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Regulatory Analysis and Development,
PPD, APHIS, Station 3A-03.8
4700 River Road
Unit 118
Riverdale, MD 20737-1238

Pursuant to the notice found at 73 Fed. Reg. 60008 (October 9, 2008), the Center for Food Safety ("CFS") provides the following comments on the USDA, Animal and Plant Health Inspection Service's ("APHIS") Proposed Rules for the Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms. 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. CFS represents 67,000 members throughout the country that support organic agriculture and regularly purchase organic products.[1] In addition to the comments submitted herein, CFS is concurrently submitting 11,851 comments from CFS Food Network members opposing the new rules as proposed.

INTRODUCTION

The United States government's regulatory oversight of genetically engineered crops in the United States has been a dismal failure. Millions of acres of these crops have been planted, yet the environmental and health consequences of this widespread planting have not been studied. After these crops are commercialized, USDA asserts no regulatory authority and conducts no study or analysis of the human health, environmental and economic effects of the large-scale introduction of genetically engineered crops. Moreover, as thousands of genetically engineered crops continue to be tested on open fields, it has become apparent that USDA's regulatory oversight and enforcement have provided inadequate containment of these crops and analysis of their impacts.

APHIS's proposed rule, "Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms,"[2] which implements APHIS's authority under the plant pest and noxious weed provisions of the Plant Protection Act ("PPA"),[3] signals a significant step backward in the level of oversight that APHIS plans to implement over genetically engineered crops ("GE crops") and other genetically engineered organisms ("GEO"). While CFS applauds APHIS for proposing to apply its noxious weed authority to GEOs, it does so in an overly narrow manner. Furthermore, APHIS's proposal for the scope determination process drastically weakens the rule in several profound respects. For many years, the Center for Food Safety has worked to improve regulatory oversight of GE crops, including frequent

[1] See generally http://www.centerforfoodsafety.org.
[2] 73 Fed. Reg. 60008-60048.
[3] 7 U.S.C. § 7701 et seq.

engagement with APHIS. The proposed rule issued by APHIS is in many respects a disappointment.

While the newly proposed rule will greatly weaken the U.S. regulatory system for GE crops and GEOs, a number of studies published since APHIS released its draft Programmatic Environmental Impact Statement ("DPEIS") just 14 months ago underscore the importance of a stronger regulatory system for GE crops. For instance, a long-term mouse feeding study with a popular variety of genetically engineered corn conducted by Austrian government researchers revealed reduced fertility in female mice fed the GE corn vs. conventional corn, suggesting that this GE corn may harbor fertility reducing substances generated by the genetic engineering process.[4] A 2008 Norwegian study found that small aquatic organisms known as Daphnia exhibited reduced performance, including reduced fertility, when fed a common variety of GE corn but not when fed conventional corn.[5] In 2007, a US study found that consumption of GE corn debris slows the growth rate, and potentially the fertility, of small aquatic organisms known as caddisflies, versus those fed conventional corn. Since caddisflies are at the base of aquatic food webs, and the tested variety of GE corn is planted on millions of acres across the Midwest, the scientists expressed concern that this GE corn may pose a long-term threat to the health of freshwater aquatic ecosystems.[6] We stress that each of these studies involved GE crop varieties that were reviewed and approved by U.S. regulatory authorities, including APHIS, in some cases more than a decade ago.

These and other studies cast serious doubt on APHIS's claim that commercial GE crops enjoy a history of safe use, which is nothing more than an unsupported presumption. As we noted in our comments on the DPEIS, the fact that GE crops have been commercialized and grown on a wide scale does not demonstrate a history of safe use.[7] Furthermore, the National Academy of Sciences has issued a report indicating that such a presumption of safety is unwarranted and "nonscientific" due to the lack of environmental monitoring of deregulated GE crops, "so any effects that might have occurred could not have been detected. The absence of evidence of an effect is not evidence of absence of an effect."[8] Lack of evidence of impact does cannot equal a reasonable certainty of safety. Thus, APHIS's presumption of safety, which underpins its move to weaken the rules governing GEOs, is a false one.

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[4] Velmirov, A, Binter, C and J. Zentek (2008). "Biological effects of transgenic maize NK603 x MON810 fed in long term reproduction studies in mice," Federal Ministry for Health, Families and Youth, Government of Austria, October 2008.

[5] Bohn, T., Primicerio, R., Hessen, D.O. and T. Traavik (2008). "Reduced fitness of Daphnia magna fed a Bt transgenic maize variety," Archives of Environmental Contamination and Toxicology, published online March 18, 2003.

[6] Rosi-Marshall, EJ et al (2007). "Toxins in transgenic crop byproducts may affect headwater stream ecosystems," Proceedings of the National Academy of Sciences 104(41): 16204-16208.

[7] CFS Comments on DPEIS, pp. 55-56 (hereinafter "CFS Comments") (Attachment 1).

[8] NAS (2002). *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation,* Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants," National Research Council, National Academy of Sciences, 2002, at 79 (hereinafter "NAS Report.")

Neither has it been demonstrated with reasonable scientific certainty that GE crops commercialized in the US cause no harm to human health. The US Food and Drug Administration ("FDA") does not approve GE crops as safe, but rather explicitly places the responsibility for GE crop safety on the crop developer, and has no mandatory regulatory system in place for such crops. Under its 1992 "Statement of Policy: Foods Derived From New Plant Varieties,"[9] the FDA created the general presumption that foods derived from GE crops – past and future – would not require mandatory pre-market human health/safety testing, and set up a weak voluntary consultation process. Under this system, 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. To the extent that short-term "performance" feeding trials are conducted (e.g. with poultry), they are not designed to detect potential toxicity of the GE crop (i.e. no toxicological "endpoints"), but rather only to measure performance parameters of commercial interest, such as weight gain.

CFS has extensive experience with GE crop safety testing, and to our knowledge, US regulators have never required long-term animal feeding studies with any whole GE crop. These serious deficiencies in the US regulatory process for GE crops are still more troubling in light of the Austrian government study cited above, which found that mice fed a popular variety of GE corn as 33% of their diet over a period of 20 weeks had fewer offspring and more females with no offspring than animals consuming a diet containing 33% of a highly similar conventional corn variety. CFS incorporates by reference here Appendix 1 of our comments on the DPEIS, which elaborates on deficiencies in the US regulatory system with respect to detecting human health impacts, on the example of the FDA's "early food safety evaluation."

Furthermore, APHIS has turned a blind eye to the huge and growing adverse agronomic impacts that are directly associated with the cultivation of some GE crops. For instance, herbicide-tolerant GE crops, which were grown on over 148 million acres in 2008, are engineered for the sole purpose of withstanding direct application of an herbicide. These herbicide-tolerant crop systems are associated with increased herbicide use, rapid emergence of herbicide-resistant weeds, increased weed control costs, and in a growing number of areas are increasing use of soil-eroding tillage to control resistant weeds.

APHIS regulation has been unsuccessful in many instances to prevent contamination of commercial crops with unapproved GE varieties grown in field trials. Such contamination episodes have led to rejection of US commodities in important export markets, substantial economic losses to farmers and food companies, and have rightly corroded public confidence in APHIS's regulation. Some aspects of the proposed rule will increase the likelihood of more such episodes.

