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Docket No. APHIS-2010-0047
Regulatory Analysis and Development
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Comments to USDA APHIS on the Draft Environmental Assessment on the Request for Partial Deregulation of Sugar Beet Genetically Engineered to be Tolerant to the Herbicide Glyphosate

December 6, 2010

Docket No. APHIS-2010-0047.

In 2008, the Center for Food Safety (CFS), Organic Seed Alliance, High Mowing Seeds, and the Sierra Club sued the Department of Agriculture (USDA) for deregulating Monsanto's genetically engineered (GE) Roundup Ready sugar beets (RRSB) without complying with the National Environmental Policy Act, as USDA had failed to conduct an environmental impact statement (EIS) before deregulating the crop ("*Sugar Beets I*"). On August 13, 2010, the federal court sided with CFS and banned GE sugar beets until the USDA fully analyzed the impacts of the GE plant on the environment, farmers, and the public in an EIS.

Three weeks later, USDA issued permits to GE sugar beet seed growers to allow steckling production for the continued commercialization of GE sugar beets. CFS again sued USDA, this time for illegally permitting a GE crop without any NEPA compliance. On September 28, 2010, the court ruled that CFS was likely to succeed on its claim that USDA violated NEPA and improperly segmented the project. On November 30, 2010,

the court granted CFS's motion for preliminary injunction and ordered the stecklings plowed under.

On November 4, 2010, USDA released a Draft Environmental Assessment (EA) proposing new interim measures that would further allow the continued commercialization of GE sugar beets beginning in the spring of 2011. These comments respond to the proposal in the EA.

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 over 175,000 members throughout the country that support organic agriculture and regularly purchase organic products. CFS members support the public's right to choose GE-free food and crops. These comments incorporate by reference other CFS organizational comments submitted to the docket concurrently. Concurrently, CFS is submitting 9,988 comments from CFS True Food Network members opposing the proposed interim deregulation of RR Sugar Beets (Docket No. APHIS-2010-0047).

SUMMARY

The draft EA is arbitrarily and capriciously flawed in structure, process and substance. At a minimum, an EIS is required.

The draft EA is flawed in structure because it is overly narrow in scope and stripped of any meaningful alternatives besides interim approval under the exact same measures APHIS proposed to the District Court in *Sugar Beets I* and which that Court declined to adopt. Further, APHIS' flawed understanding of its oversight authority in the event of "partial deregulation" improperly cabined its analysis. This contravenes the National Environmental Policy Act(NEPA) and the Plant Protection Act (PPA).

The draft EA is arbitrarily and capriciously flawed in process because, rather than informing APHIS's decision to enact a commercial permitting program for RRSB, the draft EA's analysis is predicated on the pre-determined and separate conclusion that APHIS will continue to allow the commercial production of RRSB, making the entire NEPA analysis a foregone conclusion – a meaningless paper exercise.

The draft EA is arbitrarily and capriciously flawed in substance because its analysis on numerous impacts is inadequate to comply with NEPA, because it entirely fails to address other significant issues, and because its conclusions that commercial production of RRSB will lead to no significant impacts to the environment, U.S. agriculture, or public health are contrary to the record evidence. Commercial production of RRSB would have numerous significant impacts on U.S. agriculture and the environment that must be acknowledged, analyzed, and meaningfully considered. At a minimum, an EIS is required.

[1] *See generally* www.centerforfoodsafety.org.

APHIS should have consulted with the Fish and Wildlife Service (FWS) about the significant impacts of commercial-scale production of RRSB on protected species. By failing to adequately assess the foreseeable impacts to protected species and failing to consult, APHIS violated the Endangered Species Act (ESA).

APHIS's decision to allow commercial production of RRSB does not comply with the Plant Protection Act (PPA) and is not based on sound science. The RRSB permitting program violates the PPA in that it promotes the proliferation of plant disease agents; noxious, herbicide-resistant weeds; and economic impacts that will harm the agricultural economy. The APHIS decision to misuse field trial permits intended for research to instead continuecommercial production without a deregulation also violates the PPA and the APA. Finally, the draft EA violates the 2008 Farm Bill both procedurally and substantively because the proposal fails to employ the mandated oversight measures directed therein.

COMMENTS

The National Environmental Policy Act

NEPA requires a federal agency such as USDA's 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] NEPA requires APHIS to take a "hard look"[4] at the environmental consequences of deregulation of RRSB, including a reasonable range of alternatives and the cumulative impacts of past and future deregulation of GE crops.

An agency first prepares an EA to determine whether a Federal action will have a significant affect on the quality of the human environment. "An environmental assessment is a 'concise public document' that '[b]riefly provide[s] sufficient evidence and analysis for determining whether to prepare an [EIS] or a finding of no significant impact.'"[5] Once an agency (or a court upon review of an agency's EA) determines the Federal action will have a significant affect, an EIS must be prepared. Here, the district court established that deregulation of RRSB will have a significant effect on the quality of the human environment and required APHIS to prepare an EIS.

An EIS serves different purposes from the EA already prepared by APHIS.[6] "An EA aims simply to identify (and assess the 'significance' of) potential impacts on the environment." An EIS, on the other hand, balances "different kinds of positive and

[2] 42 U.S.C. § 4332(2)(C).
[3] *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349(1989).
[4] *Kleppe v. Sierra Club*, 427 U.S. 390, 410 (1976).
[5] 40 C.F.R. § 1508.9(a); *Anderson v. Evans*, 371 F.3d 475, 488 (9th Cir.2004).
[6] *See Anderson v. Evans*, 314 F.3d 1006, 1022 (9th Cir. 2002).

negative environmental effects, one against the other" and "weighs negative environmental impacts against a project's other objectives."[7] "Preparation of an EIS thus ensures that decision-makers know that there *is* a risk of significant environmental impact and take that impact into consideration."[8] APHIS' decisions must be "complete, reasoned, and adequately explained."[9]

"An EIS must be prepared if substantial questions are raised as to whether a project . . . *may* cause significant degradation of some human environmental factor."[10] "Thus, a plaintiff need not show that significant effects on the environment will in fact occur; raising substantial questions whether a project may have a significant effect on the environment is enough."[11] As Courts have recognized, *"*[t]his is a low standard." [12]

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.[13] 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."[14] CEQ's regulations are applicable to and binding on all federal agencies.[15] Among other requirements, CEQ's regulations mandate that federal agencies address all "reasonably foreseeable" environmental impacts of their proposed programs, projects, and regulations.[16]

CEQ's regulations clearly lay out the purpose of an EIS. "The primary purpose of an environmental impact statement is to serve as action-forcing devices to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government."[17] An EIS shall provide "full and fair discussion of significant environmental impacts and shall inform decision makers of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment."[18] Agencies are to focus on "significant environmental issues and alternatives."[19]

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[7] *Sierra Club v. Marsh*, 769 F.2d 868, 875 (1st Cir. 1985).
[8] *Anderson v. Evans*, 314 F.3d at 1022.
[9] *Northwest Coalition for Alternatives to Pesticides v. U.S. E.P.A.*, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008).
[10] *Natural Resources Defense Council v. Winter*, 518 F.3d 658, 688 (9th Cir. 2008) (emphasis added) (quoting cases); *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1216 (9th Cir. 1998).
[11] *Id*.
[12] *Klamath Siskiyou Wildlands Ctr. v. Boody*, 468 F.3d 549, 562 (9th Cir. 2006).
[13] *See* 42 U.S.C. §§ 4321, 4344.
[14] 40 C.F.R. § 1500.3.
[15] 40 C.F.R. §§ 1500.3, 1507.1; *see, e.g., Hodges v. Abraham*, 300 F.3d 432, 438 (4th Cir. 2002).
[16] See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.
[17] 40 C.F.R. § 1502.1.
[18] *Id.*
[19] *Id.*

I. Transgenic Contamination Is Not Adequately Analyzed And Is A Significant Impact.

The EA inadequately addresses the risk for transgenic contamination by RRSB and erroneously concludes that this harm is not significant.

Contamination Is Likely

Transgenic contamination is likely and will happen by a variety of means if APHIS permits interim commercialization of RRSB. Transgenic contamination occurs through many pathways: pollination of non-genetically engineered plants by genetically engineered plants, mixing of genetically engineered seed with non-genetically engineered seed, improper seed cleaning, weather events and human error.

The EA recognizes that pollen can travel long distances and that gene flow and "beet pollination can occur over distances as great as 6 miles."[20] APHIS further admits that "increasing the isolation distance would not eliminate the potential for unwanted gene flow."[21] The potential for long distance gene flow is not novel. The administrative record in *Sugar Beets I*, summarized by the court in its summary judgment order, further evidences the likelihood for gene flow:

> Sugar beets are pollinated by both wind and insects and scientist have documented that sugar beet pollen can disperse up to 800 meters. (AR 4065 (Sugar beet "pollen can be spread extensively on the airflow (significant quantities have been recorded at distances up to 800m) and by insects."); AR 4104 ("Pollen dispersal by wind has been shown to occur up to 800 [meters] at relatively high frequencies, and under certain atmospheric conditions are likely to be dispersed more widely."); AR 2977 ("Gene flow is hard to control in wind-pollinated plants like beet.").) One report found that isolation distances of 1000 meters and 3200 meters may not be sufficient for genetically modified ("GM")-free organic operations with adjacent fields of GM sugar beet. (AR 4098; *see also* AR 4042 (suggesting that isolation distances of up to 3200 to 4800 meters (3.2 to 4.8 kilometers) may be desirable).) Another study found that wind-born pollen can be distributed at least 4,500 meters. (AR 3992; *see also* 4098-99 (noting that "no research has been carried out specifically on the movement of sugar beet pollen in atmospheric conditions such as convection currents, turbulent conditions and weather fronts" and that within twenty-four hours it is possible to estimate that pollen could be dispersed up to 864,000 meters (864 kilometers) in turbulent conditions).)

Sugar Beets I, Summary Judgment Order, *Center for Food Safety v. Vilsack*, 2009 WL 3047227, at *7 (N.D. Cal. Sept. 21, 2009).

[20] EA at 157 ("[B]eet pollination can occur over distances as great as 6 miles in situations where there is little pollen competition and self incompatibility."); EA at 59 (citing pollen flow at distances of 2.8 miles and 8km).
[21] EA at 158.

Discovery in *Sugar Beets I* has uncovered conclusive evidence that contamination is not only likely, but a common and continuing occurrence, and that seed company containment efforts are ineffective. Due to competitive constraints and the inability to stop gene flow, contamination has become an common occurrence in seed growing. Seed companies have not been able to isolate the sources of the contaminants entering their own fields, and it is impossible to know how many other farmers' crops they have contaminated. These practices cannot be adopted by the agency, because they have proven inadequate to prevent contamination. While most of the evidence uncovered is confidential business information and not available for public release, APHIS is nevertheless privy to all the documented incidents of contamination from participation in the lawsuit.

The U.S. Fish and Wildlife Service, in a recent draft of a Biological Opinion on the effects of Roundup Ready creeping bentgrass, prepared pursuant to the Endangered Species Act (ESA), noted: "Recent escape of GM sugar beets into compost sold to homeowners illustrates the potential for products to move outside of their intended market. Sugar beets are . . . wind pollinated and were thought to be well controlled by the growers using the product. Despite best management practices, escape of the transgenes occurred."[22]

Contamination occurs frequently and is common in all GE crops, not only *Beta vulgaris*. As recently as last month, contamination stemming from a 2005 field trial of Roundup Ready Bentgrass was discovered in Ontario, Oregon, four miles from the field trial location in Idaho. Five years later, contamination is widespread and rampant, covering an estimated 27 square miles.

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.[23] 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.

