APHIS prepare an Environmental Impact Statement (EIS) to fully analyze the environmental and public health affects of the deregulation decision.

The National Environmental Policy Act ("NEPA")

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."[2] NEPA "ensures that the agency ... will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience."[3]

Recognizing the affects of new technologies on the environment, Congress explicitly stated in NEPA that "new and expanding technological advances" are activities that could threaten the environment.[4] In the legislative history, Congress expressed its concern with "[a] growing technological power … far outstripping man's capacity to understand and ability to control its impact on the environment."[5] Thus, in order to understand and control the effects of new technologies, Congress required federal agencies to consider their environmental effects by prescribing the requirements of NEPA. In addition to environmental concerns, the proposed action's possible direct, indirect, and cumulative impacts on public health must be reviewed.[6]

A threshold question is whether a proposed project will "significantly affect" the environment, thereby triggering the requirement for an EIS.[7] 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.[8] An EA must "provide sufficient evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact."[9]

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[2] 42 U.S.C. § 4332(2)(C).
[3] *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349(1989).
[4] 42 U.S.C. § 4331(a).

[5] Found. on Economic Trends v. Heckler, 756 F.2d 143, 147 (D.C. Cir. 1985) (quoting S. Rep. No. 91-296 (1969)).

[6] 40 C.F.R. § 1508.8(b); Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 106 (1983)(explaining that "NEPA requires an EIS to disclose the significant health, socioeconomic, and cumulative consequences of the environmental impact of a proposed action.").

[7] 42 U.S.C. § 4332(2)(C).
[8] 40 C.F.R. § 1508.9.
[9] *Id.*

If an agency decides not to prepare an EIS, it must supply a "convincing statement of reasons" to explain why a project's impacts are insignificant.[10] "The statement of reasons is crucial to determining whether the agency took a "hard look" at the potential environmental impact of a project."[11]

The Council on Environmental Quality (CEQ)

NEPA also established the Council on Environmental Quality and charged CEQ with the duty of overseeing the implementation of NEPA.[12] 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."[13] CEQ's regulations are applicable to and binding on all federal agencies.[14] Among other requirements, CEQ's regulations mandate that federal agencies address all "reasonably foreseeable" environmental impacts of their proposed programs, projects, and regulations.[15]

The CEQ regulations list factors that determine whether a federal action, such as deregulating MON 89788 is "significant." The CEQ regulations define the term 'significantly' for purposes of NEPA as requiring analysis of both the 'context' and the 'intensity' of the action."[16] Context is the scope of the agency action.[17] Intensity "refers to the severity of the impact" and is defined by the factors in 40 C.F.R. section 1508.27(b). Courts rely on these factors to determine "significance." Even meeting just one of the factors in 1508.27(b) may require the preparation of an EIS.[18]

USDA specifically adopted these CEQ regulations in relation to APHIS' review of genetically engineered crop.[19] The factors include:

- the degree to which the proposed action affects public health or safety;[20]

- the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks;[21]

- Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.[22]

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[10] *Save the Yaak v. Block*, 840 F.2d 714, 717 (9th Cir. 1988).
[11] Id.
[12] See 42 U.S.C. §§ 4321, 4344.
[13] 40 C.F.R. § 1500.3.
[14] 40 C.F.R. §§ 1500.3, 1507.1; see, e.g., Hodges v. Abraham, 300 F.3d 432, 438 (4th Cir. 2002).
[15] See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.
[16] *Anderson v. Evans*, 371 F.3d 475, 487 (9th Cir. 2004).
[17] *National Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 731 (9th Cir. 2001).
[18] *Ocean Advocates v. U.S. Army Corps of Engineers*, 402 F.3d at 865 (9th Cir. 2005) (*citing Nat'l Parks*, 241 F.3d at 731).
[19] 7 C.F.R. § 372.4
[20] 40 Fed. Reg. § 1508.27(b)(2).
[21] 40 Fed. Reg. § 1508.27(b)(5).
[22] 40 Fed. Reg. § 1508.27(b)(7).

As discussed herein, the commercial introduction of genetically engineered Soybean MON 89788 poses novel human health threats that constitutes unique environmental impacts and impacts to human health and safety. Following is a description of some of the impacts that the USDA must evaluate.

I. The EA's "Analysis" of the Potential Environmental Impacts Is Wholly Inadequate Because APHIS Failed to Take the "Hard Look" Required By NEPA. These Impacts Require An EIS.

As mandated by Congress, APHIS must comply with NEPA before it attempts to deregulate and allow the commercialization of genetically engineered MON 89788 and any progeny derived from it. USDA is the lead federal agency designated to undertake NEPA analysis for the commercialization of genetically engineered plant varieties. USDA's decision whether to deregulate a genetically engineered soy variety is a major federal action that may significantly affect the environment. The commercial planting of genetically engineered MON 89788 could impact a vast number of acres and will have significant impacts on the environment, including impacts to human health, as well as cumulative impacts.[23]

The draft EA, is extremely brief (18 pages) and glosses over important issues, making nothing more than a perfunctory attempt to appear to cover the impacts stemming from this deregulation. The EA only superficially covers a number of possible significant environmental impacts, as detailed below. The draft EA also relies uncritically on Monsanto's petition, which lacks a variety of important data that APHIS should have required and assessed in its draft EA.

A. APHIS Fails to Analyze MON 89788 in Comparison to the Conventional Soybean Line From Which it Was Derived

An important general inadequacy that will be addressed in more detail below is APHIS' near-total reliance on a loose comparison of MON 89788 with previously deregulated soybean line MON-04032-6, the original Roundup Ready soybean, in the draft EA. APHIS chooses this approach despite the fact that Monsanto's petition is based primarily on a comparison (inadequate though it may be) of MON 89788 to A3244, the conventional soybean from which it was derived (in addition to a variety of conventional soybean "reference lines").

APHIS' approach is deeply flawed because each new genetically engineered (GE) crop is the result of a novel transformation event that requires independent assessment based on close comparison to its closest conventional counterpart. This standard of assessment, also known as the "case-by-case" approach, is universally acknowledged among experts in GE crop testing. It is based on the unique suite of unintended effects to be expected in any given genetically engineered crop. These unintended effects are the result of the haphazard nature of the genetic engineering process, which is known to cause insertional

[23] 40 Fed. Reg. §§ 1508.27(b)(2), (5), (7)

mutagenesis in the crop's genome in a completely unpredictable manner.[24] This means that even when essentially the same gene of interest is inserted in two different transformation events (here, MON-04032-6 and MON 89788), the unintended effects accompanying each event can differ substantially. These unintended effects can include generation of novel toxins or allergens, increased levels of native toxins or allergens, and decreased nutritional content. Animal feeding trials and comprehensive assessment of the composition of the new GE crop via metabolic profiling, among other tests, are needed to detect any potentially harmful changes.[25] In such testing, the new GE crop should be compared to its conventional progenitor (here, A3244).

APHIS' review of Monsanto's petition for MON 89788 in the draft EA violates this well-established principle of GE crop testing. APHIS' assessment of MON 89788 versus A3244 is limited, beyond a bare mention of the fact that A3244 is the recipient line (EA, pp. 3-4), to a few cursory sentences reiterating Monsanto's conclusions regarding the phenotypic characteristics of MON 89788 versus A3244 (EA, pp. 8-9).