For all of these reasons, CFS calls on APHIS to carefully consider these comments, reconsider the deregulatory approach taken in this proposed rule, and formulate a final rule that is adequate to the task of protecting the environment, the interests of agriculture, and public health.

[9] 57 Fed. Reg. 22984 (May 29, 1992).

THE PROPOSED RULES SEVERELY WEAKENED SCOPE OF REGULATION

Possibly the most important deficiency in the proposed rule is a vast contraction and weakening of APHIS's role and authority in its most fundamental regulatory responsibility – determining the scope of regulation over GEOs.

In the course of APHIS's 4 ½-year process to revise its regulatory regime for GEOs, three basic approaches have emerged in the key area of regulatory scope, which is simply the definition of what APHIS does and does not regulate. These three approaches have two things in common: they all apply only to the import, interstate movement, and most importantly the release into the environment of GE organisms,[10] chiefly the outdoor cultivation of GE plants;[11] and they apply only to experimental GE organisms – that is, they exclude those GE organisms that APHIS has individually reviewed and approved for unregulated (e.g. commercial) use.[12]

With these provisos in mind,[13] the three definitions of regulatory scope are as follows, in descending order of breadth and objectivity:

1) All plants developed through the use of genetic engineering, which is also known as genetic transformation, or simply transformation. Here, the use of genetic engineering is the "trigger" for APHIS regulatory oversight of genetically engineered plants. This objective criterion is referred to below as the engineering trigger.

2) Those GE plants that are developed with the use of, or contain genetic material from, one or more of the "plant pest" organisms listed in 7 CFR 340.2. This objective criterion is referred to below as the "taxonomic trigger," and it explicitly defines the scope of regulation under APHIS's current regulations. APHIS proposes to eliminate this trigger in favor of the third option below.

3) Those GE plants that GE crop developers, in the first instance, or alternatively APHIS determines, based on a variety of subjective criteria, to be plant pests or noxious weeds as defined under the PPA. This is the discretionary approach that APHIS has proposed in the rule at issue here.

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[10] APHIS does not regulate GE organisms in contained facilities, or the intrastate movement of GE organisms.

[11] For the purposes of this rulemaking, APHIS excludes vertebrate GE animals from the scope of regulation, but does propose to regulate invertebrate GE animals (e.g. insects). Because our comments focus on GE plants, "plants" will be used interchangeably with "organisms" and "crops" throughout these comments, unless otherwise explicitly noted.

[12] In APHIS terminology, GE plants for which it has made a "determination of non-regulated status."

[13] We note that these provisos also apply in the subsequent regulatory scope discussion.

APHIS Should Use Genetic Engineering as the Trigger for Regulatory Oversight

CFS strongly supports option (1) above, the use of genetic engineering as the trigger for USDA regulatory oversight of GE crops. This is the option (alternative 2) that APHIS proposed adopting in the DPEIS (DPEIS at 168). Of the three options, this approach is the most scientifically justifiable; the most protective of the environment, public health and the interests of agriculture; the most transparent; and the most administratively efficient.

In our comments on the DPEIS, CFS provided detailed scientific arguments supporting the use of genetic engineering as the trigger for regulation and opposing exclusion of certain GE organisms from regulatory oversight, which we incorporate here by reference (CFS Comments at 43-47). In brief, genetic engineering is a novel technology with no demonstrated history of safe use; it is an imprecise technology that causes random and in some cases large-scale mutations in crop genomes;[14] it has a higher potential for generating unintended and potentially adverse human health effects than conventional breeding methods;[15] and its products, GE crops, should be subject to considerably more stringent testing than occurs at present to detect any such adverse impacts prior to field testing, and especially unregulated use.[16]

These considerations lend additional support to CFS's position that genetic engineering is the proper trigger for regulation, a position shared by a prestigious National Academy of Sciences' committee that conducted a thorough review of USDA's regulatory performance at regulating GE crops. This NAS committee argued that: "…transformation [i.e. genetic engineering] is both a useful and logically justifiable regulatory trigger,"[17] "there is a scientific basis to examining all genetically engineered crops," and "all transgenic crops should be reviewed through regulatory oversight."[18] After carefully considering the matter, the same authorities also concluded that "a full process-based trigger is consistent with the 1992 OSTP scope document."[19] In the DPEIS that forms the basis for this proposed rule, APHIS explicitly acknowledged that this NAS committee had "argued that USDA should regulate all transgenic plants, ***as there is no scientific basis on which to forecast which ones might pose a risk***."[20] Indeed, APHIS itself adopted this

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[14] 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.

[15] 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, Figure 3.1, pp. 64-65.

[16] Freese & Schubert (2004), "Safety Testing and Regulation of Genetically Engineered Foods," *Biotechnology and Genetic Engineering Reviews,* Vol. 21, p. 299-323.

[17] NAS Report at 79.

[18] Id at 83.

[19] Id at 81. The document referred to is the White House Office of Science and Technology Policy's ("OSTOP") "Exercise of federal oversight within scope of statutory authority: Planned introductions of biotechnology products into the environment," 57 Fed. Reg. at 6753-6762.

[20] APHIS DPEIS (2007). "Introduction of Genetically Engineered Organisms," Draft Programmatic Environmental Impact Statement, USDA APHIS, July 2007 at 20 (emphasis

position in its preferred alternative 2 for Issue 1, Scope of Regulatory Oversight, in the DPEIS.[21] There, APHIS explicitly stated that it would "use genetic transformation as the trigger for regulation."[22]

Failure to Use Genetic Engineering As the Trigger Will Eviscerate APHIS Regulatory Authority, Reduce Regulatory Objectivity, and Create More Administrative Burden

Inexplicably, APHIS has turned its back on sound science, the expert advice of the National Academy of Sciences, and its own preferred alternative, and disavowed this trigger in the proposed rule: "The proposed scope makes it clear that the mere act of genetic engineering does not trigger regulatory oversight…"[23] The exclusion of some GE organisms from regulatory oversight is also signaled in the very title of the proposed rule, which applies only to the "importation, interstate movement, and release into the environment of ***certain*** genetically engineered organisms" (emphasis added). APHIS also explicitly states that: "Over time, the range of GE organisms subject to oversight is expected to decrease…," and also suggests that ***groups*** of GE organisms may be exempted from oversight.[24] However, APHIS also admits that "By excluding certain GE organisms from regulation and thereby allowing an increasing number of GE organisms to be grown, the proposed exclusion provision may increase the potential for gene flow from GE crops to non-GE crops."[25]

It is hard to overstate the importance of this about face. Since the DPEIS was issued just over one year ago, APHIS's regulatory posture has changed from applying its regulatory oversight to all GE plants[26] to one in which many GE plants will likely escape regulatory oversight altogether.

Besides being more scientifically sound and protective of human health and the environment, the use of genetic engineering as the regulatory trigger has the advantages of transparency and enhancing public confidence in APHIS's regulatory process. After all, it is not unreasonable for the public to expect that a regulatory regime for GEOs does in fact apply whenever genetic engineering is used to alter an organism. This is not the case under current regulations, which employ the taxonomic trigger (option 2 above), and under the proposed regulations at issue here it would be still ***less*** true (3 above). We first address the currently employed taxonomic trigger.