In another report, "A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops," UCS enlisted the assistance of several academic experts in agricultural sciences to determine whether GE pharmaceutical-producing crops could be kept out of food. This report demonstrates how difficult this is, even for pharmaceutical crops that would be grown on small acreage and under stringent

[22] FWS Draft Biological Opinion, Roundup Ready Bentgrass, July 2009.
[23] M. Mellon and J. Rissler, Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply, Union of Concerned Scientists, 2004.

confinement, to avoid contaminating food. The authors of this report examined confinement methods, such as field separation, cleaning farm equipment, segregation of seed, and others, and found that it would still be difficult to ensure the absence of contamination.[24]

Another route of contamination that is unpredictable, but likely over time, is human error. Two academic ecologists address this in a peer-reviewed paper, and conclude that contamination by GE crops due to human error or other means has occurred numerous times, and is likely to continue to occur. This paper documents many instances where GE crops are known to have contaminated non-GE crops or food.[25] Thus, biological contamination through human error and human behavior, such as composting and exchanging seeds, must be addressed in an EIS.

Past Contamination Episodes

Past is prologue. Past contamination episodes from GE crops provide cautionary tales for why contamination is an impact that must be adequately considered in an EIS here. For example, the StarLink corn contamination showed how much damage a GE-crop can do to the agricultural economy. StarLink is a variety of corn genetically engineered to produce the Cry9C insecticidal toxin to kill certain corn pests.[26] 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.[27] 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).[28] 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

[24] 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.
[25] M. Marvier and R. Van Acker, "Can crop transgenes be kept on a leash?" Front. Ecol. Environ., 2005, vol.3, p.95-100.
[26] For the following discussion of StarLink, see Freese, B. (2001). "The StarLink Affair," Friends of the Earth, July 2001. *Available at* www.foe.org/safefood/starlink.pdf.
[27] 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)," November 2000.
[28] 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.

country were contaminated with StarLink. The USDA found StarLink contaminating 9-22% of grain samples.[29]

The extent of the contamination is startling when one considers that StarLink never represented more than 0.43% of U.S. corn acreage. While post-harvest mixing was responsible for much of the contamination, there is also abundant evidence that popcorn, sweet corn, white corn and seed corn stocks were also contaminated with StarLink.[30] These latter findings strongly suggest that StarLink pollen blown by the wind fertilized conventional corn, despite the 660-foot border strip requirement. In fact, a USDA-sponsored testing program for seed companies that had never been licensed to grow StarLink found that nearly one-fourth of these seed firms (71 of 288) had some corn lines that tested positive for StarLink. USDA had to buy back nearly 450,000 units of StarLink-contaminated seed corn at a cost of several million dollars to prevent further spread of StarLink in future years. Tainted seed dated anywhere from production year 1997 to 2001.[31]

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 one of the scientists in charge has claimed that they exceeded APHIS confinement recommendation considerably, but still experienced contamination.[32]

Rice farmers lost hundreds of millions due to rejection of LL601-contaminated rice shipments by countries in Europe and elsewhere, and the consequent sharp drops in rice prices.[33] Affected rice farmers were forced to sue Bayer CropScience, the developer of LL601, in an effort to recover their losses. In response to a petition from Bayer CropScience, APHIS subsequently deregulated LL601, but did nothing to redress the economic harms to rice farmers. Rather than accept responsibility for the episode, Bayer CropScience blamed farmers and an "Act of God" for the contamination episode.[34] Just months later, still another unapproved GE rice variety developed by Bayer CropScience,

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[29] 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.

[30] 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.

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

[32] G. Vogel, "Tracing the transatlantic spread of GM rice," Science, 2006, vol. 313, p. 1714.

[33] Weiss, R. (2006). "Gene-altered profit-killer," Washington Post, Sept. 21, 2006.

[34] Weiss, R. (2006). "Firm Blames Farmers, 'Act of God' for Rice Contamination," Washington Post, Nov. 22, 2006.

LL604, was found contaminating a popular variety of conventional rice sold to farmers as seed rice (Clearfield 131). APHIS responded by issuing several emergency action notifications to distributors of Clearfield 131 to halt sales of the contaminated seed rice.[35] As a result, rice farmers in the South experienced a severe shortage of seed rice for the 2007 season.[36] APHIS conducted an investigation into the contamination episodes, but was unable to determine precisely how they occurred.[37] Courts have subsequently found Bayer negligent in every bellwether case, with total damages estimated at a billion dollars.[38]

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, including *Beta vulgaris*. Many factors affect gene flow frequencies, including weather conditions (precipitation, wind, temperature, humidity), which will affect insect 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.[39] 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.[40]

The Court in *Sugar Beets I* found the above contamination incidents significant. "The Court finds it significant that there have been instances in which genetically engineered corn, cotton, soybean and rice have mixed with and contaminated the conventional crops."[41]

Enforcement

Despite efforts by APHIS to implement effective protocols and efforts by seed companies to minimize any contamination any contamination or cross-pollination, "there are examples of where such efforts were ineffective; either because the conditions were later determined to be insufficient or the conditions were not followed. In other instances, the causes of the contamination were never discovered. These incidents are too numerous for

[35] USDA APHIS (2007). "Statement by Dr. Ron DeHaven regarding APHIS hold on Clearfield CL131 long-grain rice seed," March 5, 2007. http://www.aphis.usda.gov/newsroom/content/2007/03/content/printable/gericeseed_statement.doc.
[36] Bennett, D. (2007). "Arkansas' emergency session on CL 131 rice," Delta Farm Press, March 1, 2007.
[37] USDA (2007). "Report of LibertyLink Rice Incidents," October 2007.
[38] *See, e.g.*, *In re Genetically Modified Rice Litigation*, 666 F.Supp.2d 1004 (E.D. Mo. Oct. 9, 2009); *In re Genetically Modified Rice Litigation*, 2009 WL 4801399 (E.D. Mo. Dec. 9, 2009).
[39] (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.
[40] MA Rieger et al., "Pollen-mediated movement of herbicide resistance between commercial canola fields," Science, 2002, vol. 296, p. 2386-2388.
[41] *See Sugar Beets I*, 2010 WL 964017, at *2.

this Court to declare confidently that these permits provide sufficient containment to protect the environment."[42]

This is not unusual for APHIS. APHIS is repeatedly unable to contain field trials, which represent the most restrictive level of oversight.[43]

Numerous government reports have strongly criticized APHIS' failures at GE crop permit oversight:

- GAO Report - November 2008[44]

The 2008 GAO recommended that, in light of known contamination episodes from GE crops that have caused significant economic damage, the USDA should "monitor[] for other unintended consequences, such as economic impacts on other agriculture sectors, such as organic crops, which may become contaminated by GE crops."[45]

The 2008 GAO Report documents six events of GE crops contaminating the food and feed supply, including:

- the 2000 StarLink Corn incident, causing $26 to $288 million in economic damages;
- the 2002 Prodigene Corn contamination incident where a GE corn designed to create a pig vaccine protein contaminated non-GE corn;
- the 2004 Syngenta Bt Corn incident where a pesticidal Bt corn determined not to suitable for commercialization was illegally released onto 37,000 acres;
- the 2006 Event 32 Corn incident where 72,000 acres were planted to 3 lines of corn contaminated with regulated GE pesticidal corn;
- and the 2006 Liberty Link Rice 601 and 604 incident where GE rice contaminated export rice stocks causing economic damages of over $1 billion.

Such contamination events are not isolated incidents, as many biotechnology proponents argue. Rather, as the GAO explained, "the ease with which genetic material from crops can be spread makes future releases likely."[46] "While the specific causes of unauthorized releases vary by incident, from cross-pollination of regulated and conventional crops to the mislabeling of bags of seeds, they highlight the challenges of containing regulated GE crops given the porous nature of biological systems and the potential for human error."[47]

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[42] *Sugar Beets II*, 2010 WL 4869117, at *3.
[43] Since USDA discontinues any oversight once a GE crop is deregulated, the field trial contaminations are among the only contaminations documented by the agency. This does not in any way imply they are the only contaminations that occur.
[44] *GENETICALLY ENGINEERED CROPS: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring, available at* http://www.gao.gov/new.items/d0960.pdf
[45] *Id.* at 48.
[46] *Id.* at 3.
[47] *Id.* at 14.

Consequently, GAO, in its 2008 GE crop report, recommended that APHIS address the unintended release of GE crops and coordinate strategies for post commercialization monitoring, including mandatory monitoring for evolution of resistant weeds by university or other independent agronomic experts, with continuing regulatory authority to mitigate risks if and as they arise.

- 2005 USDA Inspector General Report[48]

In 2005, the USDA's Office of the Inspector General (OIG) conducted an audit covering GE crop field trials conducted in 2002 and 2003, finding numerous basic deficiencies in APHIS oversight. A few of the more flagrant deficiencies are noted below:

1. In most cases, APHIS does not know where or even if many field tests have been planted. In 85% of the permits and 100% of notification field trials that OIG reviewed, only the company's business address, or the state and county of the field trial, was listed as the planting location.

2. APHIS does not require submission of written protocols, and thus does not review them, prior to issuing a notification permit. OIG notes that an APHIS report completed in 2001 concluded that some notification protocols might not be adequate to meet its field test performance standards and identified several major areas in need of improvement.

3. "APHIS did not maintain a list of planted GE fields." This recalls a similar deficiency in tracking permit information noted by a previous OIG report in 1994, suggesting that APHIS has not corrected this fundamental defect since that time, nearly a decade ago.

4. APHIS failed to conduct scheduled inspections of numerous field trials of both pharmaceutical-producing crops and other experimental GE crops grown under notification. Only 1 of 12 sites inspected by OIG in 2003 had all 5 required inspections; only 18 of the 55 required inspections were performed for the other 11 sites.

5. In two cases, the OIG inspectors discovered that a total of 2 tons of harvested pharmacrops had been stored onsite for over 1 year, without APHIS' knowledge, and thus without APHIS inspection of the storage facility, one of many "requirements" of pharmaceutical crop field trial permits.

"In general, the problem is that there are many routes whereby contamination may occur, including cross pollination between GE and non-GE fields, accidental mixing of seeds, contamination of seeds by farm equipment, and human error."

Finally, Congress also passed new law in the 2008 Farm Bill directly as a response to APHIS' repeated past failures at containment of GE crops. *See* The Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, Title X, § 10204, 122 Stat. 2105 (2008).

[48] Available at http://www.usda.gov/oig/webdocs/50601-08-TE.pdf.

APHIS has failed to implement these measures by the statutory deadline of 18-months or apply them to this proposal.[49]

If APHIS cannot prevent genetic contamination from a few acres subject to lengthy lists of restrictions, protocols, inspections, and reports, it cannot credibly claim it can contain an industry-wide commercial process with its countless risk points, particularly when it has yet to complete a NEPA document beyond an EA.

Further, the evidence presented at the *Sugar Beets II* evidentiary hearing made clear that, even with the existence of protocols purported to minimize any environmental harm, there is a significant risk that the plantings pursuant to the permits will cause environmental harm.

The *Sugar Beets II* court also noted contamination is likely, and not just from gene flow:

> Plaintiffs have further demonstrated a likelihood of harm stemming from the entire cycle of genetically engineered sugar beet plantings and production. If the stecklings are transplanted and replanted to produce seed, and the remainder of the planting and production cycle of genetically engineered sugar beets moves forward, the potential for contamination, including through cross-pollination merely increases. The evidence demonstrates that there are points of vulnerability where contamination is likely at every production stage. Even Intervenor-Defendants, despite their best efforts, have not been able to prevent contamination.

Sugar Beets II, Amended Order Granting Preliminary Injunction, *Center for Food Safety v. Vilsack*, No. C 10-04038, 2010 WL 4869117, at *3 (N.D. Cal. Dec. 1, 2010).