The need for a full assessment of MON 89788 versus A3244 is strengthened by:
1) Monsanto's use of a completely different transformation method to generate MON 89788 (Agrobacterium-mediated gene delivery to soybean meristem) versus particle acceleration to generate MON-04032-6 (EP, p. 3); and
2) Use of a different promoter for MON 89788 (chimeric, derived from figwort mosaic virus and *Arabidopsis thaliana*), versus the P-E35S from cauliflower mosaic virus for MON-04032-6 (EA, p. 3).

These substantial differences in the processes and genetic materials used to generate MON 89788 versus MON-04032-6 increase the potential for a different suite of unintended effects that requires analysis through close comparison of MON 89788 to its conventional progenitor.

B. APHIS' Analysis of the Roundup Ready Soybean System is Grossly Inadequate

Like MON-04032-6, the original Roundup Ready soybean, MON 89788 is to be deployed as part of a Roundup Ready soybean system, defined by Monsanto as: "[t]he utilization of Roundup agricultural herbicides plus Roundup Ready soybean…" (petition, p. 4).

APHIS' assessment of MON 89788 and associated herbicide use is grossly inadequate because it is based almost completely on a comparison to MON-04032-6, which was deregulated in 1994. By assuming MON-04032-6 as an unproblematic baseline for its assessment of MON 89788, APHIS virtually ignores over a decade of research pointing to substantial agronomic and environmental problems with the Roundup Ready soybean system (discussed below).

[24] Wilson, A.K. et al (2006). "Transformation-induced mutations in transgenic plants: analysis and biosafety implications," *Biotechnology and Genetic Engineering Reviews*, Vol. 21, Dec. 2006, pp. 209-234.
[25] Freese, W. and D. Schubert, op. cit.

This draft EA represents the first time in 12-13 years that APHIS has had an opportunity to address the growing agronomic and environmental problems associated with the Roundup Ready soybean system. This is because APHIS deregulation of a GE crop is absolute, permanently removing the deregulated line from regulatory oversight. Thus, APHIS has not addressed problems that have developed since the deregulation of the original Roundup Ready soybean in 1994. It would represent a flagrant dereliction of duty for APHIS to ignore this substantial body of research in its assessment of the similar Roundup Ready soybean system based on MON 89788. Furthermore, because deregulation is absolute and applicable to all progeny derived from MON 89788, APHIS' assessment must also be prospective in nature, and take account of likely future ramifications of the deregulation.

It is worth noting that APHIS' sister agency, the Environmental Protection Agency, grants time-limited registrations to the pesticidal proteins (so-called "plant-incorporated protectants" or PIPs) produced in GE crops under its jurisdictions. These registrations are typically 5-7 years in length. EPA grants time-limited registrations to enable it to consider new data concerning PIPs and the GE crops in which they are produced. If new scientific research indicates that a PIP has a previously unnoticed human health or environmental effect, EPA can choose not to re-register the PIP, or re-register the PIP and associated GE crop under altered conditions to ameliorate the harm. The fact that APHIS has no corresponding mechanism for periodic reassessment of GE crops under its jurisdiction makes it all the more important that APHIS conduct a rigorous analysis for all deregulation decisions, including the one at issue here.

Another EPA practice that APHIS should consider emulating is increased use of external peer-review. EPA regularly convenes Scientific Advisory Panels of independent experts to advise it on issues related to GE, pesticide-producing crops, while APHIS has no similar mechanism. The National Academy Sciences urged APHIS to increase external review of its decision-making process in a critical report issued in 2002.[26]

As indicated in detail below, APHIS needs to conduct a thorough and critical review of MON 89788 in comparison to its conventional progenitor, A3244, and in addition a thorough and critical review of the Roundup Ready soybean system, in the context of an environmental impact statement.

C. APHIS' Compositional Analysis of MON 89788 is Deficient

Monsanto's compositional analysis of MON 89788, and APHIS' review of it, are deficient in several respects. First, Monsanto tested far too few components of MON 89788 (forage and/or grain) to determine whether or not it is compositionally equivalent to its conventional progenitor, A3244. For forage samples, Monsanto conducted a rough

[26] *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, 2002. http://books.nap.edu/catalog/10258.html.

proximate analysis of levels of moisture, overall protein, overall fat, ash, acid detergent fiber and neutral detergent fiber. For soybean seed, Monsanto conducted the same tests, and in addition measured levels of amino acids, certain fatty acids, trypsin inhibitor, lectin, three isoflavones, phytic acid, stachyose, raffinose and Vitamin E (petition, Appendix E). Completely absent were any tests on mineral content of forage or seed, in particular micronutrients that play essential roles in the resistance of soybeans to disease and the nutritional quality of both forage and soybean seed.

The need for analysis of micronutrient levels in MON 89788 is demonstrated by accumulating research that shows glyphosate application to glyphosate-tolerant soybeans and other glyphosate-tolerant crops can inhibit uptake of micronutrients, including manganese, iron, potassium, boron and zinc.[27] The huge increase in overall glyphosate use over the past 15 years, driven primarily by the introduction of RR crop systems, reinforces the need for such analysis. Glyphosate use in American agriculture has increased by six-fold from just 1992 to 2002.[28] RR versions of soybeans and corn, and to a lesser extent cotton, are increasingly grown in rotation, meaning that each year, more prime cropland is sprayed more frequently with glyphosate, with increasing rates applied in many areas to control resistant weeds. While glyphosate is generally regarded as less toxic than many weed killers, a growing body of research suggests that continual use of this chemical may make RR plants more susceptible to disease and prone to mineral deficiencies than conventional crops, as well as reducing their yields.

When glyphosate is sprayed on Roundup Ready crops, much of the herbicide ends up on the surface of the soil, where it binds to soil particles in the top layer. Here it is degraded by microorganisms. However, studies showing that this glyphosate has no adverse effects on soil microorganisms and the nutrients they make available to crops have been done without considering the rhizosphere, the zone immediately adjacent to roots.

New research that focuses on the rhizosphere, where plants obtain most of their nutrients, shows that glyphosate is exuded from the roots of RR crops into the rhizosphere, and thus is distributed throughout the soil wherever roots penetrate.[29]

Glyphosate in the rhizosphere can alter the community of microorganisms in such a way as to interfere with availability of important mineral nutrients. Also, the Roundup Ready

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[27] Neumann, G. et al. (2006). "Relevance of glyphosate transfer to non-target plants via the rhizosphere," *Journal of Plant Diseases and Protection* 20:963-969; Lorenz, N. and R. Dick, eds. (2006). "Proceedings of the Glyphosate Potassium Symposium 2006," hosted by AG Spectrum of Iowa, and the School of Environment and Natural Resources, Ohio State University, July 25-26, 2006.

[28] Cerdeira, A.L. and S.O. Duke (2006). "The current status and environmental impacts of glyphosate-resistant crops: a review," *J. Environ. Quality* 35:1633-1658.