At present, only those GEOs that are plant pests, or contain or were developed with genetic material from plant pests designated in 7 CFR 340.2 are subject to mandatory regulation.[27] This

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added).
[21] Id. at 168.
[22] Id.
[23] 73 Fed. Reg. at 60012.
[24] Id.
[25] DPEIS at 169.
[26] That is, regulating the import, interstate movement, and environmental release of all experimental GE plants that have not been explicitly reviewed and granted a determination of non-regulated status by APHIS.
[27] We say "mandatory" because APHIS does have the discretion to regulate other GE organisms,

list of plant pests includes organisms whose genetic material is used in the genetic engineering of many but not all GE plants.[28] As a result, any GE plant generated ***without*** the use of such genetic material "would not necessarily be considered a regulated article," and the "field release of [such] transgenic plants could escape APHIS oversight."[29] This little-known loophole makes the current system non-transparent, and rightly erodes public confidence in APHIS's regulation of GE plants.

The reason this defective taxonomic trigger for regulation was adopted in 1987 is the long-standing bias of the biotechnology industry and APHIS against making any fundamental regulatory or statutory distinction between GE crops and those produced with conventional breeding techniques.[30] In effect, the taxonomic trigger has allowed APHIS to misleadingly reassure the public and even the scientific community that all GE plants are subject to regulation,[31] while at the same time preserving the option of excluding certain GE organisms or classes of GE organisms from regulation in the future.

The future is now. In the rule at issue here, APHIS proposes to: 1) Reject the engineering trigger that it preferred in the DEIS; 2) Eliminate the current taxonomic trigger by "deleting the list of organisms which are or contain plant pests" at 7 CFR 340.2;[32] and 3) Replace the latter with a discretionary approach to regulation led by the GE crop developer rather than APHIS. These changes would have three undesirable consequences. First, replacement of the objective

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though to the best of our knowledge it has not done so, unless one counts optional "courtesy permits," which are discussed futher below.

[28] NAS Report at 106-07: "A transgenic organism is considered a regulated article if it is a plant pest or if it or a gene donor or vector used in its construction are plant pests according to a long list of taxa listed in 7 CFR 340.2." Note that "transgenic" is a synonym for "genetically engineered."

[29] NAS Report at 107.

[30] In APHIS's brief response to comments in the proposed rule, APHIS essentially rejects the engineering trigger as inconsistent with the US government's commitment to product-based regulation, that is, regulating on the basis of a crop's traits, versus the process used to develop it. After exhaustive consideration of this matter, however, NAS (2002) concluded that use of the engineering trigger was NOT inconsistent with an approach that focuses risk assessment on the properties of the GE crop "product." See NAS quotes to this effect above.

[31] 73 Fed. Reg. at 60021. The lack of transparency of APHIS's regulatory scope is illustrated well by the fact that even many GE crop developers have been misled into thinking that all GE crops are subject to APHIS regulation. APHIS issues optional "courtesy permits" for those GE crops not subject to regulation. APHIS notes that the application form for optional courtesy permits is identical to the form for required permits, and refers to the widespread misunderstanding among researchers that courtesy permits are required rather than optional. The entire confusing courtesy permit system is the unfortunate result of APHIS's unwillingess to make ALL genetic engineered crops subject to mandatory regulation by stipulating use of genetic engineering as the trigger for regulation. APHIS proposes to eliminate the courtesy permit system in the proposed rule. CFS can support this move ONLY if APHIS reverses course and adopts genetic engineering as the trigger for regulatory oversight.

[32] 73 Fed. Reg. at 60015.

taxonomic trigger by the discretionary approach would open the door wide to unregulated cultivation of GE crops that should be regulated, due to biased or faulty scope determinations by GE crop developers based on fuzzy criteria subject to wide-ranging, subjective interpretation. Second, APHIS's entire regulatory system would become still less transparent, further eroding public confidence in its oversight. Third, APHIS consultations with GE crop developers to determine whether their products are subject to regulation would pose an unnecessary burden on APHIS staff resources that would be better devoted to risk assessment, inspections and other activities. We address these consequences in more detail below.

The Proposed Rules Essentially Grant Self-Certification to Developers

APHIS notes that: "Under current regulations, there is no explicit statement of the relative responsibilities of the Administrator and regulated parties in determining whether an organism met the definition for regulated article and therefore would be subject to the regulations."[33] The unstated reason for this is that the taxonomic trigger, despite its weaknesses, at least provided a clear and unambiguous criterion for making such determinations.

With the proposed discretionary approach, however, the GE crop developer would make the primary determinations as to whether their crops fall under APHIS's regulatory jurisdiction. APHIS blithely assumes that GE plant developers will "correctly apply the criteria in 340.0 to determine whether the GE organism is subject to the regulations,"[34] seemingly blind to the obvious interest of regulated parties in avoiding regulation when possible. The potential for GE plant developers to improperly avoid regulatory oversight is increased by the fuzzy nature of the criteria in 340.0 (which are discussed further below); as even APHIS concedes: "it may not be readily apparent to the responsible person for a GE organism whether or not the organism falls within the scope of 340.0."[35] In these cases, responsible persons "*may* consult with APHIS"[36] if they so choose. The fuzziness of APHIS's proposed scope is further blurred by confusing and vague reference to different "level[s] of knowledge" that apply to scope determinations vs. "determinations regarding such things as necessary permit conditions…."[37]

In sum, APHIS proposes a system in which GE crop developers are granted the primary responsibility for deciding whether or not they are regulated, and so will have the ability to "self-certify" their GE plants as beyond the bounds of APHIS regulation. This opens the door to the unregulated planting of experimental GE crops that should in fact be regulated, without the knowledge of, much less review by, APHIS. Such a voluntary consultation process is exceedingly non-transparent and would certainly erode public confidence in the products of agricultural biotechnology. APHIS should consider, in particular, the corrosive effect this discretionary approach would have on public confidence in important export markets for US commodities (e.g. Japan, European countries), where more scientifically-grounded and

[33] 73 Fed. Reg. at 60011.
[34] Id.
[35] 73 Fed. Reg. at 60012.
[36] Id. (emphasis added).
[37] Id.

precautionary regulatory regimes prevail, and where citizens already give little credence to assurances of safety from US regulators.

The Public Will Be Cut Out of the Scoping Process

Under this newly proposed, highly discretionary process that resembles self-certification, there is no process by which the public could review a determination of regulatory applicability or provide its comments on whether the regulations should apply. Where an applicant declines to apply the new rules – essentially through self-review – there is no transparency or review process whatsoever. Further, where a developer consults with APHIS for a determination on whether the regulations apply, there is similarly no process by which the public or other interested parties can be involved. As the proposed rules state: "Because the **Administrator may make such a determination <u>at any time</u>** the Administrator receives information that a GE organism is within the scope, APHIS expects that developers will seek early consultation with APHIS on whether the regulatory scope covers their GE organism."[38] Thus, APHIS can make a determination without any notice to the public whatsoever. Furthermore, the proposed regulations state: "APHIS plans to make information publicly available by posting and maintaining information on its website about the determinations it makes pursuant to this consultation process to help the public and regulated entities understand which organisms are subject to the regulations."[39] Thus, after a determination, APHIS will only make this information public by posting on a website **<u>after the fact</u>**. This affords the public no notice or opportunity for comment, and would be in violation of the Administrative Procedure Act.[40]

The Proposed Rules Will Increase Regulatory Burden on APHIS

Finally, to the extent that GE crop developers do choose to consult with APHIS to make scope determinations, this represents an unnecessary burden on APHIS staff resources that would be better devoted to other activities, such as risk assessment. This administrative burden could be entirely avoided by making genetic engineering the trigger for regulation.