The documented record of repeated, unexpected gene flow undercuts APHIS's assurances that they know what isolation distance will be effective, or how to prevent seed mixing. Moreover, the evidence shows that human error is often a factor in contamination events.[50] Protocols—whether government mandated or voluntary industry guidelines—are of no value when they are not followed, intentionally or otherwise.

Stewardship techniques and pinning guidelines—which seed companies tout and APHIS espouses as proposed "protective measures"—have repeatedly proven to be ineffective. Harm resulting from contamination is "likely" because APHIS doesn't have resources to adequately monitor compliance with permit conditions over such a broad geographic span.

[49] *See infra* Section VI.
[50] *Sugar Beets II*, Evidentiary Hearing, 11/3/2010 Tr., 321:23-25; 322:1-25; 323:1-24 (N.D. Cal. 2010).

Uncertainty

Uncertainty is one of the factors that CEQ enumerates for purposes of requiring an EIS.[51] APHIS' proposal is unprecedented. Never before has the agency permitted interim planting and commercial use before deregulation, for any GE crop. Faced with the Court's decision to make RRSB once again illegal, the agency is making it up as it goes along in order to keep commercialization going for the industry. This unprecedented proposal comes along with the following backdrop of broader unanalyzed unknowns: GE crops are still a relatively novel and new concept, a 17-year old experiment. The agency has never completed an EIS for *any* GE crop. The agency has never implemented a partial deregulation for any GE crop. Nor has the agency completed the programmatic EIS for its proposed regulatory amendments to its GE crops regulations under the Plant Protection Act. Nor has the agency ever consulted with a sister agency on the impacts of a GE crop under the Endangered Species Act. Nor has the agency implemented the Congressional mandates of the 2008 Farm Bill that it overhaul its permitting oversight. Hence, the agency's current proposal is rife with uncertainty. An EIS is required.

Contamination is a Significant Impact

Despite documented incidents of *Beta vulgaris* contamination, APHIS nevertheless concludes that commercializing RRSB will not have significant impact on the human environment. Yet there is ample evidence that contamination is a significant impact. Therefore, this conclusion is contrary to NEPA.

As the *Sugar Beets I* court noted when granting summary judgment on the NEPA claims: *"*In light of the large distances pollen can travel by wind and the context that seed for sugar beets, Swiss chard, and table beets are primarily grown in one valley in Oregon, Plaintiffs have demonstrated that deregulation may significantly effect the environment."[52] During the remedies phase of the litigation in *Sugar Beets I*, discovery uncovered frequent incidents of contamination in sugar beet crops and other *Beta vulgaris* crops.[53] APHIS once again dismisses this contamination as not significant, even though it is clear that this contamination can have a significant impact on both humans and the environment.

In the draft EA, APHIS attempts to justify the impacts of contamination. APHIS admits that gene flow in sugar beets occurs at distances as great as 6 miles, but dismisses the potential impacts as irrelevant. APHIS further attempts to diminish the likely significant harm from gene flow by relying on certain commercial seed growing practices to minimize, although not eliminate, the effects.[54] APHIS states that increasing isolation distances would help protect farmers from contamination but would "substantially reduce

[51] 40 CFR § 1508.27(5) (Intensity. This refers to the severity of impact. Responsible officials must bear in mind that more than one agency may make decisions about partial aspects of a major action. The following should be considered in evaluating intensity: ... (5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.").
[52] *Sugar Beets I*, 2010 WL 3047227, at *9 (N.D. Cal. 2009).
[53] *See Sugar Beets I*, Pls' Opp'n and Reply in Supp. of Mot. for Perm. Relief (filed under seal).
[54] EA at 157.

the number of *Beta* seed growers" in the Willamette Valley, indicating that APHIS's goal is not protecting farmers from contamination but instead "maximizing the number of growers in the valley."[55]

As history indicates, contamination in *Beta* crops will cost farmers their right to sow the crops of their choice and consumers the right to feed their families non-GE food. The *Sugar Beets I* court expressly found that this was cognizable harm pursuant to NEPA in his underlying order. "[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," and that "[a]n action which potentially eliminates or … greatly reduces the availability of a particular plant ... has a significant effect on the human environment."[56]

Due to the likelihood of significant environmental impact, APHIS cannot approve this draft EA and permitting scheme while it prepares an EIS on the deregulation of RRSB. CEQ's regulations are clear: "[u]ntil an agency issues a record of decision as provided in Sec. 1505.2 [], no action concerning the proposal shall be taken which would have an adverse environmental impact."[57] APHIS has just begun the EIS on RRBS. Compliance with CEQ's regulations, which are binding on all agencies, requires that no action concerning the deregulation of RRSB should be taken if it would have an adverse environmental impact.

In order to justify continued commercialization during the preparation of the EIS, APHIS has hastily prepared an EA in lip service to that foregone conclusion, finding that commercialization of RRSB will not have a significant impact on the environment. The draft EA is rife with indications that permitting the commercialization under the proposed scheme "may affect" the quality of the environment and hence require an EIS. APHIS admits:

- Sugar beets will occasionally bolt (produce a seed stalk that may untimely flower) in their first year of production;[58]
- It is possible that in the coexistence area, H7-1 sugar beet will pollinate conventional sugar beet, Swiss Chard or table beet;[59]
- USDA is aware of studies that show that beet pollination can occur over distances as great as 6 miles;[60]
- Cross pollination could potentially result in adventitious (inadvertent) presence of genetic material from the crop in one field into a nearby crop's field;[61]
- Sugar beet seed plants are prone to shattering during seed harvest;[62]
- Negligible pollen movement is expected into conventional sugar beet lines;[63]

[55] EA at 158.
[56] *Sugar Beets I*, 2010 WL 3047227, at *9 (N.D. Cal. 2009).
[57] 40 C.F.R. § 1506.1
[58] EA at 54.
[59] EA at 61.
[60] EA at 157.
[61] EA at 153.
[62] EA at 95.
[63] EA at 152.

- From 2003 – 2007, there were 102 incidents of non-compliance with issued permits;[64]
- Bolters from a sugar beet field may flower at the same time as bolters from a vegetable seed field;[65]
- In the U.S., there are 10 weed species with glyphosate-resistant biotypes and 6% of the total population of herbicide tolerant crops contains some glyphosate-resistant weeds.[66]

Further, the EA does not take into consideration the potential contamination risks from unknown breeder plots, unpinned plots, and non-commercial plots. APHIS hangs its hat on proposed restrictions, many of which were rejected by the court in *Sugar Beets I*, to mitigate these risks, but this does not negate the potential for adverse environmental impact that may occur.

It is also well established that "[a]n EIS must be prepared if substantial questions are raised as to whether a project ... may cause significant degradation of some human environmental factor."[67] In other words, if a project, in this case permitting RRBS commercialization, "may affect" the environment, the EIS is required. The draft EA exemplifies the need for an EIS by disregarding the risks of biological contamination from cross pollination, seed mixing, weather events, or human error, the threat of glyphosate resistant weeds, and the harm to the public by reducing or eliminating a farmers choice to grow his or her crop of choice and the public's right to choose organic and non-GE crops.[68] The Supreme Court posited that an interim measure such as the proposal could well require its own EIS.[69]

Finally, APHIS claims that successful confinement during this commercial permitting will be evidence for the suitability of RRSB to once again obtain deregulated status.[70] However, under NEPA, APHIS must conduct controlled environmental impact studies, not test drive the agency decision on the human environment or use interim measures as an experiment to find support for an EIS on deregulation. Interim action cannot be used as a litmus test for deregulation. Independent studies must be conducted determining whether RRSB commercialization, in whole or in part, may affect the environment.

Due to the strong likelihood of contamination and significant other harms to the environment and the public (including but not limited to harms from weed resistance,

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[64] EA at 151.
[65] EA at 161.
[66] EA at 93.
[67] *Sugar Beets I*, 2010 WL 3047227, at *5.
[68] *See* EA at 20-23.
[69] *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2758 n.5 (2010) ("We do not express any view on the Government's contention that a limited deregulation of the kind embodied in its proposed judgment would not require the prior preparation of an EIS. . . . Because APHIS has not yet invoked the procedures necessary to attempt a limited deregulation, any judicial consideration of such issues is not warranted at this time."); *id.* at 2761 ("If APHIS may partially deregulate RRA before preparing a full-blown EIS – a question that we need not and do not decide here …").
[70] EA at 24.

plant disease, increased glyphosate load on the environment, and loss of consumer and farmer choice, all detailed in comments submitted separately by CFS and others), the proposed commercialization of RRSB in the draft EA is arbitrary and capricious. APHIS must either wait for the court ordered EIS from *Sugar Beets I* analyzing these issues, or at a minimum conduct an independent EIS on this project.

APHIS failed to analyze other commercial RRSB permits

The draft EA is deficient because APHIS failed to include analysis of the entire RRSB commercialization cycle, as required by NEPA. Among other lapses, the EA omits any analysis of the permits granted in September, 2010 to allow steckling production of RRSB and begin (unlawfully) that production. The draft EA is based on future production of RRSB and pretends that process has not yet begun. It does not take into consideration the commercial permits granted in September, 2010 for RRSB steckling production.[71]

II. Commercialization Will Cause Significant Interrelated Economics Impacts.

NEPA requires that economic effects are relevant and must be examined "when they are interrelated with natural or physical environmental effects."[72] APHIS concludes that the commercialization will only have significant impacts on sugar beet seed companies, growers, and processors, but does not adequately examine the potential economic impacts on organic and non-GE farmers. Contamination of non-GE and organic *Beta* crops will in fact cause significant economic harm to organic and non-GE farmers that must be addressed under NEPA. Failure to acknowledge this economic harm, and subsequently focus only on harm to the GE producer, and failure to find this harm as a significant impact is arbitrary, capricious, and an abuse of discretion.

Moreover, "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.'"[73] Another NEPA goal is to "maintain, whenever possible, an environment which supports diversity and variety of individual choice."[74] Accordingly, as the courts have held, "[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."

APHIS's claim that there will be no impacts on organic farmers or organic consumers because the presence of a transgenic contamination does not constitute a violation of the National Organic Standards, is equally arbitrary and capricious.[75] Genetic engineering is prohibited under the Organic Foods Production Act (OFPA). The standard prohibits any

[71] *Center for Food Safety v. Vilsack*, No. C 10-04038, 2010 WL 4869117, at *8 (N.D. Cal. Dec. 1, 2010)
[72] *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 944 (9th Cir. 2005) (quoting 40 C.F.R. §1508.14).
[73] *Id*. (emphasis in original) (quoting 42 U.S.C. § 4331(b)(3)).
[74] *Geertson Seed Farms v. Johanns*, 2007 WL 518624, at *8 (N.D.Cal. 2007).(quoting 42 U.S.CC. § 4331(b)(4)).
[75] *See* EA at 119–120.

inputs from excluded methods such as genetic engineering; thus any contaminated seeds that are used to grow organic crops violate the standard. There is no tolerance for transgenic contamination in OFPA standard or implementing regulations. Further during the implementation of OFPA, the Department of Agriculture 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.[76]

Further, the organic market place will not permit transgenic contamination. For organic consumers, organic requires products be free of any GE contamination. Organic farmers and businesses that are contaminated risk market rejection, lost business and reputation. The *Geertson* court found:

> [E]ven APHIS is uncertain whether farmers can still label their products organic under the federal government's organic standards. Second, many farmers and consumers have higher standards than what the federal government currently permits; to these farmers and consumers organic means not genetically engineered, even if the farmer did not intend for his crop to be so engineered. . . . Third, and most importantly, APHIS's comment simply ignores that these farmers do not want to grow . . . genetically engineered alfalfa, regardless of how such alfalfa can be marketed.[77]

The draft EA's conclusion here is inadequate, as in *Geertson*: "APHIS reasoning that farmers will 'not necessarily' be prohibited from labeling their products as organic is wholly inadequate."[78]

The EA takes pains to present evidence that catastrophic economic consequences will result if sugar beet seed companies are not allowed to produce RRSB seed this growing season. According to the EA, the unavailability of RRSB seeds will cause sugar production to decrease by 37%, effectively forcing the permanent shutdown of 8 of the 22 sugar processors in the United States. However, this portion of the EA relies entirely on one person's analysis: Dr. Sexton. Dr. Sexton's analysis in *Sugar Beets II* was disavowed by the court: "Dr. Sexton [did not] evaluate what impact existing inventories of conventional or genetically engineered sugar beet seed held by the seed producers would have on his analysis and conclusions. Therefore, the Court finds Dr. Sexton's

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[76] 65 Fed. Reg. 13534-35 (Mar. 13, 2000) (emphasis added). Like in this record where over 200,000 members of the public expressed concern that release of GE alfalfa will contaminate organic alfalfa, during the rule-making for organic 275,000 members of the public expressed concern that GE be prohibited in organic production.)