[29] Motavalli, P.P. et al. (2004). "Impact of genetically modified crops and their management on soil microbially mediated plant nutrient transformations," *J. Environ. Qual.* 33:816-824; Kremer, R.J. et al. (2005). "Glyphosate affects soybean root exudation and rhizosphere microorganisms," *International J. Analytical Environ. Chem.* 85:1165-1174; Eker, S. et al. (2006). "Foliar-applied glyphosate substantially reduced uptake of iron and manganese in sunflower (Helianthus annuus L.) plants," *J. Agric. Food Chem.*, published on web 12/08/2006.

crops themselves are less efficient at taking up these minerals,[30] and glyphosate in the plants after they have been sprayed can immobilize mineral nutrients.[31] The resultant mineral deficiencies have been implicated in various problems, from increased disease susceptibility to inhibition of photosynthesis.

This research indicates the need for a thorough analysis of potential inhibition of micronutrient uptake in MON 89788, including measurement of micronutrient levels in all soybean plant tissues. In light of the research cited above, the lack of micronutrient analysis is puzzling, to say the least. It is even more puzzling when one considers that Monsanto did provide such data in prior petitions for deregulation of other Roundup Ready crops, for instance, Roundup Ready alfalfa.

"Forage samples were collected from all plots and analyzed for nutritional components. Compositional analyses of the forage samples included proximates (protein, fat, ash and moisture), acid detergent fiber (ADF), neutral detergent fiber (NDF), lignin, amino acids, and minerals (calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc), as well as carbohydrates by calculation. In all, 35 different components were analyzed to assess the composition of Roundup Ready alfalfa." (RR alfalfa deregulation petition 04-110-01p)

APHIS should require Monsanto to submit test results on the levels of a broad range of micronutrients/minerals in forage and seed samples of glyphosate-treated MON 89788. APHIS should also require submission of lignin levels in glyphosate-treated MON 89788 under a range of temperatures, given studies indicating increased lignin levels and an associated greater tendency to stem-splitting in the original Roundup Ready soybean, particularly under conditions of extreme heat. As noted above, these data were submitted for RR alfalfa. The studies noted above as well as additional research in this area are appended to these comments as Appendix I.

APHIS' draft EA provides no analysis of Monsanto's compositional analysis, merely reiterating Monsanto's conclusions in a few sentences in section VI. 7 (EA, p. 13).

D. APHIS Fails to Consider the Potential for the Roundup Ready Soybean System to Increase Susceptibility to Plant Disease in MON 89788 and Other Crops

As noted above, inhibition of micronutrient uptake in RR soybeans treated with glyphosate can increase the susceptibility of RR soybeans to disease. The presence of glyphosate in the root zone of RR crops can also promote the growth of certain plant disease organisms that reside in the soil, such as *Fusarium* fungi.[32] Even non-RR crops

[30] Gordon, B. (2006). "Manganese nutrition of glyphosate-resistant and conventional soybeans," in Great Plains Soil Fertility Conference Proceedings, Denver, CO, March 7-8, p. 224-226.
[31] Bernards, M.L. et al. (2005). "Glyphosate interaction with manganese in tank mixtures and its effect on glyphosate absorption and translocation," *Weed Science* 53: 787-794
[32] Kremer et al (2005), op. cit.; for an early overview, see Benbrook (2001), "Troubled Times Amid Commercial Success for Roundup Ready Soybeans: Glyphosate Efficacy is Slipping and Unstable Transgene Expression Erodes Plant Defenses and Yields," AgBioTech InfoNet Technical Paper No. 4, May 2001. http://www.biotech-info.net/troubledtimes.html.

planted in fields previously treated with glyphosate are more likely to be damaged by fungal diseases such as Fusarium head blight, as has been demonstrated with wheat in Canada.[33] This research suggests that glyphosate has long-term effects that persist even after its use has been discontinued. In addition, glyphosate can persist for a long time in some soils without being degraded, and can be remobilized under certain conditions, damaging plants grown later.[34]

When fields are sprayed with Roundup many times a year, year after year, as is now the case with the widespread adoption of Roundup Ready varieties of different crops, these changes in soil microorganisms and mineral nutrient availability may increase the susceptibility of RR soybeans or other crops following RR soybeans to certain plant diseases, and may also create the conditions for serious impediments to future yields.

Surprisingly, Monsanto's field tests of MON 89788 for its phenotypic and ecological assessments (petition, pp. 66-84), including disease susceptibility, were conducted without application of glyphosate (petition, Appendix G, bottom of page 199). Since Roundup Ready crops are invariably grown with application of glyphosate as part of the "Roundup Ready soybean system" (petition, p. 4), Monsanto's field tests without glyphosate application are virtually meaningless for real world cultivation conditions.

APHIS provides no analysis of the potential for increased disease susceptibility of MON 89788 grown in the Roundup Ready soybean system, or of other crops grown in rotation with MON 89788. Instead, APHIS merely reiterates Monsanto's conclusions concerning disease and insect susceptibility of MON 98788 in the space of a single sentence (EA, p. 13). APHIS should demand a repeat of these tests with application of glyphosate in the context of preparing an environmental impact statement.

E. APHIS Fails to Analyze the Potential for Damage to Symbiont Organisms, Reduced Nitrogen Fixation, Reduced Yields and Related Effects

Glyphosate is toxic to *Bradyrhizobium japonicum*, an important nitrogen-fixing symbiont that colonizes soybean roots, due to the sensitivity of its EPSPS enzyme to inhibition by glyphosate.[35] This raises the concern that glyphosate exuded from the roots of glyphosate-sprayed, Roundup Ready plants could harm this important symbiont, and thereby decrease RR soy nitrogen fixation, growth and yield. Several studies conducted in both growth chambers and in the field have found that glyphosate application to glyphosate-tolerant soybeans reduces foliar nitrogen content, seed nitrogen content, biomass and yields, especially under conditions of water stress, early application of

[33] Fernandez, M.R., et al. (2005). "Crop production factors associated with Fusarium Head Blight in spring wheat in Eastern Saskatchewan," *Crop Sci.* 45:1908-1916.
[34] Cornish, P.S. and S. Burgin (2005). *Residual effects of glyphosate herbicide in ecological restoration, Restoration Ecology* 13: 695-702.
[35] Zablotowicz, R.M. and K.N. Reddy (2007), "Nitrogenase activity, nitrogen content, and yield responses to glyphosate in glyphosate-resistant soybean," *Crop Protection* 26: 370-376.

glyphosate, and high application rates.[36] Roundup Ready soybeans have been reported to perform more poorly than conventional soybeans under hot, dry conditions in Brazil and Paraguay,[37] perhaps due to adverse impacts on the interaction with *B. japonicum*, and/or the increased potential for stem-splitting in RR soybeans in hot conditions.[38]

Given this suggestive evidence of harm to the symbiont interaction between *B. japonicum* and soybean roots, and the consequences this could have for the nutritional content, health and yield of RR soybeans, it is obviously necessary to test the Roundup Ready soybean system based on MON 89788 for such effects. Surprisingly, Monsanto's "symbiont interaction" tests (petition, p. 81) were performed on MON 89788 to which glyphosate had NOT been applied. In addition, the tests were conducted under only one moderate temperature and water moisture regime (petition, Appendix I, pp. 221-222). Thus, this testing has virtually no value in determining whether or not the MON 89788 Roundup Ready soybean system is subject to reduced nitrogen fixation, yields or other effects noted above under real-world production conditions, which include both application of glyphosate and a range of temperatures and soil moisture conditions.

APHIS' draft EA not only fails to consider any of the research cited above, it does not even mention, much less analyze, Monsanto's symbiont interaction testing. APHIS must require that Monsanto submit appropriate tests on MON 89788 treated with glyphosate under a range of temperature and soil moisture conditions to assess these important parameters.