Under the proposed rule, GE plants that are imported, moved interstate or released into the environment would be subject to APHIS regulation if:

i) The unmodified parent plant from which the GE plant was derived is a plant pest or noxious weed, or
ii) The trait introduced by genetic engineering could increase the potential for the GE plant to be a plant pest or noxious weed, or
iii) The risk that the GE plant poses as a plant pest or noxious weed is unknown, or
iv) The Administrator determines that the GE plant poses a plant pest or noxious weed risk.

Until the passage of the Plant Protection Act, APHIS regulated GE plants as potential plant pest risks under the authority of the Federal Plant Pest Act (FFPA) of 1957. This statute was enacted

[38] 73 Fed. Reg. 60012 (emphasis added).
[39] Id.
[40] 5. U.S.C. § 553

decades before the advent of genetic engineering technology, to prevent the introduction of damaging pests and plant disease agents from abroad, and to mitigate the adverse effects of such pests and pathogens. The definition of "plant pest" reflects these concerns:

> Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.[41]

Under the Plant Protection Act, which subsumes both the FPPA and the Noxious Weed Act of 1974, APHIS has proposed using both its noxious weed and its plant pest authority to regulate GE plants. A "noxious weed" is defined as:

> Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.[42]

While the plant pest definition can be construed broadly with reference to indirect injury or damage, it explicitly mentions only one narrow category of plants (parasitic plants). Genetic engineering has rarely if ever been applied to parasitic plants, or to make non-parasitic plants parasitic. This raises the question of how APHIS has thus far applied its plant pest authority to subject GE plants to regulatory oversight. The answer is the taxonomic trigger discussed above. APHIS has made broad use of its plant pest authority to deem any plant that has been genetically engineered with the aid of a plant pest, or to incorporate DNA from a plant pest, designated in 340.2 a "regulated article" subject to its oversight. If APHIS eliminates the taxonomic trigger as proposed, GE crop developers may well avoid regulatory oversight by construing the plant pest definition much more narrowly than APHIS has until now via use of the taxonomic trigger. Similarly, they will likely construe noxious weed in narrow terms.

In a hypothetical example, under APHIS's proposed discretionary approach, a GE crop developer who plans to field test an herbicide-tolerant GE crop would be subject to the current regulations by virtue of the 340.2-listed plant pest organism *Agrobacterium* used in its development. The same developer could avoid regulation under the new, discretionary approach proposed in these new rules. Even where such a GE crop has weedy relatives to which it could transfer its herbicide-tolerance trait via cross-pollination, making them resistant to the herbicide and hence more difficult to eradicate; and even where conventional varieties of the crop are also grown in the planned area of release, to which the GE crops could likewise transfer the GE herbicide-tolerance trait via cross-pollination (hence causing negative market effects); under the proposed system, absent the taxonomic trigger, this crop would not necessarily be regulated

[41] 7 U.S.C. § 7702(14).
[42] 7 U.S.C. § 7702(10).

because the use of *Agrobacterium* would no longer trigger regulatory oversight.[43] Under the proposed scheme, the GE crop developer would be left to apply the four scope criteria with reference to the definitions of "plant pest" and "noxious weed" that originated in statutes that were statutorily defined many years prior to the first commercial introduction of GE plants.

The move to eliminate the taxonomic trigger without replacing it with some objective standard will create ambiguity, confusion and poor oversight because the newly proposed criteria provide too little guidance and clarity into when a GEO is governed under the regulations. Under proposed § 340.0 (b)(1)(i), which is the only objective criterion of the four, regulation of GE crops would be triggered only in the exceedingly unlikely event that its unmodified parent is a parasitic plant or a noxious weed. Proposed § 340.0 (b)(1)(ii) opens the door wide to wide-ranging interpretation. In the above hypothetical example, while a strong argument could perhaps be made that the experimental GE plant's herbicide tolerance trait might damage or injure any harvests of conventional crops that it contaminates through lost market value, and so indeed has "increased the potential" of the plant to be a plant pest, a GE crop developer might very well construe plant pest in the narrowest possible terms. Noting that parasitic plants are the only plant category named in the definition of plant pest, the developer might self-certify his/her crop as unregulated because the herbicide tolerance trait does not increase the potential of the plant to be a parasitic plant. Similarly, one might be able to make a strong argument that the herbicide tolerance trait increases the potential of the crop to be a noxious weed, based on the likelihood that the trait will enter related weeds and make them still "weedier" – that is, more difficult and expensive to control, harming the interests of agriculture. If herbicide use increases to control such a weed, there may also be harms to the environment and public health. Once again, however, a GE crop developer might very well construe "noxious weed" in a much narrower sense. For instance, a developer might examine the list of 98 federally listed noxious weeds, decide that any herbicide-tolerant weeds generated due to introduction of the GE crop do not pose similar risks, and proceed with unregulated planting of said crop, without even consulting with APHIS.

Proposed § 340.0 (b)(1)(iii), the third criterion, offers little help here: "[t]he risk that the GE plant poses as a plant pest or noxious weed is unknown..." GE plant developers can develop plausible theoretical arguments that there is sufficient information about their GE plants to preclude unknown plant pest or noxious weed risks, particularly since they are free to construe the terms narrowly. Yet such theoretical arguments, while they may sound quite impressive, can easily be proven wrong by realities in the field. In comments on the DPEIS, CFS describes a striking example in which the *ex ante* predictions by competent agronomists as to the agronomic impacts of certain GE crops were proven decisively wrong by field experience with these crops, with huge and growing adverse impacts.[44]

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[43] Note that in most cases, the plant pest organisms under 340.2 are not themselves responsible for the trait or issue of concern. In this example, for instance, *Agrobacterium* is utilized merely as a tool to introduce the herbicide-tolerance gene that makes the crop herbicide tolerant.

[44] CFS Comments at 58. In the years before introduction of GE herbicide-tolerant crops, some experts in the field of weed science predicted on the basis of theoretical considerations that herbicide use associated with such crops would not lead to rapid development of herbicide-resistant weeds – a prediction that has been proven decisively wrong by experience in the field.

Proposed § 340.0 (b)(1)(iv), the fourth criterion, involves a positive affirmation by APHIS that a GE plant poses a plant pest or noxious weed risk. At first glance, this might seem to answer the objections raised above concerning GE crop developers applying the criteria of 340.0 in overly narrow terms so as to improperly escape regulation. However, this would be the case only if GE plant developers were required to consult with APHIS. They are not. APHIS quite clearly places primary responsibility for making scope determinations on the GE crop developer, with no consultation requirement. "Under the proposed regulations, the responsible person for a GE organism could correctly apply the criteria in 340.0 to determine whether the GE organism is subject to the regulations."[45] In those cases where "it may not be readily apparent to the responsible person for a GE organism whether or not the organism falls with the scope of 340.0...," that person "***may*** consult with APHIS,"[46] but is not required to do so.