[77] 2007 WL 518624 at *7.

[78] *Id*. at *7.

conclusions regarding the extent of economic harm to be greatly exaggerated."[79] Hence, a federal court has found Dr. Sexton's testimony unreliable. To the extent the EA relies on it, the EA is arbitrary and capricious.

APHIS did not consult an independent expert in agricultural economics; rather, it consulted Dr. Sexton, who had been hired by sugar beet seed companies to testify on their behalf in the litigation. Moreover, APHIS's EA seems to rely heavily on this dire prediction when explaining its preference for Alternative 2. One hired gun's doomsday scenario is an inadequate basis for foreclosing the "no action" alternative.

The EA also fails to factor in the prohibitive cost for non-GE farmers of detecting contamination through routine testing, even though it counts seed companies' "compliance costs" as among the socio-economic impacts of Alternative 2. Moreover, the EA proposes only one method of testing for contamination that does not rely on extrapolating from a representative sample, and that one method would require that the conventional or organic farmer purchase Roundup.[80] (The farmer would spray Roundup on one leaf of each plant, and any leaves not shriveled up would belong to a contaminated plant.)

Testing for GE traits is expensive, especially for small farmers. According to the foremost expert on genetic testing, testing a nursery plot of 500 plants would cost $12,500.[81] This does not include the significant costs associated with sampling those 500 plants, maintaining traceability of all 500 samples back to the individual plants in the field, and conducting confirmatory testing of putative positives. Even if a compositing strategy could be carried out for the nursery plot, the costs would be reduced by only 50% or at most 75% except in cases where every plant in the plot turns out to be GE-free. If testing is done in duplicate, as is prudent, costs would be doubled. In any case, costs are not trivial and must be analyzed.

The Court in *Sugar Beets I* found the industry's claims of harm without merit and outweighed by the risk to the environment of continued planting under the exact same measures APHIS proposes here.[82] And in *Sugar Beets II* the Court again strongly disfavored APHIS and industry claims of economic harm: "Finally, to the extent the Court considers the assertions of likely economic harm made by Defendants and Intervenor-Defendants, the Court finds that these anticipated losses do not outweigh the potential irreparable damage to the environment established by Plaintiffs."[83] To the extent the EA relies on these harms as justification or gives them weight, in contravention of Court decisions, the agency's decision is arbitrary and capricious.

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[79] *Sugar Beets II*, 2010 WL 4869117, at *7 (N.D. Cal. Dec. 1, 2010).
[80] EA at 159.
[81] *Sugar Beets I*, Fagan Decl. at ¶ 9 (June 4, 2010).
[82] *Sugar Beets I*, Summary Judgment Order, Center for Food Safety v. Vilsack, 2009 WL 3047227, at *7-9 (N.D. Cal. Sept. 21, 2009).
[83] *Sugar Beets II*, Amended Order Granting Preliminary Injunction, *Center for Food Safety v. Vilsack*, No. C 10-04038, 2010 WL 4869117, at *11 (N.D. Cal. Dec. 1, 2010

III. Commercialization Will Cause Significant Impacts on the Public

The biological contamination caused by commercial-scale production of RRSB will have concomitant significant impacts on the public. These impacts include compromised freedom of choice for farmers to grow organic or non-GMO crop varieties, as well as compromised freedom of choice for consumers who wish to avoid genetically engineered foods. The court in *Sugar Beets I* has already determined that these are impacts that significantly affect the human environment.[84]

Non-GMO and Organic Farming

Biological contamination by RRSB compromises farmers' freedom to grow what they choose by increasing the risk of market rejection and making the cost of keeping GE elements off their fields prohibitively expensive. There is a significant—and by some counts, growing—contingent of U.S. farmers who refuse to grow GE crops, including farmers of *Beta vulgaris* varieties.[85] These farmers go to great lengths to ensure that they can certify to their GE-conscious buyers that their harvest contains no GE material.[86] If they are unable to make such a guarantee, their crop faces market rejection, including from important export markets.[87] Unfortunately, the constant threat of RRSB material coming into contact with these farmers' fields means they are forced to either succumb to pressure to grow GE varieties, or to put costly protective measures in place. These measures include frequent testing of their fields and, in the event of contamination, even more costly eradication.[88] Many farmers find that these costs make non-GE farming unprofitable, effectively eliminating their choice to grow non-GE.[89] The fact that some non-GE growers cannot choose to grow non-GE crops because they are forced to bear the costly externalities of other farmers' GE production represents a significant impact on the public.

These same impacts are only amplified in the case of organic farmers. For organic farmers, maintaining certification and consumer confidence requires meeting an even more demanding standard. Moreover, maintaining organic certification is crucial to having any profitable market for their crop at all. Without organic certification and consumers' confidence that the final product contains no GE material, organic farmers face market rejection. Additionally, one of the consequences of failing to meet the organic standard is lost certification for multiple growing seasons.[90] Thus, contamination

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[84] *Sugar Beets I*, 2009 WL 3047227, at *9.
[85] *Sugar Beets I*, Morton ¶ 15, Tipping ¶ 10.
[86] *Sugar Beets I*, Morton ¶ 15, Tipping ¶ 10.
[87] *Sugar Beets I*, Decls. of Lively ¶ 19, Behar ¶¶ 15-16, Siemons ¶¶ 27-30, Funk ¶¶ 17-18, Potter ¶ 10, Hammond ¶ 17, Squire ¶ 16, and Falck ¶ 9.
[88] *Sugar Beets I*, Decls. of Thompson at ¶¶ 9, 13-14, Lively at ¶¶ 14-15, Siemon; ¶¶ 16-20, Clarkson at ¶ 19, Morton ¶ 15, Potter ¶¶ 8-9, Falck ¶ 7, Funk ¶¶ 13-14, Hammond ¶¶ 12-13, Blue ¶ 21, and Fagan ¶¶ 4-15.
[89] *Sugar Beets I*, Morton ¶ 15, Tipping ¶ 10.
[90] *See, e.g.*, 7 CFR § 205.202 ("Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as 'organic,' must: . . . Have had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop . . .").

by commercial-scale RRSB also threatens organic farmers' ability to choose and maintain control over what they grow in their fields.

Consumers

USDA claims that there is no difference between GE and non-GE derived sugar. But consumers choose non-GE for a variety of reasons, such as the environmental harm from GE crops and production systems and the economic harm to non-GE farmers. Biological contamination compromises consumer choice by effectively forcing GE foods like GE table beets and GE Swiss chard on consumers who do not want them. When GE crops contaminate non-GE fields, it reduces the number of growers who can certify that their crop is non-GE or organic. This effect has consequences all the way down the supply chain, resulting in less variety for consumers at the point of purchase. As noted *supra*, compromised consumer choice in this case is recognized as a significant impact on the human environment. USDA must fully analyze this impact in an EIS.

IV. APHIS's Alternatives Analysis Is Inadequate.

The draft EA's Alternatives Section is legally deficient. "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."[91]

The consideration of alternatives furthers NEPA's 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."[92] An alternatives analysis must foster both informed decision making and informed public participation.[93] 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.[94] Informed and meaningful consideration of alternatives is thus an integral part of the statutory scheme.[95]

APHIS lists three alternatives in the EA: (1) deny the petition request for partial deregulation; (2) allow RRSB production under 7 C.F.R. 340 (APHIS's field trial provisions); and, (3) partial deregulation of RRSB with Monsanto and KWS overseeing implementation and monitoring of cultivation conditions.

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[91] 40 C.F.R. § 1508.9; *Center for Biological Diversity v. National Highway Traffic Safety Admin*., 538 F.3d 1172, 1217-18 (9th Cir. 2008).
[92] *Calvert Cliffs' Coordinating Committee, Inc. v. United States Atomic Energy Commission*, 449 F.2d 1109, 1114 (D.C. Cir.1971).
[93] *Westlands Water District v. U.S. Dept. of Interior*, 376 F.3d 853, 872 (9th Cir. 2004).
[94] *Id.*
[95] *See Bob Marshall Alliance v. Hodel*, 852 F.2d 1223, 1228 (9th Cir. 1988).

APHIS's preferred alternative is alternative 2. Under this alternative, RRSB would be grown subject to permit conditions under 7 CFR Part 340 "consistent with conditions proposed to the Court."[96] Planting would require the grower to obtain a permit, whereas importation and interstate movement would only require notification and meeting performance standards set by APHIS.

Growers need to obtain permits prior to the production of any of the following: non-flowering stecklings, seeds (whether from flowering stecklings or directly from basic seed), and sugar beet root. The information required on the permit would be the same information that APHIS required of the four sugar beet seed companies who obtained permits in September of this year. These requirements are also listed in 7 CFR Part 340.4. The draft EA states that CBI-redacted versions of all permits would be available on its FOIA reading room website.

APHIS would keep confidential the exact locations and size of permitted fields. Non-GE growers need to call a hotline in order to get the "approximate distances from the nearest male-fertile event H7-1 seed crop." With this restriction, APHIS is once again placing the burden on non-GE growers to preserve the integrity of their crop from GE contamination.

As a condition of receiving the permits, processors would be required to amend their contracts with growers to require growers to adopt confinement measures described in the APHIS permits. Third party auditors trained by APHIS would conduct inspections and audits of permitted fields in order to ensure compliance with permit conditions. These third parties would then submit reports to APHIS. According to the EA, APHIS would "carefully examine a *representative sample* of cooperative/processor records to ensure compliance with the Agency's permit conditions."

Other conditions imposed by the permits include:

- 4-mile isolation distances between male RRSB plants and all other *Beta* seed crops.
- During flowering, fields must be scouted for male sterile RRSB plants producing pollen, and any such plants must be destroyed.
- As before, all non-GE *Beta* material must, at all stages of production, be kept separate from RRSB. Likewise, equipment that might be used for other *Beta* cultivation cannot be used for RRSB production in the same growing year.
- Sexually compatible *Beta* varieties cannot be planted in the same field in the same growing year.
- Measures to force same-year sprouting of volunteers are required, and any volunteers that sprout must be destroyed.
- Root crop fields must be surveyed to identify and eliminate bolters before they produce pollen or seed. Additionally, applicants must randomly select a representative sample of their fields and inspect for bolters. If any are found, APHIS must be notified.

[96] EA at 25–26.

As discussed *supra*, these measures will not be enough to contain contamination. USDA's past experience with contamination incidents, again as discussed *supra*, provides ample evidence that USDA and the public cannot count on permittees' compliance with APHIS-imposed conditions to prevent the inadvertent spread of GE crops. USDA cannot control how vigilant growers will be, nor does it have the resources to effectively monitor compliance. What APHIS is proposing is completely unprecedented. Moreover, human error has been a consistent factor in past contamination incidents, demonstrating that USDA cannot prevent biological contamination simply by mandating conditions for permits. NEPA does not permit USDA to paper over these faults with alternative 2.