F. APHIS' Draft EA Fails to Provide a Meaningful Assessment of Glyphosate-Resistant Weeds Fostered by the Roundup Ready Soybean System, Alone and in Combination with Other Roundup Ready Crop Systems

Glyphosate resistance in weeds has developed with incredible rapidity over just six years, corresponding with the period of widespread introduction of Roundup Ready soybeans and cotton. In contrast, there was only one confirmed glyphosate-resistant weed in the U.S. in the 22 years from 1976, when Monsanto first introduced the chemical in the U.S., through 1998.[39] Concern began building in 2001, when a farm journal reported:

[36] Zablotowicz et al (2007), op. cit.; King, C.A., L.C. Purcell and E.D. Vories (2001). "Plant growth and nitrogenase activity of glyphosate-tolerant soybean in response to foliar glyphosate applications," Agron. J. 93: 179-186.

[37] FoEI (2007). "Who Benefits From GM Crops: An Analysis of the Global Performance of GM Crops (1996-2006)," Friends of the Earth International, January 2007, Sections 4.10 & 5.2. http://www.foei.org/publications/pdfs/gmcrops2007full.pdf.

[38] Coghlan, A. (1999). "Monsanto's modified soya beans are cracking up in the heat," New Scientist, Nov. 20, 1999.

[39] The sole resistant weed by 1998 was rigid ryegrass in California. See website of The Weed Science Society of America. http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go

"Resistance to glyphosate (Roundup) is emerging all around the world, potentially jeopardizing the 2.5 billion dollar market for genetically modified herbicide tolerant crops"[40]

According to a joint statement by ten prominent weed scientists:

"It is well known that glyphosate-resistant horseweed (also known as marestail) populations have been selected in Roundup Ready soybean and cotton cropping systems. Resistance was first reported in Delaware in 2000, a mere 5 years after the introduction of Roundup Ready soybean. Since that initial report, glyphosate-resistant horseweed is now reported in 12 states and is estimated to affect 1.5 million acres in Tennessee alone."

The list of confirmed glyphosate-resistant weeds in the U.S. now stands at seven: Palmer amaranth, common waterhemp, common ragweed, giant ragweed, horseweed, Italian ryegrass and rigid ryegrass.[41] Other weeds being investigated for glyphosate resistance include cocklebur and lambsquarters,[42] morning glories[43] and tropical spiderwort.[44] The spread of tropical spiderwort resistant to glyphosate, particularly in Georgia, is associated with the dramatic increase in Roundup Ready cotton acreage in recent years. Other weeds developing resistance to glyphosate, or at risk of the same, include annual grasses such goosegrass (confirmed glyphosate-resistant biotypes in Malaysia), foxtails, crowfootgrass, signal grasses, panicums, crabgrasses and Johnsongrass.[45]

While glyphosate-resistant weeds are worst in the South and East, they are rapidly spreading throughout the Midwest. Missouri is now home to at least three confirmed glyphosate-resistant weeds – common waterhemp, common ragweed and horseweed – and glyphosate-resistant horseweed was confirmed in Nebraska in 2006. Weed experts in the Midwest are predicting further spread of glyphosate-resistant weeds in their states. For instance, Michael Owen, agronomist at Iowa State University, is concerned that with over 90% of soybeans in Iowa planted to Roundup Ready varieties, the rapid adoption of Roundup Ready corn will lead increasingly to "an increasing number of crop acres where glyphosate will follow glyphosate" in the popular corn-soybean rotation.[46] Appendices II and III submitted with these comments contain a number of scientific, farm press, and related articles that show the high level of concern about glyphosate-resistant weeds among America's leading weed scientists.

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[40] Farmers Weekly (2001). "Glyphosate resistance is showing a worldwide rise," *Farmers Weekly*, Nov. 23, 2001. http://www.connectotel.com/gmfood/fw231101.txt.
[41] http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go
[42] Roberson, R. (2006). "Pigweed not only threat to glyphosate resistance," Southeast Farm Press, Oct. 19, 2006.
[43] UGA (2004). "Morning glories creeping their way around popular herbicide, new UGA research reports," University of Georgia, August 23, 2004.
[44] USDA ARS (2004). "Little-known weed causing big trouble in Southeast," USDA ARS News Service, August 24, 2004.
[45] Robinson, E. (2005). "Will weed shifts hurt glyphosate's effectiveness?" Delta Farm Press, Feb. 16, 2005.
[46] Owen, M.D.K. (2005). "Update 2005 on Herbicide Resistant Weeds and Weed Population Shifts," 2005 Integrated Crop Management Conference, Iowa State University.

Monsanto and APHIS continually point out that herbicide-resistance in weeds is a well-known phenomenon that occurs with many different herbicides, implying that glyphosate-resistant weeds are not a serious or special concern. This view is at stark variance with the consensus of leading American weed scientists. For instance, weed scientist Alan York of North Carolina State University concedes that: "Resistance is not unique with glyphosate," but goes on to state that: ***"What makes glyphosate resistance so important is our level of dependence on glyphosate***" (emphasis added).[47]

This "level of dependence" on glyphosate is precisely what both Monsanto in its petition and APHIS in its draft EA ignore. APHIS' cursory treatment of glyphosate-resistant weeds offers no meaningful analysis. A few of the basic issues that APHIS would need to address in a serious analysis of glyphosate-resistant weeds, but completely fails to discuss, include:

1) A quantitative assessment of the increase in glyphosate use in U.S. agriculture;
2) Quantitative assessment of increased glyphosate application rates needed to control various glyphosate-resistant weed species;
3) Quantitative assessment of the increased frequency of glyphosate application needed to control various glyphosate-resistant weed species;
4) Figures or estimates of the portion of the increased use of glyphosate attributable to Roundup Ready crop systems, including RR soybeans;
5) The potential for vastly increased rates of glyphosate-resistant weed development from the growing trend to plant RR crops every year, either RR soy following RR soy, or of special concern, RR corn following RR soybeans in the popular soybean-corn rotation;
6) Quantitative assessment of the acreage affected by glyphosate-resistant weeds in soybeans or any other crop;
7) Prospective assessment of the growth in acreage affected by glyphosate-resistant weeds based on current trends in glyphosate use and adoption of RR crop systems, especially RR corn.

Absent such analysis, APHIS' cursory treatment of the glyphosate-resistant weed issue does not by any stretch of the imagination amount to analysis of this issue.

The absence of serious analysis of glyphosate-resistant weeds is particularly puzzling given APHIS' explicit recognition, in 2001, that weed resistance was an environmental issue that should be analyzed in environmental impact assessment of herbicide-tolerant crops.[48] At that time, APHIS and EPA established a joint working group that required APHIS to consult with EPA regarding the development of weed resistance related to new herbicide-tolerant crops, such as Roundup Ready soybeans. There is no indication in the draft EA that APHIS consulted with EPA on this issue.

[47] Yancy, C. (2005). "Weed scientists develop plan to combat glyphosate resistance," Southeast Farm Press, June 3, 2005.
[48] 67 Fed. Reg. 60934, 60939, Sept. 27, 2002.

Glyphosate-resistant weeds are already leading to reductions in conservation tillage, increasing soil erosion, increased production costs for growers, and a return to more toxic herbicides to control weeds no longer readily controlled by glyphosate.