In essence, the proposed scope determination process is little better than an honor system, in which APHIS trusts the GE crop developer to do the right thing. This will inevitably result in the virtual unregulated planting of experimental GE crops, and will vastly increase the likelihood of adverse impacts on the environment, public health, and the interests of agriculture. It will also corrode public confidence in both APHIS regulation and GE plants still further.

APHIS must revise the proposed regulations at the very least to prevent the type of self-certification described above. Further, APHIS should return to its preferred alternative in the DEIS to make the use of genetic engineering the clear, unambiguous, objective trigger for regulation.

THE PROPOSED REGULATIONS ABANDON HIGHER STANDARDS FOR PERMITTING PHARMA CROPS AND FAIL TO SUFFICIENTLY PROTECT HUMAN HEALTH

In these newly proposed regulations, APHIS missed a golden opportunity to eliminate the risks posed to public health and the environment by the untested pharmaceuticals in biopharmaceutical ("pharma") crops. Despite substantial support from the scientific community, the food industry, public interest groups and farmers, APHIS rejected both of the more protective alternatives proposed in the DPEIS. These alternatives would have banned outdoor cultivation of pharmaceutical-producing crops altogether (3) or allowed field testing only if the crop has no food or feed uses (4). CFS argued at length in comments on the DPEIS that APHIS regulations and permit conditions cannot sufficiently minimize the risks posed by these crops, making it necessary for it to adopt Alternative 3 from the DPEIS, which "would mitigate the consequences of unintended releases to the greatest extent."[47] Failing that, we urge APHIS to adopt alternative 3.

Biopharmaceuticals are often extremely potent compounds that can have biological activity at extremely low levels, for instance insulin (millionths of a gram) or granulocyte macrophage colony stimulating factor, a potent hormone active at even lower levels. Both of these

[45] 73 Fed. Reg. at 60011.
[46] 73 Fed. Reg. at 60012 (emphasis added).
[47] DPEIS at 146.

substances have been field tested in food crops. There is often little or no scientific evidence available on the impacts of these potent compounds through inhalation, ingestion, or dermal contact, the routes by which humans or animals might be exposed to food crops contaminated with such compounds. Given their potency, exposure to very low levels could have hazardous effects.

No prescribed confinement regime offers adequate security to provide the needed 100% containment for substances of this nature, particularly given the potential for human error, extreme weather events, and the occasional negligence of field trial operators and government regulators. This explains why numerous authorities have urged against the use of GE food crops for production of experimental pharmaceuticals. For instance, two National Academy of Sciences committees have argued against open-air cultivation GE pharmaceutical-producing food crops:

"…it is possible that crops transformed to produce pharmaceutical or other industrial compounds might mate with plantations grown for human consumption, with the unanticipated result of novel chemicals in the human food supply."[48]

"Alternative nonfood host organisms should be sought for genes that code for transgenic products that need to be kept out of the food supply."[49]

Even the editors of Nature Biotechnology argued against use of food crops for biopharming, noting that: "Current gene-containment strategies cannot work reliably in the field … Can we reasonably expect farmers to [clean] their agricultural equipment meticulously enough to remove all GM seed?"[50]

In light of these recommendations, APHIS's bland assurance that it has seen no evidence that these crops pose unreasonable risk is entirely unconvincing. Because of the lack of evidence as to the effects of these ***medically untested*** pharmaceuticals through likely routes of exposure, the "no evidence" APHIS refers to is in most cases lack of any evidence rather than evidence of no harm.

Rather than adopting one of these two more protective alternatives, APHIS has concluded that "the proposed permitting procedure and the use of stringent permit conditions can effectively minimize the risks that may be associated with the environmental release of such GE plants."[51] As indicated above, this is an unscientific statement that is not backed by any empirical evidence on the risks or lack of risks posed by even a single biopharmaceutical compound grown in a pharma crop. The proposed system opens the door to weakened oversight, thus increasing the

[48] NAS Report at 68.
[49] National Research Council, National Academy of Sciences, "Biological Confinement of Genetically Engineered Organisms," 2004, p. 7.
[50] Nature Biotechnology (2002). "Going with the flow," Editorial, Vol. 20, No. 6, June 2002, p. 527.
[51] 73 Fed. Reg. 60020.

potential for pharma crops to contaminate the food supply and pose significant health risks to U.S. citizens. It must therefore be rejected in favor of alternative 3 or alternative 4.

Since 2006, APHIS had placed pharma crops in a special class by imposing a special oversight program over pharma crops.[52] In its "Draft guidance for APHIS permits for field testing or movement of organisms with pharmaceutical or industrial intent," APHIS has required that field trials of pharma crops be approved only through a more stringent permit process, and imposed specific permit conditions on permit holders of pharma crops, including but not limited to: field test confinement practices like spatial separation from other crops, machinery cleaning requirements, post-harvest land use restrictions, site security requirements, and more stringent record keeping and other administrative requirements.[53] APHIS has also required more stringent reporting requirements for pharma crops.[54] Under the existing program, APHIS inspects pharma crop field tests more often than other permitted field tests or tests subject to notification.[55]

Under the newly proposed rules, APHIS has abandoned any special or particular regulatory oversight and will acquire considerable discretion to place pharma crops in lower-risk categories than are appropriate. Furthermore, APHIS has an opportunity to strengthen its oversight of pharma crops as it applies its "noxious weed" authority under the PPA to GEOs. However, statements in the proposed regulations indicate that APHIS will not capitalize on this opportunity and instead plans to take an overly narrow interpretation of its responsibility under thus authority: "the noxious weed definition should not be interpreted so broadly as to provide APHIS with the legal responsibility or authority to … prevent GE crops from entering the food supply."[56] Also, statements in the proposed regulations, made in response to comments on the DPEIS, indicate that APHIS does not view pharma crops as posing any special risks:

APHIS's failure to acknowledge the unique risks associated with pharma crops and to classify pharma crops as high risk, or to impose special restrictions is alarming and of grave concern given APHIS's track record with contamination in pharma crops and GE crops generally. Furthermore, APHIS offered no empirical evidence to support its claim in the DPEIS that the current system of permit conditions "are sufficiently stringent that the field tests pose no significant risk to the environment, including human health."[57] APHIS should not stand on this same conclusion now to justify its failure to more stringently regulate pharma crops. The only way to ensure that experimental pharmaceuticals produced in GE crops pose no risk to public health or the environment is 100% containment, which is not possible.