Further, alternative 2 and 3 are essentially identical, the only difference being the entity in charge of enforcement (APHIS or Monsanto). The identical nature of the two alternatives is underscored by the fact that both alternatives present the same analysis of impacts on the environment. In fact, there are numerous places in the EA where the impacts from alternatives 2 and 3 are listed as identical, including but not limited to:

- The possibility of gene flow from RRSB root crop and commingling of the two varieties;[97]
- gene flow from RRSB seed production to vegetable production Beta seed crops;[98]
- possibility of gene flow from a sugar beet field to a root crop field;[99]
- Impacts of weed management in sugar beet root production and sugar beet root production;[100]
- Impacts relating to volunteer beet control;[101]
- Impacts relating to surveying and removing bolters from root production fields;[102]
- Conditions for root production the same as for seed production.[103]

Accordingly the EA's alternatives analysis effectively includes the same alternative twice, making it arbitrary and capricious. An EIS is required.

Here APHIS should choose the "no action" alternative in light of all the potential impacts of its proposal. That said, APHIS's interpretation of partial deregulation in alternative 3 and elsewhere is incorrect and makes its alternatives analysis arbitrary and capricious. The EA claims that once it deregulates in part, as alternative 3 posits, APHIS no longer has authority and therefore the seed companies would have to install and oversee any control and containment measures. This is an erroneous interpretation of the agency's PPA authority of GE crops. APHIS's determination in the EA of the scope of its "in part" deregulation authority is arbitrary and capricious.[104] APHIS claims that only the industry can set any limits of a partial deregulation, but nothing in the Plant Protection Act or its implementing regulations so constricts APHIS's authority to only that type of

[97] EA at 155.
[98] EA at 86.
[99] EA at 161.
[100] EA at 167.
[101] EA at 181.
[102] EA at 182.
[103] EA at 183.
[104] 7 C.F.R. § 340.6(d)(3)(i).

application of a partial deregulation. Agencies cannot define the project so narrowly that it foreclosed a reasonable consideration of alternatives;"[105] they "cannot define its purpose and need so as to winnow down the alternatives until only the desired one survives."[106] "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.'[107] 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 so limited that only industry can "regulate" a partial deregulation.

On the contrary, APHIS has the PPA authorityto require continuing limitations on growers after partial deregulation. APHIS has broad authority under both the Plant Pest and Noxious Weed provisions of the PPA to control GE crops, including post-deregulation. In addition to being contrary to the PPA, APHIS' cramped view of its partial deregulation authority is contrary to the Supreme Court's decision in *Monsanto*, which indisputably viewed the agency has having considerable post-deregulation authority.[108]

Additionally, the 2002 Study by the National Academy of Sciences also recommended post-commercialization monitoring:

> [S]hort-term experiments and general characterization of plant traits may not pickup all environmental effects of transgenic crop plants. It is therefore important to conduct postcommercialization testing to determine if the precommercialization testing proto-cols adequately assessed risks (i.e., validation of precommercialization decisions). It also is important to set up long-term, postcommercialization monitoring programs to record trends in predicted effects, and to detect effects that were not predicted by precommercialization testing . . .Postcommercialization testing or validation programs are an essential part of any quality control program.[109]

Relatedly, APHIS rejected four other possible alternatives out of hand, again mostly due to its inaccurate view of its partial deregulation authority. Accordingly the Alternatives analysis, based on this erroneous interpretation, is arbitrary and capricious and requires an EIS.

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[105] *Davis*, 302 F.3d at 1119; *Klamath-Siskiyou Wildlands Center v. U.S. Forest Service*, 373 F. Supp. 2d 1069 (E.D. Cal. 2004)
[106] *Klamath-Siskiyou Wildlands Center v. U.S. Forest Service*, 373 F. Supp. 2d 1069 (E.D. Cal. 2004).
[107] *Center for Biological Diversity v. National Highway Traffic Safety Admin*, 538 F.3d 1172, 1213 - 1214 (9th Cir. 2008).
[108] *See, e.g., Monsanto*, 130 S.Ct. at 2760 (detailing potential partial deregulations with accompanying administrative orders "mandating" isolations distances and an an "agency plan" to "police vigorously" compliance with such order).
[109] 2002 NAS Report at 192.

V. The Draft EA's Analysis Of Cumulative Impacts Is Inadequate.

The potential cumulative impacts associated with RRSB must be disclosed and analyzed in an EIS. NEPA requires an agency to consider possible cumulative impacts of deregulating a regulated article.[110]

"A cumulative impact is defined as 'the impact on the environment which results from the incremental impact of the section 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."[111]

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."[112] NEPA requires agencies to consider the cumulative impacts of proposed actions.[113] Specifically, an EA must provide a quantified assessment of a project's environmental impacts when combined with other projects.[114] The EA cannot simply discuss the direct effect of the project and conclude that there are no cumulative impacts.[115] Instead, cumulative impacts must be evaluated along with the direct and indirect effects of a project and its alternatives.

The D.C. Circuit's analysis in *Grand Canyon Trust v. FAA* is instructive. In that case, the FAA based its FONSI for a replacement airport on, *inter alia*, its determination that the incremental difference in noise levels between the existing airport and the proposed airport was "negligible."[116] The court determined that the FAA's EA and FONSI determination violated NEPA because they did not include any assessment of the total noise impact from the replacement airport. The court explained:

> "[A] meaningful cumulative impact analysis 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."
> . . .

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[110] 40 C.F.R. § 1508.27(b)(7). *Oregon Natural Resources Council v. U.S. Bureau of Land Management*, 470 F.3d 818, 822 (9th Cir. 2006*); Geertson Seed Farms v. Johanns*, 2007 WL 518624, *10 (N.D.Cal. 2007).
[111] *Id*.
[112] *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…")
[113] 40 C.F.R. § 1508.27(b)(7).
[114] *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 972 (9th Cir. 2006).
[115] *Id.*
[116] *Grand Canyon Trust v. FAA*, 290 F.3d 339, 340 (D.C. Cir. 2002).

> "The analysis in the EA, in other words, cannot treat the identified environmental concern in a vacuum, as an incremental approach attempts."[117]

Thus, the agency is required to assess both the incremental impacts from the proposed project *and* the total impacts when combined with existing conditions.

The cumulative impacts analysis in APHIS' draft EA is lacking in that it limits its analysis to two topics: glyphosate-tolerant weeds and impacts related to changes in tillage and herbicide usage. The cumulative impacts analysis does not address stacking or seed market concentration, and underestimates the impacts that the increase glyphosate-tolerant crop systems will have on global climate change. Moreover, the EA lacks any assessment whatsoever of whether there will be cumulative impacts from commercial permits already issued.

Stacking

While RRSB is currently the only existing GE sugar beet, it is possible that in the future, additional lines of GE sugar beet will be created with traits that can be "stacked." Stacking of GE crops may create significant environmental impacts that have not before been analyzed anywhere, such as "super-glyphosate tolerance." For instance, in other GT crops, GE crop producers intend on stacking up to three mechanisms of glyphosate-tolerance in a single plant. This will allow more frequent applications of higher doses of glyphosate, perhaps over the entire growing season of the crop. Such super-tolerance will enable vastly increased use of glyphosate (over already exorbitant and growing levels) in an attempt to keep up with the rapidly growing level of glyphosate-resistance found in various weed species. The end result is a vicious circle of rising glyphosate use to control resistant weeds, followed by increased weed resistance, which in turns drives still more chemical use. New GT crop varieties have also begun to stack glyphosate-resistance with resistance to older, more toxic pesticides like 2,4-D, demonstrating that the proliferation of glyphosate-resistant weeds is driving the creation of new stacked crops, which will in turn drive the return to the use of more toxic herbicides. While Monsanto has yet to propose such stacking in sugar beets, it is a potential future impact that APHIS must address in an EIS.

Seed Market Concentration

The draft EA does not discuss seed market concentration. Yet, research and development suffer from seed market concentration. Seed companies have aggressively undermined independent researchers' ability to fully investigate their patented crops' performance.[118] Seed companies often want the right to approve all publications, which researchers find unreasonable. This chills research on GE crops.

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[117] *Id.* at 345-346 (internal citations omitted).

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

The privatization and concentration of the worlds seed supply is a serious and continuously evolving problem, compounded with each new GE crop deregulation. "It is estimated that the top ten seed corporations around the globe hold 49-51% of the commercial seed market, and the top ten agro-chemicals control 84% of the agrochemicals market. Likewise, all genetically modified (GM) seeds are bio-patented by multinational corporations and 13 commercial corporations own 80% of the GM food market." [119] As the practical options become limited to varieties patented by Monsanto and the major seed companies, there are effects on the price of seed, and in this case, the price of sugar beets, the price of sugar, and the cost of groceries.

The Department of Justice has noticed the effects. In August of 2009, it announced that it will investigate anticompetitive conduct in the seed industry, the recent ability to patent seed having led to unprecedented seed industry concentration.[120] Major seed companies set out to acquire ownership of, or control over, smaller firms, leading to the number of corn seed producers, for example, dropping from over 300 to merely a handful of large firms able to muster the capital for genetic manipulation through laboratory operations. It has been estimated that Monsanto can exercise influence in pricing and vending practices for over 90 percent of the germplasm of corn and soybeans, even though the market share is in the 30 to 40 percent range for these two major crops. The commercialization of RRSB further exacerbates Monsanto's influence over seed process and market consolidation. The general public is adversely affected, as increased seed prices are reflected in the cost of food. Concentration of the seed industry "affects virtually every farmer in the country and in a very vital way," and has drawn large crowds at unprecedented hearings scheduled by the antitrust division of the Department of Justice and USDA this year.[121]

For these and other reasons, the EA does not adequately address the cumulative impact of seed market concentration. The seed market concentration impacts of a deregulation of RRSB constitute a significant cumulative impact.

Global Warming

APHIS' discussion on the cumulative impact of glyphosate-tolerant crop systems on global warming relies on unsupported presumptions. First, APHIS inaccurately bases its conclusion that glyphosate use will not increase on the fact that glyphosate is currently being used. Additionally, APHIS assumes that farmers and producers will follow label restrictions for glyphosate use and that this adherence to application guidelines will somehow protect fish populations from the toxic effects of herbicides in snowmelt.

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

[120] *Sugar Beets I*, Harl Decl. ¶ 5.

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

Conservation Tillage

The draft EA also touts conservation tillage as a cure to soil erosion and air pollution.[122] However, APHIS should have consulted USDA researchers, who examined this very question of tillage practices with glyphosate-tolerant soybeans.[123] First of all, USDA data show that the dramatic increase in conservation tillage for soybeans (from 25 to 60% of U.S. soy acres) occurred from 1990-1996.[124] Monsanto's HT soybeans were first introduced in 1996, and so could not have had anything to do with this dramatic shift to conservation tillage, except perhaps in 1996, when roughly 10% of soybean acres were planted to glyphosate tolerant varieties. In the following three years, from 1997 to 1999, as glyphosate-tolerant soybean adoption increased from 17% to 56%, the acreage under conservation tillage actually decreased a bit, further undermining the supposed "conservation-tillage-promoting" effect of HT soybeans.[125]

Data on soybean varieties and tillage systems was analyzed for 1997. Although USDA determined that "[a] larger portion of the acreage planted with herbicide-tolerant soybeans was under conservation tillage than was acreage growing conventional\ soybeans" in 1997,[126] did the adoption of HT soybeans cause this difference? Determining causality requires more sophisticated statistical methods, because "[d]espite the relationship between conservation tillage and adoption of herbicide-tolerant crops, cause and effect is uncertain. Availability of the herbicide-tolerant technology may boost conservation tillage, while use of conservation tillage may predispose farmers to adopt herbicide-tolerant seeds." In order to understand causality, an econometric model was used to look at both decisions together.