Mechanical tillage, once common, has been on the decline for years as farmers switch to "no-till" or conservation (minimal) tillage practices in order to reduce labor costs and fuel expenditures, as well as decrease the soil erosion that often accompanies plowing. The rise of glyphosate-resistant weeds is beginning to reverse this trend.[49] For instance, acreage under conservation tillage in Tennessee dropped by 18% in 2004, as farmers turned back to the plow to control glyphosate-resistant horseweed; Tennessee counties with the largest cotton acreage experienced the largest decline in conservation tillage, from 80% to just 40%. It is estimated that resistant horseweed has reduced the area under conservation tillage in Arkansas by 15%, with similar trends reported in Missouri and Mississippi.[50] The reduction in conservation tillage associated with glyphosate-resistant weeds, and resulting increased soil erosion, is an agronomic and environmental impact that APHIS needs to analyze in the context of an environmental impact statement on MON 89788.

An Arkansas weed scientist estimated that the state's growers would have to spend as much as $9 million to combat glyphosate-resistant horseweed in 2004.[51] Larry Steckel, weed scientist at the University of Tennessee, estimates that on average, glyphosate-resistant pigweed will cost cotton growers in the South an extra $40 or more per acre to control.[52] This represents a substantial burden, as cotton farmers' average expenditure on ***all*** pesticides (insecticides and herbicides) was $61 per acre in 2005.[53] USDA ERS 2007b). Arkansas extension agent Mike Hamilton estimates that an uncontrolled outbreak of glyphosate-resistant horseweed in his state has the potential to cost Arkansas cotton and soybean producers nearly $500 million in losses, based on projected loss in yield of 50% in 900,000 acres of Arkansas cotton and a 25% yield loss in the over 3 million acres of Arkansas soybeans.[54]

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[49] APHIS, following Monsanto, attributes the rise of conservation tillage to adoption of RR crops in the draft EA (EA, p. 3). It is interesting that APHIS adopts Monsanto's view here, in light of the fact that a USDA expert notes that the steep rise in conservation tillage (at least in soybeans) came from 1990-1996, before the introduction of RR soy, and that the share of soybean acres grown with conservation tillage stagnated after 1996. See Fernandez-Cornejo & McBride (2002), "Adoption of Bioengineered Crops," U.S. Dept. of Agriculture, Economic Research Service, Agricultural Economic Report No. 810, May 2002, p. 29.

[50] Steckel, L., S. Culpepper and K. Smith (2006). "The Impact of Glyphosate-Resistant Horseweed and Pigweed on Cotton Weed Management and Costs," presentation at Cotton Incorporated's "Crop Management Seminar," Memphis, 2006.
http://www.cottoninc.com/CropManagementSeminar2006/SeminarProceedings/images/Steckle%20Larry.pdf

[51] AP (2003). "Weed could cost farmers millions to fight," *Associated Press*, 6/4/03, http://www.biotech-info.net/millions_to_fight.html.

[52] Laws, F. (2006a). "Glyphosate-resistant weeds more burden to growers' pocketbooks," *Delta Farm Press*, November 27, 2006, http://deltafarmpress.com/news/061127-glyphosate-weeds/

[53] USDA ERS (2007b). Cost and return data for cotton production: 1997-2005. USDA Economic Research Service, last accessed January 12, 1997.
http://www.ers.usda.gov/data/CostsandReturns/data/recent/Cott/R-USCott.xls

[54] James, L. (2005). "Resistant weeds could be costly," Delta Farm Press, July 21, 2005.

The potential for economic losses to farmers from glyphosate-resistant weeds fostered by the Roundup Ready soybean system, in combination with other Roundup Ready crops systems (corn, cotton) is a serious issue that APHIS must address in the context of an environmental impact statement on MON 89788.

Over-reliance on Roundup Ready crops and glyphosate has dampened research into new herbicides, meaning none are on the horizon.[55] Meanwhile, growers will increasingly turn to older, more toxic herbicides, such as paraquat and 2,4-D, to control glyphosate-resistant weeds.[56] The potential for increased use of more toxic herbicides to control glyphosate-resistant weeds requires serious analysis by APHIS in the context of an environmental impact statement on MON 89788.

G. The EA Is Defective Because APHIS Improperly Relied on EPA's and FDA's Regulations Instead of Conducting an Independent NEPA Evaluation of the Environmental and Health and Safety Impacts of MON 89788.

In its EA, APHIS impermissibly relied on EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq*.) and Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq*.) regulations and failed to conduct an independent NEPA evaluation of the environmental effects associated with the deregulation.[57] APHIS cannot solely rely on another agency's evaluation of environmental effects under a separate statute to adequately fulfill its own NEPA obligations.[58] In *Save Our Ecosystems*, the Ninth Circuit held that the Forest Service could not rely on EPA's registration process for herbicides under FIFRA to address environmental impacts pursuant to NEPA.[59]

APHIS' reliance on FDA is more problematic given the limited nature of FDA's process. FDA created a voluntary consultation process in which FDA receives from biotechnology companies a bare summary of food safety and nutritional data regarding its proposed crop. The agency does not even make its own determinations of safety; rather, it merely states its understanding that a biotechnology company has concluded the crop is safe, and that further FDA approval or premarket review is not required.[60] Moreover, APHIS relied on a FDA process that was not even complete, but rather notes that "a final FDA decision is pending."[61] This cursory process in no way resembles or can be considered

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[55] Mueller, T.C., P.D. Mitchell, B.G. Young and A.S. Culpepper (2005). "Proactive versus reactive management of glyphosate-resistant or –tolerant weeds," *Weed Technology* 19:924-933; Yancy, C.H. (2005). "Weed scientists develop plan to combat glyphosate resistance," *Southeast Farm Press*, June 1, 2005. http://southeastfarmpress.com/mag/farming_weed_scientists_develop/.

[56] Roberson (2006), op. cit.

[57] EA at 5.

[58] *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984); *Or. Envtl. Council v. Kunzman*, 714 F.2d 901, 905 (9th Cir. 1983).

[59] *747 F.2d at 1248 (explaining that FIFRA only requires a cost-benefit analysis and holding that FIFRA "does not require or even contemplate the same examination that the [agency] is required to undertake under NEPA"); see also Wash. Toxics Coal. v. U.S. EPA, 413 F. 3d 1024, 1032 (9th Cir. 2005).*

[60] See 57 Fed. Reg. 22984 (FDA's Policy on Foods Derived from New Plant Varieties).

[61] EA at 5.

sufficiently equivalent in scope nor depth to the searching, "hard look" required of APHIS by NEPA. Thus, APHIS must prepare an EIS to address the pesticide and food issues that it impermissibly deferred to the other agencies.

H. The EA Fails to Adequately Analyze Potential Harm to Wildlife, Including Endangered Wildlife, From the Deregulation of Monsanto's MON 89788, In Violation of NEPA and the Endangered Species Act.

Recent studies demonstrate that common versions of Roundup herbicide that contain a surfactant (i.e. POEA, or polyethoxylated tallowamine) to aid penetration of the active ingredient (glyphosate) into plant tissue are extremely toxic to the tadpoles and juvenile stages of certain species of frogs, killing 96-100% of tadpoles after three weeks exposure and 68-86% of the juveniles after just one day.[62]

APHIS' draft EA lacks any analysis of the potential impacts of glyphosate use on MON 89788 on amphibian populations. This issue should be considered in the context of an environmental impact statement.