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[52] Draft guidance for APHIS permits for field testing or movement of organisms with pharmaceutical or industrial intent, USDA APHIS, 2006 (March 31), available at *www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf*.
[53] Id.
[54] Id. at pp 24-25 (requiring a pharma crop permit holder to submit five separate reports or notices: a pre-planting notice, a planting report, a pre-harvest notice, a field test report, and a volunteer-monitoring report.)
[55] Id. at 30 ("a field test may have five inspections during the growing season and two additional inspections postharvest; however APHIS may inspect more frequently in some cases.")
[56] 73 Fed. Reg. 60029
[57] DPEIS at 144

To our knowledge, there have been three reports of pharmaceutical crop contamination. APHIS itself makes oblique reference to one such incident in which pharmaceutical corn "volunteers" (plants sprouting from unharvested seed that appear in the following season's crop) contaminated 500,000 bushels of soybeans in Nebraska, necessitating their seizure and destruction at an estimated cost of $3 million.[58] In the same year, 155 acres of conventional corn was destroyed due to concern that it had cross-pollinated with pharmaceutical corn grown in a field trial in Iowa.[59] Another possible contamination episode was suggested by Chris Webster of the drug company Pfizer, who stated at a meeting on pharma crops hosted by the U.S. government, that: "We've seen it on the vaccine side where modified live seeds have wandered off and have appeared in other products."[60]

The potential for further such episodes is enhanced by APHIS' shoddy regulation of pharma crops. The newly proposed regulations will unfortunately continue the same minimalist regulatory failure. In 2005, the USDA's Inspector General published an audit finding numerous deficiencies in APHIS oversight of pharmaceutical crop field trials. Below, we quote at length from the Inspector General's report to illustrate how far APHIS' performance in this area lags behind its own stated standards:[61]

> **APHIS loses sight of two tons of harvested pharma crops**
>
> We found that two large harvests of GE pharmaceutical crop were stored for over a year by Applicant F cooperators (farmers conducting field tests for Applicant F), even though the permits did not contain information about the storage period so that it could be assessed by APHIS. During our field site reviews, we found that an Applicant F cooperator stored more than half a ton of a GE pharmaceutical crop for 15 months. In another State, 1.4 tons remained in storage at the cooperator's farm for 17 months. The cooperators said that they were waiting for instructions from Applicant F, who eventually instructed them to ship the harvests back to their headquarters. Although the permit applications for the field tests in these two States disclosed that the harvests would be shipped back to Applicant F's headquarters, they did not indicate when the shipments would occur. Thus, the lengthy storage of the pharmaceutical harvests was not approved

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[58] DPEIS at 38. APHIS fails to note that this episode involved pharmaceutical corn. See Toner, M. (2002). "Alarms sound over 'biopharming' – tainted crops cast doubt on gene altering," The Atlanta Journal and Constitution, Nov. 17, 2002; and "Something Funny Down on the Pharm," Popular Science, April 2003, which later reveals that the contaminated soybeans were destined for veggie burgers and infant formula.

[59] "GM crop mishaps unite friends and foes," New Scientist, Nov. 18, 2002. http://www.newscientist.com/news/news.jsp?id=ns99993073

[60] See "Plant-Derived Biologics Meeting" transcript, April 5 & 6, 2000. www.fda.gov/cber/minutes/plnt2040600.pdf, p. 77.

[61] Office of Inspector General, Southwest Region, "Audit report: Animal and Plant Health Inspection Service controls over issuance of genetically engineered organism release permits," Audit 50601-8-Te, USDA, December 2005, *available at www.usda.gov/oig/webdocs/50601-08-TE.pdf*.

by APHIS and the safety protocols of the storage facilities could not be assessed. Also, PPQ did not perform inspections during the extended storage to ensure that the GE crops were safely contained in the facilities.[62]

Locations of pharma crop field trials often not reported

Our review of 53 permit field sites included 20 field sites planted under 13 pharmaceutical and industrial permits**.** All 13 permit holders were required to submit planting notices and 12 were required to submit 4-week/28-day reports. However, only 8 of those 12 permit holders were required to provide GPS coordinates on their 4-week/28-day reports; three failed to provide this information. Although not required to do so by APHIS, one permit holder indicated the specific field site location on the planting notice.[63]

Deficient reviews of applications for pharmaceutical crop field trials

During our fieldwork, we obtained copies of the official files for 10 pharmaceutical permits, which APHIS considers high-risk. Our review found that the files did not contain sufficient information to disclose the extent of the biotechnologist's reviews or the criteria they used to arrive at their decisions. Although the files contained letters to State regulatory personnel, we found that other required documentation was not always in the files. For all 10 of the permits, the tracking sheet was not in the file or not initialed. For 7 of 10 permits, the form to identify the plant's genes and other characteristics was also not in the file or not completed. Furthermore, nine of the approved permits had not undergone supervisory review, an essential control over the application approval process.

Even if the required documentation had been present in the files, we concluded that it would not be sufficient to describe the biotechnologists' complete review process. Specifically, the documentation was not sufficient because it did not describe the scope of the biotechnologists' review of risks associated with introducing a particular GE plant and how the applicant planned to mediate those risks. Scientific criteria for approving a field test application might address the likelihood of the unintentional spread of GEOs or the establishment of wild GEO populations, and the effects of regulated GE crops on other species.[64]

"Required" inspections not conducted

Specifically, APHIS announced to the public that pharmaceutical and industrial field sites would be inspected 5 times during the 2003 growing season, but, in fact, we found that only 1 of 12 sampled pharmaceutical field test sites met this requirement.[65]

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[62] Id. at 41-42
[63] Id. at 15
[64] Id. at 25 (footnote omitted)
[65] Id. at 28

Post-harvest permit requirements violated, posing risk that "volunteer" pharma crops will contaminate food supply

> In September 2003, we visited a field test site where a permit holder had planted a pharmaceutical crop in 2002. PPQ had not inspected the site during the postharvest monitoring period in 2003. When we visited the site, we learned that the permit holder's cooperator had planted soybeans on the field, violating APHIS requirements that restrict the production of food and feed crops at pharmaceutical and industrial GE field test sites in the following season. Those GE field test sites are to be left fallow in the following growing season so that volunteer GE plants are not inadvertently harvested with an unregulated food crop. Although the cooperator's 2003 monitoring record stated that the 2002 GE field was fallow, the cooperator told us that he had planted unregulated soybeans in the former GE field and cut them down the day before our visit. He left the soybeans standing in the larger field surrounding the former GE field.[66]

Pharmaceutical and industrial substances should not be produced in GE food or feed crops in the environment. Growth in contained structures needs to follow methods that do not allow gene flow to occur. For example, typical greenhouse vent systems would allow pollen to escape and should not be allowed.

Similarly, industrial compounds are not intended for consumption and therefore may have a higher possibility of harming non-target organisms. Such compounds may generally be more likely to be harmful to non-target organisms, because they are not intended to be consumed, or only to be consumed for medical purposes. For example, the industrial product avidin produced in corn has insecticidal properties (NAS 2002). In addition, aprotinin, a blood-clotting protein, has been grown in corn as a plant-made pharmaceutical; but it was originally classified as a "novel protein" and grown under notification. It has been shown to increase the mortality of honeybees, and may affect other organisms.[67] Also, some industrial enzymes are allergenic, and many pharmaceutical compounds have harmful side effects.

Therefore, APHIS should have adopted Alternative 3 from the DPEIS, which "would mitigate the consequences of unintended releases to the greatest extent."[68] This is the only acceptable alternative given the special risks to human health and the environment posed by even low-level contamination of the food supply with bioactive pharmaceuticals.