At least for soybeans in 1997, growing an HT variety did not predispose farmers to adopt no-till methods. "The most interesting result in the simultaneous model was the interactive effects of the no-till and herbicide- tolerant seed variables. Farmers using no-till were found to have a higher probability of adopting herbicide-tolerant seed, but using herbicide-tolerant seed did not significantly affect no-till adoption. The result seems to suggest that farmers already using no-till found herbicide-tolerant seeds to be an effective weed control mechanism that could be easily incorporated into their weed management systems. Alternatively, the commercialization of herbicide-tolerant soybeans did not seem to encourage the adoption of no-till, at least at the time of the survey in 1997."[127]

Past Commercial Permits

APHIS' draft EA also violates NEPA because it fails to account for the cumulative impacts of its proposed commercial permitting scheme in light of commercial permits

[122] EA at 132-33.
[123] Fernandez-Cornejo, J. and W.D. McBride (2002). "Adoption of Bioengineered Crops," U.S. Dept. of Agriculture, Economic Research Service, Agricultural Economic Report No. 810, May 2002. http://www.ers.usda.gov/publications/aer810/aer810.pdf.
[124] *Id*. at Figure 11.
[125] *Id*. at Figure 11.
[126] *Id*. at 29
[127] *Id*. at 59.

already issued. As discussed *supra*, NEPA requires a cumulative impacts analysis in which the agency considers the environmental impact that "results from the incremental impact of the action when added to other *past*, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions."[128] APHIS has already issued, *inter alia*, four permits for commercial production of RRSB. Thus, in order to comply with NEPA, APHIS is required to assess what cumulative effect, its proposed commercial permit scheme will have when combined with the environmental impacts of the four commercial permits already issued. However, APHIS' draft EA makes no mention of the cumulative impact of the four commercial permits already issued combined with the proposed commercial permitting scheme. APHIS' failure to include this analysis in its final EA would be a violation of NEPA and is arbitrary, capricious, and contrary to law.

Glyphosate-Resistant Weeds

The EA's analysis rejects any significant relationship between Roundup Ready crops and the emergence of glyphosate-resistant weeds. It claims that weed resistance is a problem no matter which herbicide a farmer uses, and that other things being equal, glyphosate is less harmful for the environment than the six or so herbicides that farmers would otherwise need to combine to protect conventional crops. The draft EA does not recognize, much less refute, the prevalent evidence that farmers growing Roundup Ready crops tend to over-apply Roundup, which over time has led to the more rapid development of glyphosate-resistant weeds (or "super weeds"). This omission from the EA is even more appalling given that APHIS officials were recently called to testify before Congress about the development of super weeds.[129]

The EA incorrectly assumes that because farmers are contractually obligated to observe label restrictions and apply no more glyphosate to their crops than Monsanto's Technical Use Guide (TUG) allows, these farmers never over-apply. The EA also states that because farmers are required to grow RRSB no more often than every three years, crop rotation will necessarily prevent the emergence of glyphosate-resistant weeds. Again, the EA makes the mistake of assuming that just because conditions or restrictions are in place, they will necessarily be observed and enforced.

As evidence that farmers will in fact apply glyphosate at the TUG-required levels, the EA states that farmers know that it is in their best interest to prevent the emergence of glyphosate-resistant weeds. However, the EA does not provide a complete picture of the incentives at work here. Farmers have a more immediate and direct incentive to ensure that this season's crop does not get ruined by weeds. Also, Monsanto has an incentive not to enforce the TUG requirements as contractual obligations because, should

[128] 40 C.F.R. § 1508.7 (emphasis added); *see, e.g.*, *Natural Res. Def. Council v. U.S. Forest Serv*., 421 F.3d 797, 814 (9th Cir. 2005).

[129] "Are Superweeds an Outgrowth of USDA Biotech Policy?" Part I: Hearing Before the H. Subcomm. on Domestic Policy, 111th Cong. (2010), *available at* http://oversight.house.gov/index.php?option=com_content&view=article&id=5054:are-superweeds-an-outgrowth-of-usda-biotech-policy&catid=66:hearings&Itemid=31.

glyphosate-resistant weeds emerge (and they already are), they would likely benefit from holding the patent on the next generation of Roundup. Moreover, over-application of glyphosate boosts Monsanto's sales in the near-term. Thus, the EA's claim that Monsanto and farmers' self-interest will protect the environment from glyphosate-resistant weeds lacks any merit whatsoever. Nor can the agency properly rely on mitigation measures from a third party.

Further comment on the inadequacy of the agency's weed resistance analysis will be submitted by CFS separately and are incorporated by reference here.

VI. The EA Fails To Analyze Significant Impacts To Public Health.

Public health issues may be significant environmental impacts. 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."[130] Moreover in the APHIS draft programmatic EIS, issued July 7, 2007, APHIS listed impacts on human health as a category of impacts of its NEPA assessment.[131] Accordingly, APHIS's EA must address any potential human health or safety risks and determine whether those human health and safety impacts are significant.

If those impacts are found not to be significant, there must be a convincing statement of reasons. Accordingly, APHIS has its own duty to comply with NEPA, including assessment of potential significant impacts to public health and safety. APHIS cannot merely defer to EPA and FDA.

Yet APHIS defers to EPA on the toxicity of glyphosate and appears only to have reviewed the data supplied to EPA.[132] APHIS claims that it has been twelve years since EPA's decision to increase glyphosate tolerances and no new peer-reviewed data has demonstrated a need for re-assessment of the original decision.[133] However, APHIS does not consider the emerging data on the impacts of the Glyphosate-Tolerant Crop System. These health impacts must also be analyzed. Roundup use has been associated with increased risk of non-Hodgkin's lymphoma and hairy cell leukemia in pesticide applicators,[134] and increased risk of neurobehavioral disorders in children of Roundup applicators.[135] Roundup/glyphosate has been shown to inhibit steroidogenesis.[136] Both

[130] 40 C.F.R. § 1508.27(b)(2).
[131] Draft Programmatic EIS at 67-90.
[132] EA at 137.
[133] EA at 137.
[134] Hardell et al (2002). Exposure to pesticides as risk factor for non-Hodgkin's lymphoma and hairy cell leukemia: pooled analysis of two Swedish case-control studies," *Leuk. Lymphoma*, 43(5):1043-9.
[135] Garry et al (2002). "Birth Defects, Season of Conception, and Sex of Children Born to Pesticide Applicators Living in the Red River Valley of Minnesota, USA," *Environmental Health Perspectives,* 110, Suppl. 3, 441-449.
[136] Walsh et al (2000). "Roundup inhibits steroidogenesis by disrupting steroidogenic acute regulatory (StAR) protein expression," *Environmental Health Perspectives*, 108(8):769-76.

Roundup and glyphosate have been found to inhibit the aromatase enzyme involved in estrogen production, though Roundup was more potent.[137]

APHIS also erroneously defers to FDA's consultation on food safety on H7-1 RRSB. FDA's voluntary consultation process is insufficient. It is based on a statement of policy, not a binding regulation. 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. The manufacturer merely sends FDA a summary of its findings. FDA makes no findings of its own. FDA did not prepare any NEPA documentation (no EA or EIS) on its policy nor provide notice and comment. In any event, APHIS cannot solely rely on another agency's evaluation of effects to the human environment under a separate statute to adequately fulfill its own NEPA obligations.[138]

It is well accepted that genetic engineering has a greater likelihood of producing unintended effects than traditional breeding, some of them hazardous or detrimental.[139] Unintended effects are rarely well-understood, but can result from extensive mutations to the organism's genes caused by the genetic engineering process[140] 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.

VII. APHIS' Failed To Comply With The Endangered Species Act (ESA) And Consult Other Federal Agencies On Impacts To Threatened And Endangered Species (TES).

Failure to Consult

APHIS failed to consult with the U.S. Fish & Wildlife Service (USFWS) and/or the National Marine Fisheries Service (NMFS) as is required under Section 7 of the ESA on the potential effects on TES and their critical habitats.

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[137] Richard et al (2005). "Differential Effects of Glyphosate and Roundup on Human Placental Cells and Aromatase," *Environmental Health Perspectives*, 113: 716-720; for a comprehensive review of the adverse human and environmental impacts of glyphosate, see: FoE UK (2001). "Health and Environmental Impacts of Glyphosate," Friends of the Earth UK, July 2001. http://www.foe.co.uk/resource/reports/impacts_glyphosate.pdf.

[138] *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).

[139] 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.

[140] 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.

As APHIS itself acknowledges, Section 7 of the ESA requires APHIS to consult with USFWS and/or NMFS to determine whether its action "'may affect' listed species or critical habitat" under the ESA.[141] 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 TES which are likely to be affected by such action.[142]

Here, APHIS claims it evaluated the potential effects of the release of H7-1 sugar beet on any listed or proposed TES or any designated or proposed critical habitat.[143] APHIS determined that "it is unlikely that H7-1 sugar beet poses a hazard to TES animal species based on its own determination that "the composition of H7-1 sugar beet is similar to other commercial sugar beet plants with the exception of enhanced levels of [glyphosate resistance]."[144] Additionally, APHIS "considered the effect of the H7-1 sugar beet production on critical habitat or habitat proposed for designation and could identify no difference from effects that would occur from the production of other sugar beet varieties."[145] APHIS concluded that the release of H7-1 sugar beet proposed in the EA "will have no effect on listed species of species proposed for listing and would not affect designated critical habit or habitat proposed for designation."[146] Finally, based on these conclusions, APHIS decided that "consultation and/or the concurrence of the USFWS and/or the NMFS are not required."[147]

Yet, aside from obtaining a list of TES for each of the states where sugar beets could be grown under the EA from FWS's Environmental Conservation Online System website, there is no evidence that APHIS consulted with the FWS and/or NMFS.[148] Instead, APHIS relied on data submitted in the petition and its summaryof other agency findings and research studies.[149] Thus, prior to the environmental release of H7-1 sugar beets under the scope of the EA, APHIS must consult with FWS and/or NMFS.

Glyphosate Use

The analysis of glyphosate toxicity is also lacking and requires consultation. The impacts of glyphosate are part and parcel of the glyphosate-tolerant crop system. As discussed in other CFS comments submitted separately and incorporated by reference herein, any deregulation will dramatically increase the amount and acreage of glyphosate use and its consequent impacts on the environment.