APHIS' EA is also inadequate because it fails to address threats to the endangered species. NEPA requires the agency to consider "the degree to which the action may adversely affect an endangered or threatened species or its habitat . . ."[63] Potential threat to an endangered species is a significant environmental impact that must be reviewed in an EIS. [64]

APHIS says it analyzed the potential impacts on species, see EA at 9-10. However APHIS' analysis was anything but specific to the deregulation at issue. APHIS did not consult with anyone from a Service agency such as Fish and Wildlife. Rather, APHIS merely looked at the *general*, non-specific listing of *all* threatened and endangered species on the FWS website. APHIS determined the new promoter of MON 89788 would have "no effect" on any protected species because it had love mammalian toxicity and its potential to be a food allergen was minimal.[65]

This fails to comport with NEPA or the ESA.

I. The EA's Analysis of Impacts on Agricultural Commodities and Organic Farming Is Inadequate.

The direct socio-economic impact associated with any agency action in granting a permit for field testing of a regulated article must be analyzed prior to taking such action. Indeed, the Council on Environmental Quality (CEQ) regulations implementing NEPA

[62] Relyea, R.A. (2005a). "The impact of insecticides and herbicides on the biodiversity and productivity of aquatic communities," *Ecological Applications* 15(2): 618-627; Relyea, R.A. (2005b). "The lethal impact of Roundup on aquatic and terrestrial amphibians," *Ecological Applications* 15(4): 1118-1124.
[63] 40 Fed. Reg. § 1508.27 (b)(9).
[64] 40 Fed. Reg. § 1508.27 (b)(9).
[65] EA at 9.

state that such impacts must be analyzed.[66] Specifically, the CEQ regulations state: When an environmental impact statement is prepared and economic or social and natural or physical environmental impacts are related, then the environmental impact statement will discuss all of these effects on the human environment.[67] The economic impacts are related, indeed intertwined with the environmental impacts because the economic impacts stem directly from the fundamental change to the conventional, organic, or wild plant, i.e., the genetic contamination from GE crops.

Federal courts have also upheld that NEPA requires, where economic analysis forms the basis of choosing among alternatives, that the analysis not be misleading, biased or incomplete.[68] As one court has noted, "In some instances environmental costs may outweigh economic and technical benefits and in other instances they may not. But NEPA mandates a rather finely tuned systematic balancing analysis in each instance."[69] Another Court has recently held that the intertwined economic impacts on organic farmers of the deregulation of a genetically engineered crop must be analyzed in an EIS.[70]

In this instance, the USDA has failed to provide adequate analysis of the socio-economic impacts on farmers and food processors whose crops or food products are contaminated with MON 89788. The agency's EA fails to adequately address these impacts on farmers, users or exporters of either organic and conventional, non-genetically engineered crops. Indeed, given the Plant Protection Act's (PPA) goal of addressing U.S. agricultural product exports and imports, this failure is even more egregious.[71] The impact of MON 89788 contamination must be adequately assessed.

With regard to impacts on organic farming, first, the draft EA assumes that the responsibility for preventing contamination of organic production falls on the organic producer, rather than on the manufacturer of this GE soy variety or farmers who grow it. Second, it fails to evaluate whether and to what extent segregation of MON 89788 from conventional soy is possible. APHIS failed to evaluate, require or describe steps that Monsanto or those who buy and plant its Roundup Ready soy could take to minimize or eliminate contamination of neighboring crops or to limit the spread. Third, the EA assumes that the only potential problem for organic producers is whether and how they could continue to be certified as organic. APHIS ignores the separate and distinct question, whether soy contaminated with genes from Monsanto's soy could be marketed as organic production.

The EA claims that it is "not likely" that organic farmers or other farmers will be significantly impacted by the expected commercial use of MON 89788. EA at 13.

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[66] The Supreme Court has held that the regulations are entitled to substantial deference by the courts. Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 372 (1989).
[67] 40 C.F.R. § 1508.14
[68] Seattle Audubon Society v. Lyons, 871 F. Supp. 1291, 1324 (W.D. WA 1994).
[69] Sierra Club v. Sigler, 695 F.2d 957, 978 (5th Cir. 1983).
[70] *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. February 12, 2007).
[71] See generally 7 U.S.C. 7701.

APHIS claims there will be no impacts on organic farmers because the presence of a detectable residue of a product of excluded methods (i.e. transgenic) does not necessarily constitute a violation of the National Organic Standards. This analysis is incomplete and devoid of any analysis about the current organic marketplace. During the implementation of the Organic Food Production Act the USDA made it clear that the agency views the organic rule as a marketing standard based upon consumer expectations. This approach was stated in its treatment of "excluded methods" (i.e. genetic engineering). The USDA has stated:

Products created with modern biotechnology techniques have been tested, approved by the appropriate regulatory agencies and can be used safely in general agricultural production. At the same time, consumers have made clear their opposition to use of these techniques in organic food production. This rule is a marketing standard, not a safety standard. Since the use of genetic engineering in the production of organic foods runs counter to consumer expectations, foods produced through excluded methods will not be permitted to carry the organic label. 65 Fed. Reg. 13534-35 (March 23, 2000) (emphasis added).

Therefore it is not clear whether the marketplace in organic will accept any "adventitious presence" of genetically engineered soy or other crops. In addition, many manufacturers and farmers undertake significant efforts (and financial burdens) to ensure that their products do not use plants contaminated with "adventitious presence." If APHIS is going to make such an assertion, it must analyze whether the marketplace and market-based standards will actually tolerate "adventitious presence" and the impact that such a tolerance will have on organic agricultural producers, processors, and consumers.

APHIS must adequately analyze the socio-economic impacts of the proposed deregulation on organic producers, in compliance with NEPA, in an EIS.

J. The EA's "Analysis" of Alternatives is Inadequate.

APHIS' analysis of alternatives in the EA was insufficient because APHIS failed to adequately analyze the alternatives it identified in the EA.[72] EAs must include analysis of the alternatives to the proposed action.[73] APHIS makes nothing more than an inadequate, perfunctory and cursory showing, lacking any real analysis, of the other alternatives besides the preferred alternative. The alternative of partial deregulation (alternative C) is mentioned at the outset and then never discussed again, let alone "analyzed."[74] The no action alternative (alternative A) is also mentioned as an alternative; [75] afterwards, the EA adds a meaningless, tacked-on sentence to the end of

[72] *See Bob Marshall Alliance v. Hodel*, 852 F.2d 1223, 1228 (9th Cir. 1988).
[73] Id. at 1229 ("consideration of alternatives requirement is both independent of, and broader than, the EIS requirement. In short, any proposed federal action involving unresolved conflicts as to the proper use of resources triggers NEPA's consideration of alternatives requirement, whether or not an EIS is also required.")
[74] EA at 6.
[75] EA at 5;

several paragraphs, presumably in order to make the appear that it actually analyzed this alternative. This is not meaningful analysis and is inadequate to comply with NEPA.