APHIS' failure to provide the level of regulation proposed in the DPEIS Alternative 3 constitutes a continued failure to protect human health. Further, as APHIS is incorporating its noxious weed authority into 7 CFR 340, it must address human health impacts.[69] As discussed below, failure

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[66] Id. at 30 (footnote omitted).
[67] For case studies of avidin and aprotinin as expressed in corn, see appendices 2 and 3 of Freese, B. (2002). "Manufacturing Drugs and Chemicals in Crops: Biopharming Poses New Threats to Consumers, Farmers, Food Companies and the Environment," Friends of the Earth, July 2002. Available at: www.foe.org/biopharm/.
[68] DPEIS at 146.
[69] 7 U.S.C. 7702(10).

to do so would constitutes an arbitrary and capricious, overly narrow interpretation of the PPA.

APHIS SHOULD ABANDON THE "LOW LEVEL PRESENCE" POLICY WHICH WOULD PERMIT UNDETERMINED LEVELS OF BIOLOGICAL CONTAMINATION

APHIS proposed "Low Level Presence" policy in the proposed regulations at 7 CFR 340.7(g)(2) is a major step backward from its duty to protect farmers and consumers from biological contamination associated with gene transfer from pollen flow, seed mixing, volunteers, and other routes CFS argued against the adoption of this policy in its comments on the DEIS and incorporate those comments here.[70]

CFS here reiterates its support for Alternative 4, or imposition of a strict confinement regime on all field tests of GE crops equivalent to that presently required only for GE pharmaceutical and industrial crops.

CFS has several concerns. First, there is potential for food safety or environmental risks from contamination of commercial food supplies by unapproved GE crops, especially given the lack of definition of what constitutes "low level." It is quite remarkable that APHIS here proposes to codify a policy whose very title refers explicitly to some numerical quantity, yet fails to provide any indication whatsoever what that quantity might be; and fails to make any provision for actually measuring the purported "low level" presence in contaminated commercial supplies in general or in any given case, much less stipulate any quantitative measurement techniques or procedures for establishing the level.

What might the actual level of unapproved GE crop contaminating commercial supplies be? Does "low-level" mean 0.01% presence of the contaminant, 0.1%, 1% or 10%? Is there anything at all in the policy to prevent still higher levels of "presence" from being deemed "low level"? This failure to provide any information whatsoever on quantity, measurement or procedures to determine quantity, etc, with respect to "low level presence" undermines the legitimacy of this policy from the start.

While most "low level presence" events will probably not pose undue harm, there is no way to predict this beforehand. In some cases, extremely low levels of contamination could pose health concerns. For instance, GE StarLink corn was never approved for human consumption due to concerns that its insecticidal protein (Cry9C) might cause allergies. After StarLink contaminated the food supply, expert scientific advisors to the EPA stated that ***there was no minimal level of StarLink's Cry9C insecticidal protein that could be judged safe for human consumption.***[71] Thus, zero tolerance was the only acceptable standard to protect human health.

APHIS maintains that the Low Level Presence policy is science-based, and that it will forego remedial action only when there is no danger to human health. But this is not the case. We

[70] CFS Comments at 70-83.
[71] "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.

address the radical deficiencies in the rubber-stamp procedural steps involved in the FDA's scientifically flawed "early food safety evaluation" in Appendix 1 of our DPEIS comments (Attachment 1).

Additionally, biological contamination is not a static or temporary phenomenon. Because GEOs are living organisms that reproduce and spread their genetic information, the possibility of genetic amplification, spreading and persistence is a critical concern, particularly in cases where the organisms in question has a selective advantage (such as an herbicide-tolerant crop in fields where herbicides are applied). As a federal court found recently, "Once gene transmission occurs and a farmer's seed crop is contaminated with the [] gene, there is no way for the farmer to remove the gene from the crop or control its further spread."[72] Thus, zero tolerance must be the standard.

The criteria APHIS has proposed to determine whether contamination is subject to remedial action fails to consider critical information necessary to protect critical sectors of the agriculture community, such as organic farmers and processors, as well as farmers, processors and exporters selling seeds and grains to foreign markets. Even where a GE plant expresses identical or "nearly identical proteins,"[73] for example, biological contamination from a GE crop would eliminate organic markets and consumers choice because organic markets reject any level of GE contamination. When creating the Organic Food Production Act, the USDA indicated that the presence of GE contaminants would render a product unmarketable as organic. The Department explained, "[C]onsumers have made clear their opposition to the use of [GE] techniques in organic food production. **This rule is a marketing standard**, not a safety standard. **Since use of genetic engineering in the production of organic food runs counter to consumer expectations, [GE foods] will not be permitted to carry the organic label**."[74] Here, under the criteria for determining when a contamination event would be actionable, there is no indication that an absence of such negative market effects to organic would be considered in determining when remedial action should not be taken. Thus, at the very least, APHIS should adopt measures that would prevent a decision of 'no remedial action' where organic crops could be contaminated. Given the ultimate goal of the PPA – to protect the American agricultural

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[72] *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007) *aff'd*, 541 F.3d 938 (9th Cir. 2008).

[73] Proposed 7 CFR § 340.7(g)(2)(i).

[74] 65 Fed. Reg. 13534-35 (Mar. 13, 2000) (emphasis added). The DEIS states, "The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards." DEIS at 160. However, the federal court explicitly rejected this rationale: that "[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." *Geertson Seed Farms,* 2007 WL 518624, at *6. APHIS's failed to adequately assess impacts to organic agriculture, particularly in light of this LLP Policy, thus the EIS is inadequate.

economy – failure to do so would arbitrarily and capriciously contravene the plain language and intent of the PPA.[75]

Similarly, foreign markets like Japan and Europe have proven to be rightly sensitive to contamination of food shipments with unapproved GE crops, and in some cases have rejected shipments that contain even low levels of contaminant. As a result, biological contamination can destroy foreign markets for certain crops doing great harm to individuals as well as the U.S. agricultural economy. We saw this during the LL601 contamination incident. This episode caused substantial economic damage to U.S. rice exports, significant harm to U.S. rice farmers and the rice industry as a whole, and a loss of faith in the wholesomeness of the U.S. food supply.[76] Elevation of the unscientific and economically damaging "Low Level Presence" policy into federal statute will further and rightly increase skepticism of US regulators and GE crops among the American public as well as citizens in other countries, creating new levels of insecurity, suspicion, and possible market rejection in foreign markets due to ambiguity and unscientific nature of standards permitting such contamination. Given the ultimate goal of the PPA, to protect the American agricultural economy,[77] at the very least, APHIS should adopt measures that would prevent a decision of 'no remedial action' where crops grown for sensitive markets could be contaminated. Failure to do so would arbitrarily and capriciously contravene the plain language and intent of the PPA.[78]

Furthermore, permitting biological contamination, or failing to take remedial action when biological contamination of this sort occurs, contravenes the federal court's precedent indicating that biological contamination is a significant environmental impact cognizable under the National Environmental Policy Act ("NEPA"). As the court stated, "An action which potentially eliminates or least greatly reduces the availability of particular plant … has a significant effect on the environment."[79] Adoption of the "Low Level Presence" policy in the PPA, which essentially allows for contamination where APHIS, in its discretion, determines that remedial action is not necessary, fails to sufficiently protect from the very type of contamination the court found to be significant in the GE alfalfa context.[80]

We urge APHIS to adopt 100% containment as ***management goal***, setting the bar as high as possible so as to make the inevitable lapses in gene containment extremely rare events. While such standards would increase costs somewhat for both APHIS and field trial operators, they would also prevent substantial economic losses to farmers and the food industry in the future from the increased incidence of contamination and market rejection episodes that will accompany continued application of the Low Level Presence policy. We note that APHIS should, but does not, assign any cost to lost market value from the varying incidence of

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[75] 7 U.S.C. § 7701.
[76] *See* CFS Comments at 79-81.
[77] 7 U.S.C. § 7701.
[78] Id.
[79] *Geertson Seed Farms,* 2007 WL 518624, at *10 (quoting C.F.R. § 1508.27(b) ("A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial.")).
[80] The DEIS failed to consider

contamination episodes to be expected with differing gene confinement regimes in its economic analysis.