A 1986 EPA Guidance for the Reregistration of Pesticide Products Containing Glyphosate (EPA Case No. 0178), identifies three listed species that, according to EPA's consultation with the USFWS Office of Endangered Species, may be jeopardized by use

[141] *Id.* at 227.
[142] *Id.*
[143] EA at 227.
[144] *Id.* at 229.
[145] *Id.* at 231.
[146] *Id.*
[147] *Id.*
[148] *Id.* at 228.
[149] *See id.* at 228-29.

of the compound (jeopardy being the highest level of effect under the Sec. 7 regulations). In particular, for use of glyphosate in a "crop cluster" in that document, the then-listed species jeopardized were *Solano grass,* the *Valley elderberry longhorn beetle,* and the *Houston toad*. (Each of those species is still listed.) EPA also stated that many endangered plants may be at risk from glyphosate. The EPA's 1993 Re-registration Eligibility Decision (RED) for Glyphosate, the most current registration for the compound, confirmed and expanded on this 1986 jeopardy opinion, stating:

> *The Agency does have concerns regarding exposure of endangered plant species to glyphosate. In the June 1986 Registration Standard, the Agency discussed consultations with the US Fish and Wildlife Service (FWS) on hazards to crops, rangeland, silvicultural sites, and the Houston toad which may result from the use of glyphosate. Because a jeopardy opinion resulted from these consultations, the agency imposed endangered species labeling requirements in the Registration Standard to mitigate the risk to endangered species. Since that time, additional plant species have been added to the list of endangered species.*[150]

APHIS relied on EPA's analysis of the potential impacts on TES from glyphosate use in the context of EPA's reviewing authority pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[151] It concluded that "EPA has considered potential impacts to TES as part of their registration and labeling process for glyphosate."[152] APHIS concluded that EPA's label restrictions and Monsanto's guidance to growers are sufficient "to reduce the possibility of exposure and adverse impacts to TES from glyphosate application to H7-1 sugar beet."[153] Based on these findings, APHIS concluded, without further consultation with the EPA, that "the use of…glyphosate for H7-1 sugar beet production will not adversely impact listed species or species proposed for listing and would not adversely impact designated critical habitat or habitat proposed for designation."[154]

However, EPA's prior registration of these herbicides does not alleviate APHIS of its duty to comply with the ESA and NEPA.[155] The FIFRA registration process is very different than review pursuant to NEPA and the ESA. Instead, APHIS relied on EPA's analysis of glyphosate use in the context of H7-1 sugar beet production without its own analysis even though EPA has made no determinations on the impacts on TES from glyphosate use on crops **since 1993**.[156] Even then, in 1993, EPA named the *Houston toad* as jeopardized by glyphosate use in association with its use on crops, but the RED failed to even list the other two species that had been found to be in similar jeopardy as of 1986,

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[150] Online at www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf, at p. 70.
[151] *Id.* at 232-33.
[152] *Id.* at 233.
[153] *Id.*
[154] *Id.*
[155] *Wash. Toxics Coal. v. U.S. EPA*, 413 F. 3d 1024 (9th Cir. 2005); *Or. Envtl. Council v. Kunzman*, 714 F.2d 901 (9th Cir. 1983).
[156] EPA's September, 1993, Re-registration Eligibility Decision ("RED") for glyphosate (No. 738-R-93-014).

the *Solano grass* and the *Valley elderberry longhorn beetle*. It also failed to even preliminarily list the many other potentially-affected species that were listed between 1986 and 1993, even though it acknowledged that many would be affected.[157] Because Section 7 of the ESA mandates each federal agency to "insure any action…by such agency…is not likely to jeopardize the continued existence of any endangered species or threatened species…"[158] APHIS must consult with the EPA regarding the specific impacts of glyphosate use in conjunction with the release of H7-1 sugar beet under the current EA.

VIII. The Proposed Commercial Permitting Program Does Not Comply With The Plant Protection Act.

Field Trial Permits and Notifications are for Research Experimentation, Not Commercialization

In September of 2010, APHIS began issuing permits for commercial production of Roundup Ready sugar beet (RRSB) seed, purportedly under 7 CFR 340. Following Judge White's September 28, 2010 ruling and in response to a petition for "partial de-regulation" by Monsanto's parent company, APHIS released an EA for the issuance of permits for commercial production of RRSB.

This use of the permitting procedure for environmental releases is unprecedented: permits are meant to be used in the research and development phase of crop production, not as a piecemeal substitute for deregulation. "These permits have gone far beyond the scope of what has been done before – granting permits for commercially grown genetically engineered crops."[159] This misuse of the permitting process is a departure from past agency policy, and therefore illegal without formal rulemaking procedures including proper public notice and comment. The notice and comment associated with this EA is insufficient to meet the requirements of the PPA; the public notice must indicate that the agency is initiating a *rulemaking* proceeding, which USDA's notice of this draft EA does not. APHIS has repeatedly indicated that the purpose of permitting field tests is experimental: to determine *pre*-commercialization whether new crop varieties posed a plant pest risk.

The plant pest framework that initially served as the basis for regulating bioengineered crops envisioned permits as an experimental tool to determine whether new crops posed a risk to the environment. USDA first began permitting field tests (also known as field trials and environmental releases) of genetically engineered crops in 1987 under the Federal Plant Pest Act (FPPA) and the Plant Quarantine Act (PQA), before the passage of the Plant Protection Act. In regulating the environmental release of GE crops, USDA indicated that it would use its existing regulatory scheme for preventing plant pests as a

[157] *Id.*
[158] 16 U.S.C. § 1536(a)(2) (2010).
[159] *Center for Food Safety v. Vilsack*, No. C 10-04038, 2010 WL 4869117, at *13 (N.D. Cal. Dec. 1, 2010)

foundation.[160] Under that regulatory structure, new or foreign crops required permits for environmental releases until USDA could determine that they did not pose a plant pest risk.[161]

USDA explained the application of this approach to bioengineered crops in a policy statement: "USDA will evaluate the environmental impacts in the context of *individual experiments* that encompass the entire range of *experimentation* from contained facilities to *open field testing*."[162] In simultaneously released proposed rules, APHIS stated, "For the past several decades, the Department has been issuing from 1,000 to 3,000 plant pest permits per year *for scientific or experimental purposes*."[163] The final rules echoed this understanding of the field tests.[164] This language is evidence that the open field tests of GE crops were conceived as part of an experimental phase in research and development, not part of commercial-scale production.

APHIS made this position more explicit when it amended the field test permit regulations in 1993. In the notice of the final rule, APHIS clarified that field test permits and petitions to deregulate were one *prerequisite* to commercialization, along with FDA and EPA's pre-commercialization requirements:

> APHIS wishes to clarify that the FPPA and PQA are intended to protect American agriculture and the environment against the introduction and dissemination of plant pests. *They are not statutes for the commercialization or marketing of plants*. Therefore, the petition process allows APHIS to determine, based upon the review of data, whether certain transgenic plants which are regulated articles should continue to be regulated. Currently prior to commercialization, new plant varieties, including those varieties produced through biotechnology, must comply with State and Federal marketing statutes such as State seed certification laws, the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In this regard, the Food and Drug Administration and the Environmental Protection Agency which administers [sic] these statutes have published policy or proposed policy statements in the Federal Register. . . . The petition process, which addresses the initial field testing of

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[160] Department of Agriculture, Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23336, 23338 (June 26, 1986)
[161] *Id.* at 23342.
[162] Department of Agriculture, Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23336, 23338 (June 26, 1986) (emphasis added).
[163] USDA APHIS, Proposed Regulations: Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests, 51 Fed. Reg. 23352, 23355 (June 26, 1986) (emphasis added).
[164] USDA APHIS, 52 Fed. Reg. 22892, 22896, Rules and Regulations, Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason To Believe Are Plant Pests (June 16, 1987) ("One commenter indicated that a general understanding of [environmental release] has been that release occurs if an *experiment* does not take place within the confines of a laboratory where the organism can be physically contained and remedial measures taken in the event of an accident. APHIS agrees with the commenter . . ."). Points 27 and 28 in this Federal Register notice likewise proceeded under the assumption that the purpose of the field tests was as an "experiment." *Id.* at 22901.

> transgenic plants, supplements these commercialization requirements. To the extent the *petition* process is viewed as addressing commercialization, it should be viewed as an interim measure pending adoption of the Administration's policy for reviewing and approving applications to commercialize genetically engineered plants and other products."[165]

The language in this Federal Register notice could not be clearer: field test permits and petitions for deregulation are pre-commercialization requirements. In subsequent Federal Register notices, APHIS implicitly maintains this understanding of field test permits by making references to their experimental or research value.[166] In one of the most recent Federal Register notices by APHIS, the Agency devotes a significant portion of the notice to discussion of the impacts of the permits on researchers and developers, with no discussion whatsoever of the impacts on commercial production.[167] This notice also discusses situations in which environmental releases result in "low-level mixing . . . with commercial seed and grain,"[168] strongly suggesting that environmental releases are separate from commercial production, whether GE or conventional.

Here, APHIS attempts to misuse the field trial permitting scheme to commercialize regulated article GE crops. APHIS' proposed permitting program constitutes a significant deviation from its current regulations regarding field test permits and commercialization of GE crops. If APHIS wishes to commercialize a crop, it must use its deregulation authority in whole or in part. As discussed *supra* the partial deregulation authority allows the agency to retain continuing oversight and monitoring of partially deregulated crops. APHIS cannot use its permitting scheme to make an end run around the deregulation requirement.

APHIS is effectively amending its current rules pertaining to how GE crops are commercialized. This kind of agency action requires APHIS to formally propose a rule

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[165] USDA APHIS, 58 Fed. Reg. 17044, 17051, Rules and Regulations, Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status (March 31, 1993) (emphasis added).

[166] *See e.g.*, USDA APHIS, 66 Fed. Reg. 51340, 51345, Proposed Rules, Plant Pest Regulations: Update of Current Provisions (October 9, 2001) (addressing why an environmental release of a plant pest would ever be necessary):

> "We also recognize that there are circumstances under which the release of other plant pests might be a necessary element of a testing or research protocol. . . . proposed § 330.203(a)(2) would provide that a plant pest not listed in proposed § 330.202(c)(1) may be released into the environment *only for research or testing purposes* and only if the release is authorized by an APHIS permit and is conducted in accordance with any safeguards assigned as a condition of the permit."

Although this section discusses 7 CFR 330 and not 7 CFR 340, it still reveals APHIS's understanding of the utility and purpose of field test permits, whether for GE crops or conventional crops.

[167] USDA APHIS, 73 Fed. Reg. 60008, 60025–60037, Proposed Rules, Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms (October 9, 2008) (for example, "Both of these recordkeeping requirements would be added because some researchers or developers were found to be unclear about what management and communications practices were needed to prevent unauthorized releases, and also about their responsibilities and the measures they must take in the event of an unauthorized release.").

[168] *E.g. id.* at 60048.

through a notice published in the Federal Register and allow the public to comment on it.[169] Therefore, if APHIS enacts this commercial permitting system, it will be arbitrary, capricious, and contrary to law.[170]

APHIS did not Make a Plant Pest Determination ("Plant Pest Authority")

Commercialization of GE crops under PPA also requires a plant pest determination with the deregulation decision.[171] By statute, "plant pest" is defined as: "any living stage of any of the following that can directly or indirectly injure, cause damage to . . . any plant or plant product."[172] APHIS's regulations defined a "plant pest" as "[a]ny living stage (including active or dormant forms) of . . . bacteria [among other organisms] . . . or any organisms similar to or allied with any of the foregoing . . . which can directly or indirectly injure cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."[173] The regulations further reference with regard to plant pest analyses: "indirect plant pest effects on other agricultural products."[174]

APHIS's proposed permitting program violates APHIS' own PPA regulations because it commercializes RRSB production without first making a determination that RRSB do not pose a plant pest risk. An agency must follow its own regulations.[175] Because of the novel nature of GE crops, some may have unpredictable characteristics when released into the environment.[176] To address this problem, APHIS passed regulations requiring the Agency to make such a determination prior to allowing the commercialization of a GE crop.[177] With this proposal to again commercialize APHIS has not made any determination that RRSB do not pose a plant pest risk. Failure to make such a determination before permitting commercial production of RRSB is arbitrary, capricious, and contrary to law.

Additionally, APHIS's failure undertake a PPA plant pest determination in the case of RRSB constitutes a departure from longstanding agency practice, a proposed change that *itself* requires notice and comment procedures. "If a new agency policy represents a

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[169] 5 U.S.C. § 553.
[170] 5 U.S.C. § 706(2)(A).
[171] *See* 7 CFR § 340.6 (providing that petition for deregulated status may be granted if Secretary determines that the applicant's crop does not pose a plant pest risk).
[172] 7 U.S.C. § 7702(14).
[173] 7 C.F.R. § 340.1.
[174] 7 C.F.R. § 340.6(c)(4).
[175] *Wilson v. Commissioner of Social Sec*., 378 F.3d 541, 545 (6th Cir. 2004) ("It is an elemental principle of administrative law that agencies are bound to follow their own regulations.").
[176] *See* 73 Fed. Reg. 60008, 60012
[177] 7 CFR § 340.6(e); *see also* 58 Fed. Reg. 17044, 17052 (March 31, 1993) ("APHIS disagrees with one commenter's contention that an exemption from regulated status deprives the public of access to information regarding releases of transgenic plants. This statement does not accurately represent the history of organisms determined to have nonregulated status. This determination of safety for a transgenic plant is based upon scientific evidence, which may include successful field tests that have been approved after Agency environmental assessments and findings of no significant impact, and other scientific data and public comment indicating that the constructs pose no significant plant pest risk.").

significant departure from long established and consistent practice that substantially affects the regulated industry, the new policy is a new substantive rule and the agency is obliged, under the APA, to submit the change for notice and comment."[178] In the absence of a formal rule, an unexplained departure from established agency practice is arbitrary and capricious under the APA.[179] In practice, APHIS has always preceded commercialization of GE crops with a determination that the crop does not pose a plant pest risk.[180] APHIS's failure to do so here without notice and comment rulemaking constitutes a violation of the APA.