NEPA requires that federal agencies consider alternatives to recommended actions whenever those actions "involve[ ] unresolved conflicts concerning alternative uses of available resources."[76] The goal of the statute is to ensure "that federal agencies infuse in project planning a thorough consideration of environmental values."[77] The consideration of alternatives requirement furthers that goal by guaranteeing that agency decision-makers "[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."[78] NEPA's requirement that alternatives be studied, developed, and described both guides the substance of environmental decision-making and provides evidence that the mandated decision-making process has actually taken place.[79] Informed and meaningful consideration of alternatives-including the no action alternative-is thus an integral part of the statutory scheme.[80]

III. APHIS Failed to Adequately Assess the Cumulative Impacts of Deregulation of MON 89788

The deficient draft EA failed to adequately address several significant issues, such as the cumulative impacts of increasing glyphosate use from the Roundup Ready soybean system, combined with other Roundup Ready crop systems, and the potential impacts from future "stacking" of MON 89788 with other GE soybean varieties.

APHIS utterly fails to address or analyze *any* cumulative impacts anywhere in the EA. This is arbitrary and capricious action and a violation of NEPA.[81]

NEPA requires agencies to consider the cumulative impacts of their proposed actions.[82] By definition, cumulative effects must be evaluated along with direct and indirect effects of a project and its alternatives. "'Cumulative impact' is 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

[76] 42 U.S.C. § 4332(2)(E).
[77] Conner v. Buford, 836 F.2d 1521, 1532 (9th Cir. 1988).
[78] Calvert Cliffs' Coordinating Committee, Inc. v. United States Atomic Energy Commission, 449 F.2d 1109, 1114 (D.C.Cir.1971) (emphasis added).
[79] Id.
[80] *See* Bob Marshall Alliance v. Hodel, 852 F.2d 1223, 1228 (9th Cir. 1988).
[81] *See* 40 C.F.R. § 1508.25; Kern v. U.S. Bureau of Land Mgmt., 284 F.3d 1062, 1076 (9th Cir. 2002).
[82] 40 C.F.R. § 1508.25(c); Utahns for Better Transp. v. United States Dep't of Transp., 305 F.3d 1152, 1172 (10th Cir.2002); Kern v. United States Bureau of Land Mgmt., 284 F.3d 1062, 1076 (9th Cir.2002); Vill. of Grand View v. Skinner, 947 F.2d 651, 659 (2d Cir.1991).

undertakes such other actions."[83] Individually minor, but collectively significant actions, taking place over time, can generate cumulative impacts.[84]

Analyzing cumulative impacts in EAs is crucial: The Council on Environmental Quality has noted that "in a typical year, 45,000 EAs are prepared compared to 450 EISs.... Given that so many more EAs are prepared than EISs, adequate consideration of cumulative effects requires that EAs address them fully."[85] A meaningful cumulative impact 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.[86]

In this case, APHIS failure to identify and analyze any of those cumulative impacts is egregiously violative of NEPA.[87] Nowhere in the draft EA does APHIS analyze the cumulative affects of the deregulation of MON 89788; in fact, APHIS cannot adequately address those impacts, as it does not know, *inter alia*, the extent of Monsanto's future crossing of the MON 89788 with progeny. The cumulative impacts of "stacking" require an EIS be prepared.

A. APHIS Wholly Fails to Assess the Impacts of Increasing Glyphosate Use

The Roundup Ready soybean system, combined with the Roundup Ready cotton and corn systems, have dramatically increased glyphosate use over the past 15 years. The adverse impacts addressed in Section II. are all attributable in whole or in part to the increasing volume and frequency of glyphosate application in U.S. agriculture. APHIS' failure to quantitatively assess glyphosate use, Roundup Ready crop acreage, and associated adverse agronomic and environmental impacts must be remedied in the context of an environmental impact statement.

Roundup Ready cotton comprised 82% of total cotton acreage in 2006.[88] Roundup Ready soybeans comprised 89% of soybean acreage in 2006. The introduction in 2006 of Roundup Ready Flex cotton, which tolerates twice the application rate of original RR cotton and also permits glyphosate application throughout the cotton plant's growing

[83] 40 C.F.R. § 1508.7.
[84] Id.
[85] Council on Environmental Quality, *Considering Cumulative Effects Under the National Environmental Policy Act* at 4, Jan. 1997, available at http:// ceq.eh.doe.gov/nepa/ccenepa/ccenepa.htm (last visited Feb. 26, 2002) (emphasis added).
[86] Grand Canyon Trust v. F.A.A., 290 F.3d 339, 345 (D.C. Cir. 2002).
[87] Kern v. U.S. Bureau of Land Mgmt., 284 F.3d 1062, 1076-77 (9th Cir. 2002).
[88] Calculated from: USDA AMS (2006). "Cotton Varieties Planted: 2006 Crop," U.S. Dept. of Agriculture, Agricultural Marketing Service, Cotton Program, August 2006. http://www.ams.usda.gov/cottonrpts/MNXLS/mp_cn833.xls.

season,[89] promises to lead to continued increases in glyphosate use on cotton. Roundup Ready corn, however, presents the greatest potential for increased glyphosate use.

Acreage planted to Roundup Ready corn is growing at an extremely rapid clip, from just 7.8 million acres in 2002 to 24.8 million acres in 2005, to 32.7 million acres in 2006.[90] Glyphosate use on corn has increased even more rapidly, from 3.3 million lbs. in 2002 to an astounding 23.9 million lbs. in 2005, the latest year for which USDA statistics are available.[91] Thus, as RR corn acreage roughly tripled in the four years from 2002 to 2005, glyphosate use on corn has increased by more than seven-fold. In 2002, Roundup Ready corn represented 11% of overall U.S. corn acreage, increasing to 26% of corn acreage in 2005.[92] Thus, the seven-fold increase in glyphosate use on corn from 2002 to 2005 came during a period when RR corn acreage increased from just 11% to 26% of all corn. RR corn acreage jumped to 36% of all corn in 2006.[93] Clearly, if present trends continue, glyphosate use on America's most widely planted crop could easily increase by five- to ten-fold by the end of the decade.

This development is of great relevance to the Roundup Ready soybean system because fully 71% of U.S. soybean acreage is rotated to corn (petition, p. 116). Since 89% of soybean acreage was planted to Roundup Ready soy in 2006, roughly 63% of U.S. soybean acreage represents Roundup Ready soy that is rotated to corn. If the RR corn percentage of overall corn acreage continues to climb, as appears likely, the coming years will see a huge increase in the frequency and amount of glyphosate applications. Another 13% of soybean acreage is followed by soybeans (petition, p. 116), thus another 11.6% of soybeans represents Roundup Ready soybeans followed by RR soy.

APHIS completely fails to analyze the agronomic and environmental impacts of this dramatically increasing use of glyphosate driven by the Roundup Ready soybean system in combination with other Roundup Ready crop systems. These cumulative impacts must be addressed in the context of an environmental impact statement.

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[89] Bennett, D. (2005). "A look at Roundup Ready Flex cotton," *Delta Farm Press*, 2/24/05, http://deltafarmpress.com/news/050224-roundup-flex/.

[90] "Monsanto biotechnology trait acreage: fiscal years 1996 to 2006," updated Oct. 11, 2006. http://www.monsanto.com/monsanto/content/investor/financial/reports/2006/Q42006Acreage.pdf.

[91] USDA NASS (2006). "Agricultural Chemical Usage: 2005 Field Crops Summary," National Agricultural Statistics Service, U.S. Dept. of Agriculture, May 2006. http://usda.mannlib.cornell.edu/usda/nass/AgriChemUsFC//2000s/2006/AgriChemUsFC-05-17-2006.pdf; USDA NASS (2003). "Agricultural Chemical Usage: 2002 Field Crops Summary," National Agricultural Statistics Service, U.S. Dept. of Agriculture, May 2003. http://usda.mannlib.cornell.edu/usda/nass/AgriChemUsFC//2000s/2003/AgriChemUsFC-05-14-2003.pdf

[92] USDA ERS (2006). "Adoption of Genetically Engineered Crops in the U.S.: Corn Varieties," USDA, Economic Research Service, http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm. Note that the cited percentages of overall corn acreage planted to Roundup Ready corn are calculated by adding the figures for "herbicide-tolerant only" and "stacked gene varieties." Stacked gene varieties contain the herbicide-tolerant trait as well as an insect-resistant trait. A small but unknown proportion of "herbicide-tolerant only" and "stacked gene" corn varieties are engineered for tolerance to Liberty herbicide (LibertyLink corn). We follow Monsanto in discounting the contribution of LibertyLink corn and assuming all HT corn is Roundup Ready (petition, pp. 116-17).

[93] USDA ERS (2006), op. cit.

B. APHIS' Fails to Adequately Assess the Impacts of Stacking MON 89788 with Other GE Soybean Varieties

Monsanto's petition requests deregulation not only of MON 89788, but also of any progeny derived from crosses between MON 89788 and other soybean lines, including GE soybeans that have been granted nonregulated status. Thus, the requested deregulation constitutes prospective deregulation of so-called "stacked" GE soybean varieties with the MON 89788 genetic modification and one or more additional biotechnology traits, whether already deregulated or to be deregulated in the future.

APHIS' fails to adequately assess the potential agronomic, environmental and human health impacts of this "free license" to Monsanto to generate progeny combining MON 89788 with one, two, three or any number of other GE traits.

According to experts in the risk assessment process for GE foods, "stacked" crops require application of more sophisticated testing techniques, such as metabolic profiling, than single-trait GE crops due to the enhanced potential for hazardous unintended effects that accompanies trait-stacking.

"Present approaches to detecting expected and unexpected changes in the composition of genetically modified food crops are primarily based on measurements of single compounds (targeted approach)."

"The targeted approach has severe limitations with respect to unknown anti-nutrients and natural toxins, especially in less well known crops."

"In order to increase the possibility of detecting secondary effects due to the genetic modification of plants that have been extensively modified, new profiling methods are of interest and should be further developed and validated (non-targeted approach). ***Application of these techniques is of particular interest for genetically modified foods with extensive genetic modification (gene stacking)*** meant to improve agronomical and/or nutritional characteristics of the food plant."[94]

Therefore, it would be extremely irresponsible of APHIS to grant permanent deregulation to any and all progeny of MON 89788 containing both the RR gene and any number of other GE traits introduced into other lines. APHIS' serious error here lies in its unscientific assumption that the stacking of various GE traits does nothing more than "add" an additional trait. As indicated above, the traits expressed by the various deregulated GE soybean lines that may be combined with MON 89788, and/or unintended effects associated with these stacked lines, could interact, increasing the potential for hazardous effects such as generation of novel toxins or allergens, increased

[94] KUIPER, H.A.., KLETER, G.A., NOTEBORN, H..P,J.M., KOK, E.J. (2001). Assessment of the food safety issues related to genetically modified foods. *The Plant Journal* **27**(6), 503-528.

levels of naturally occurring, low-level toxins or allergens, or decreased nutritional content. We note that soybeans are known as a major allergenic food, containing a number of allergenic proteins. These effects could be generated by the interaction of the traits in various individual, single-trait lines that each, taken by itself, may be unobjectionable. Therefore, we urge APHIS to deny Monsanto a "free license" to combine MON 89788 with any and all other deregulated GE soybean lines.

We note that USDA's past practice has been to subject at least some stacked GE crops to a separate review process. Of currently deregulated GE crops, 12 of 71 or 17% are stacked varieties. Of the GE crops currently up for deregulation, 1 of 10 are stacked.[95] In addition, APHIS does see fit to address a small subset of possible stacked progeny of MON 89788 in two paragraphs (EA, pp. 11-12). It defies logic to consider a small subset of potential stacked varieties containing MON 89788 if the deregulation to be granted is permanent, and allows prospective stacking of MON 89788 with GE soybeans to be deregulated in the future.

APHIS considers only the currently deregulated GE LibertyLink soybean line, which is engineered for tolerance to glufosinate. Yet Pioneer has two GE soybean varieties up for deregulation (high oleic soybeans and a soybean line that is resistant to both glyphosate as well as acetolactate synthase-type herbicides).[96] Many other GE soybeans are undergoing field-tests, and may be commercialized in the future.

One potential stacked GE crop that would be covered if USDA grants the petition is a GE soybean variety derived from a cross of MON 89788 and MON-04032-6. This could potentially result in a soybean variety with tolerance to greater levels of glyphosate. This would be very disturbing, as it would almost surely lead to still greater use of glyphosate, with all its negative impacts, than would be the case with MON 89788 alone. Or, MON 89788 could be stacked with Pioneer's dual-herbicide resistant soybean (which is tolerant to glyphosate), with a possibly similar effect. A precedent for a RR crop with increased tolerance to glyphosate is Monsanto's "2nd generation" Roundup Ready Flex cotton, alluded to above.

APHIS must conduct separate environmental assessments or environmental impact statements for each stacked variety of soybean containing MON 89788, and not grant a free license to Monsanto to combine MON 89788 with any other GE soybean line it chooses in the future.

As with the other issues (and arguably more so by its very nature), cumulative impacts analyses are action-specific, site-specific, and must be undertaken for each EA, for each final agency action for which NEPA is to be complied. The EA is arbitrary and capricious action.[97]

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[95] See http://www.aphis.usda.gov/brs/not_reg.html, updated to March 23, 2007.
[96] See http://www.aphis.usda.gov/brs/not_reg.html, bottom of webpage.
[97] See Klamath-Siskiyou Wildlands Center v. Bureau of Land Management, 387 F.3d 989, 997 (9th Cir. 2004) (finding EAs to be insufficient for failure to consider the specific incremental impact that would be expected from the specific timber sales at issue); Muckleshoot Indian Tribe v. US Forest Service, 177 F.3d

800, 811 (9th Cir. 1998) (invalidating and EIS because the "cumulative effects" analysis "merely provide[d] very broad and general statements devoid of specific, reasoned conclusions").

IV. Failure of FDA to Review or Approve the Monsanto's GE Soybean Argues Strongly Against Deregulation

FDA has not completed a voluntary consultation on Monsanto's MON 89788 (EA at 5). APHIS is not competent to judge whether MON 89788 or any of its prospective stacked progeny present human health risks.

In sum, APHIS' dismal failure to carry out its regulatory responsibilities provides more than sufficient grounds to justify a refusal to deregulate MON 89788, until and unless APHIS proves itself capable of properly regulating GE crops in general.

CONCLUSION

For the foregoing reasons, we request that the petition for nonregulated status for MON 89788 be denied, or in the alternative, that APHIS prepare an EIS adequately addressing all the significant environmental impacts of this action.

Respectfully submitted,

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