Sound Science

Under the PPA, decisions affecting regulated products "shall be based on sound science."[181] Sound science includes objective findings, which take into account all relevant and available data, does not disregard superior data and is based on accepted scientific method, which includes peer review and methodology that is widely used and can be replicated. Instead, the draft EA is largely based on Monsanto's own studies, which are largely not peer reviewed, publicly available, or objective.

"Sound science" would counsel that APHIS properly inform its PPA decision with its NEPA analysis, which was not done here. *See supra*. Further, even if the agency *had* informed the PPA decision with its NEPA assessment, the draft EA is chock full of unsound sciences, the result of which allows APHIS to conclude, at least preliminarily, that the deregulation will have no significant impacts. Again, *see supra.*

On March 9, 2009, President Obama issued a Memorandum entitled "Scientific Integrity" mandating that "[s]cience and the scientific process must inform and guide decisions of my Administration," with the "highest level of integrity in all aspects of the executive branch's involvement with scientific and technological issues."[182] President Obama established several core principles that indicate what constitutes scientific integrity, including:

- Having "appropriate rules and procedures to ensure the integrity of the scientific process within the agency,"
- Subjecting scientific or technological information "to well-established scientific processes, including peer review,"
- "Appropriately and accurately reflect[ing] that information in complying with and applying relevant statutory standards,"
- Making "available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions,"

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[178] *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 630 (5th Cir. 2001).
[179] *See National Cable & Telecom. Ass'n v. Brand X Internet Services*, 545 U.S. 967, 981 (2005) (citing *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co*., 463 U.S. 29, 46-57, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)).
[180] 73 Fed. Reg. 60008, 60010.
[181] 7 U.S.C. § 7701(4).
[182] Barack Obama, Memo for the Heads of Departments and Agencies, March 9, 2009, at http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/.

- Putting "in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised," and
- Adopting additional procedures, such as whistle blower protections, in order to "ensure the integrity of scientific and technological information and processes on which the agency relies."[183]

APHIS has frequently violated the tenets of sound science in its decision-making documents on GE crops in numerous ways, such as excessive reliance on applicants' analysis and data; frequent citation of dubious, industry-sponsored white papers with little or no scientific merit or review; and egregious factual errors biasing decisions in favor of applicants among other unscientific practices.

Here, it seems APHIS has again knowingly violated basic tenets of sound science. APHIS has willfully ignored high-quality data and information crucial to the draft EA—data and information well-known to it, some of it generated by its sister agencies, the Agricultural Research Service and the National Agricultural Statistics Service. Instead, APHIS has relied extensively on outdated information, misinformation from industry sources, and speculation. For example, APHIS relies on a Monsanto fact sheet as a basis for its conclusion that "[h]erbicides used on conventional sugar beets are likely to cause more environmental concerns than does glyphosate."[184] Some of the data for the draft EA's tables does not come from APHIS's own observations, but instead come from Monsanto's second-hand reporting.[185] The draft EA abounds with other examples of APHIS relying on data and studies hand-picked by the regulated companies themselves.

The draft EA also cites extensively to declarations filed in *Sugar Beets I*.[186] One such declaration appears to be APHIS's only basis for its conclusion that its proposed post-contamination contingency measures are viable.[187] Although these declarations were submitted under oath, they do not embody the rigorous methodology that the scientific community expects—and the President's Executive Order[188] demands—from science-based decision-making. Members of the scientific community do not review court filings like they do published studies. This means that the draft EA relies on sources that are unlikely to withstand the customary peer review that legitimate scientific studies undergo.

To the extent that the draft EA examines the impact of its permitting program on weed resistance, the spread of plant disease, and the impacts of glyphosate, it employs flawed

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[183] *Id.*
[184] Draft EA at 219.
[185] *See, e.g., id.* at. 249 ("Rotated crops and acreage following sugar beet production are based on communications from individual local experts. i.e., university agronomists, USDA-ARS and Monsanto field personnel."), 250 ("In 2009, glyphosate use on sugar beet . . .was roughly 1.3% of the total agricultural and fallow use of glyphosate in the US based on AgroTrak data (Gregory Watson and Keith Reding, Monsanto, personal communication, September 29-30, 2010).")
[186] *E.g.*
[187] Draft EA at 159-160 (citing Stander declaration).
[188] *See* Obama, *supra* note 85.

methodology and dubious reasoning. For more detailed analysis on this point, see separately submitted CFS comments and incorporated herein.[189]

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

In addition to physical science, sound assessments must also apply to the social sciences, for instance, to analyze the economic impacts of transgenic contamination of non-GE crops. The purpose of the PPA is summarized in its first finding: "the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds is necessary for the protection of the agriculture, environment, and economy of the United States."[190] The ultimate goal—contained in the second half of the first finding—is the protection of US agriculture and economy.[191] Disregarding available data about significant adverse economic impacts on the agricultural economy, as discussed *supra*, is not sound science, and thus further violates the PPA. Similarly, relying on the economic conclusions of an industry consultant paid to advocate the purported harm to the industry from the failure to permit commercialization in spring is not sound science. This is particularly true when, as here, a Federal Court has already found the same individual's testimony not credible. *See supra.*

Noxious Weed Authority

The PPA gives APHIS broad statutory 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.[192]

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

[189] *See* Center for Food Safety, Comments on Draft Environmental Assessment (Bill Freese), in this docket.
[190] 7 U.S.C. § 7701(1).
[191] *Id.*
[192] 7 U.S.C. § 7712(a) (emphasis added).

> agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.[193]

Thus APHIS has much more authority over RRSB 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. In fact, APHIS itself recognizes that its statutory authority is broader than it claims in this EA in its currently proposed revised 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.[194]

A noxious weed is defined to include many of the types of harms noted in these comments from biological contamination to other crops from RRSB: public health risks, damage to crops, the environment, and the interests of agriculture, for example.

Given APHIS's current rulemaking process (APHIS Docket 2008-0023), it is clear that APHIS intends to broaden the scope of how it regulates GE crops, in particular to implement its noxious weed authority, which will clarify APHIS' broader authority and allow it to better address the full range of adverse agricultural, public health, and environmental impacts associated with GE crops,[195] in order to fulfill the PPA's purpose to "protect[] the agriculture, environment, and economy of the United States."[196] APHIS's intent to more broadly construe its PPA authority in its regulations demonstrates its broad statutory authority. Its overly narrow application of that statutory authority here violates the statutory and regulatory scheme put into place to give APHIS regulatory

[193] 7 U.S.C. § 7702(10) (emphasis added).
[194] 73 Fed. Reg. 60008, 60011 (Oct. 9, 2008) (emphasis added).
[195] 7 U.S.C. § 7702(10); 73 Fed. Reg. 60013 (stating that "evaluation of noxious weed risk expands what we can consider.")
[196] 7 U.S.C. § 7701(1).

authority over GE crops.[197] For APHIS to commercialize RRSB without analyzing the noxious weed risks involved would be contrary to its current rule-making process and the PPA. Moreover the NEPA assessment of RRSB must assess any risks encompassed by APHIS' noxious weed authority and is arbitrary and capricious to the extent it fails to do so. An EIS with a broader scope is required. APHIS should also delay any decision on RRSB and any other GE crop until it finalizes its new PPA regulations.

Further, the approval of RRSB and associated glyphosate use with the Roundup Ready crop system will promote the rapid evolution and spread of noxious weeds tolerant of or resistant to glyphosate herbicide, in violation of the PPA's noxious weed provisions. RR crop systems have triggered the rapid emergence of glyphosate-tolerant and glyphosate-resistant noxious weeds by fostering near exclusive reliance on glyphosate for weed control – and by doing so on a massive and growing scale, and in ever more frequent and heavy applications. If introduced and widely adopted, RRSB will have this same noxious weed-promoting effect, both independently and cumulatively with pre-existing RR crop systems. Glyphosate-resistant weeds are noxious because of their manifold negative impacts on the interests of agriculture, human health, the environment, and farmers' welfare. Because RRSB will directly and indirectly foster and cause these significant negative noxious weed impacts, APHIS must apply its noxious weed authority to RRSB and must analyze these impacts fully in an EIS.

For a thorough analysis on this argument, *see* separately submitted CFS comments and incorporated herein.

VI. The EA Does Not Comply With The 2008 Farm Bill

The EA makes absolutely no mention anywhere of how it complies with the mandates of the Farm Bill of 2008 ("Farm Bill"). The Farm Bill States, "Not later than 18 months after the date of enactment of this Act, the Secretary shall (1) take action on each issue identified in the document entitled 'Lessons Learned and Revisions Under Consideration for APHIS' Biotechnology Framework.'"[198] The Act further states that the Secretary "shall" take actions designed to enhance APHIS's oversight of field tests, including "the quality and completeness of records," "the maintenance of identity and control in the event of an unauthorized release," "corrective actions in the event of an unauthorized release," and "the use of the latest scientific techniques for isolation and confinement distances."[199]

Congress included these provisions as part of the Farm Bill in recognition of USDA's abysmal record at containing transgenic contamination. Because APHIS' proposal is using its field trial permit and notification system, the Farm Bill applies to it. The statute's explicit reference to the Lessons Learned document demonstrates Congress's

[197] *American Paper Institute, Inc. v. American Electric Power Service Corp. et al*., 461 U.S. 402, 413 (1983) (failure to consider relevant factors in its decision making violates the PPA); 5 U.S.C. § 706.
[198] The Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, Title X, § 10204, 122 Stat. 2105 (2008) (emphasis added).
[199] *Id.*

judgment that USDA's current methods of regulating transgenic contamination—which remain unchanged since the Farm Bill's enactment—are simply unacceptable. Moreover, as evidenced by Congress's repeated use of the word "shall," these provisions are a mandate. Congress left no discretion to USDA to decide whether or when it would adopt the recommendations in the Lessons Learned document. APHIS's procedural and substantive failure to comply with the Farm Bill mandates as applied here is arbitrary, capricious, and not in accordance with the law.[200]

CONCLUSION

APHIS' proposal to allow commercial planting of RRSB, a regulated article currently undergoing a full EIS, is unprecedented. It is also unsound, lacking adequate scientific or legal support. The agency's scheme risks significant harm to farmers, the public and the environment from again commercializing RRSB, choosing to instead again rely on industry assurances and an EA flawed in structure, process and substance. Nor is there any need for this proposal: APHIS has rushed to approve this proposal at the behest of the biotech industry, even though the purported harm to them is both self-created and illusory. In the process APHIS is merely attempting to circumvent court decisions making RRSB illegal, as well as make its pending EIS on RRSB a meaningless post hoc rubber stamp. The scheme also misapplies APHIS's authority by attempting to shoehorn a commercialization decision into APHIS's permitting scheme.

The current proposal violates NEPA, the PPA, the ESA, the 2008 Farm Bill and the APA. APHIS should shelf this proposal and go back to the drawing board, beginning any further consideration with an EIS.

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[200] 5 U.S.C. § 706(2)(A).