For these reasons and others expressed in our DPEIS comments, APHIS should not codify the Low Level Presence policy. Instead, APHIS should adopt Alternative 4 of the DPEIS – gene containment standards now applied to field trials of crops that produce pharmaceutical and industrial compounds should be applied to ALL GE crop field trials.

IMPLEMENTATION OF APHIS' NOXIOUS WEED AUTHORITY IS TOO NARROW

CFS applauds APHIS for taking the critical step of including its noxious weed authority under the newly proposed regulations governing the release of GEOs. Doing so will clarify APHIS' ability to regulate GE plants that could harm the non-agricultural environment. Many GE plants could pose such broader risks. For example, stress and drought tolerance genes may increase the fitness of GE plants or wild relatives not currently considered to be noxious weeds, thereby allowing spread in natural areas.[81] Increased geographic range of stress-tolerant plants could cause harm by displacing other species or exposing non-target organisms to transgene products that could be harmful. Under this authority, APHIS will now have the authority to also regulate GE plants that may be harmful to public health.

In its proposed regulations, however, APHIS's proposed implementation of the noxious weed authority is much too narrow. First, APHIS's proposed regulations fails to address indirect harms, such as significant economic impacts, where there is no established direct harm or damage, impermissibly narrowing the PPA definition of noxious weed. APHIS's proposed regulations also impermissibly exclude human health safety testing of GE food crops. Furthermore, APHIS fails to address herbicide tolerant ("HT") crops under its noxious weed authority.

Prior to implementation of the PPA, APHIS regulated GE plants as potential plant pest risks under the authority of the Federal Plant Pest Act (FFPA) of 1957. The PPA, which subsumes both the FPPA and the Noxious Weed Act of 1974, defines a "noxious weed" as:

> ...any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.[82]

The Noxious Weed Act was enacted to control the spread of noxious weeds, in particular to prevent introduction of noxious weeds from abroad. It was enacted in 1975, nearly a decade before the first report of a GE plant (tobacco) in 1983, and two decades before the introduction of the first commercial GE plant (tomato) in 1994.[83] The framers of the Noxious Weed Act

[81] NAS (2004). "Biological Confinement of Genetically Engineered Organisms," National Research Council, National Academy of Sciences, 2004, p. 49.
[82] 7 U.S.C. § 7702(10).
[83] Lemaux, P.G. (2006). Outlook article in *California Agriculture*, University of California,

could not have formulated the statute to address the different concerns associated with GE plants.[84] Thus, it becomes important for APHIS to apply its noxious weed authority broadly and flexibly enough to address these concerns.

CFS was encouraged by APHIS's consideration in the DPEIS of using its noxious weed authority to assess GE plant-related risks beyond plant pest risks. For instance, APHIS specifically suggested it might use its noxious weed authority to assess public health and environmental effects of GE plants.[85] In our comments on the DPEIS, CFS urged APHIS to go further, and use its noxious weed authority to assess GE plants for their potential to harm, directly or indirectly, the "interests of agriculture" as well. In the proposed rule, APHIS notes that: ". . . any weed, and virtually any plant or plant product, can be evaluated by APHIS to determine whether its characteristics warrant its listing as a noxious weed."[86] APHIS, however, proposes an overly narrow application of its noxious weed authority and should revise the proposed rules in order to consider: 1) indirect harms when they are not associated with direct harms, 2) adverse economic impacts, 3) human health impacts, and 4) impacts associated with herbicide tolerant ("HT") crop systems.

1. APHIS Must Consider Indirect Harm Independently of Direct Harms under Noxious Weed Authority

In regulating noxious weeds under the PPA, APHIS must regulate both direct *and* indirect harms. The plain language of "noxious weed" is clear: "Any plant or plant product that can *directly* ***or*** *indirectly* injure or cause damage to crops (including nursery stock or plant procucts), livestock, poultry, or other interests or agriculture . . . the public health, or the environment."[87] Under this statutory definition, direct and indirect effects are given equal weight. The newly proposed regulations, however, treat direct and indirect effects in a hierarchy, triggering the evaluation of indirect effects only "[i]f direct harm or damage is established."[88] This false hierarchy of harms, regulating "indirect effects" only where there is a "direct effect," eviscerates half of the "noxious weed" definition. This arbitrary and capricious interpretation of the statute is a violation of the plain meaning of "noxious weed." Furthermore, the proposed rules state that "APHIS's determination that a plant is a noxious weed is based on notable physical harm or injury caused by the plant."[89] However, injury to the agricultural economy[90] does not come from direct physical injury alone, and the noxious weed authority requires APHIS do equally address indirect harms.

July-September 2006. http://calag.ucop.edu/0603JAS/outlook.html.
[84] CFS strongly supports enactment of new statutes specifically geared to address GE plants.
[85] USDA Draft PEIS at 21.
[86] 73 Fed. Reg. 60013.
[87] 7 U.S.C. § 7702(10).
[88] 73 Fed. Reg. 60013.
[89] 73 Fed. Reg. 60014.
[90] "the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds is necessary for the protection of the agriculture, environment, and *economy* of the United States." 7 U.S.C. § 7701(1).

That APHIS addresse indirect harms alone is critical given the many proven indirect harms associated with GEOs and GE crops in particular, including but not limited to the biological contamination of other sexually compatible non-GE plants, development of herbicide resistant "super weeds," and environmental impacts associated with increased pesticide use and other cultural practices associated with herbicide-tolerant crop systems. APHIS should also use its noxious weed authority to assess a range of other possible indirect harms, including any impacts on endangered species, and any climate change impacts from cultural practices associated with GE crop systems. In all of these cases, interrelated economic impacts must also be assessed[91] Economic harm is one such effect that could be considered "indirect" and therefore left out of the regulatory protections under APHIS' newly proposed rules. And, this is exactly what the new rule apparently intends to avoid: "APHIS does not consider significant economic effects alone that are not linked to physical damage to be sufficient to determine a plant is a noxious weed."[92] However, under the proposed rules, it is vague and ambiguous when economic loss would be considered under the noxious weed authority. On the one hand, "[o]ften APHIS quantifies the physical harm or injury in terms of economic losses. Loss in commodity value due to the presence of noxious weeds in seeds, for example, is a consequence of the anticipated physical damage that would be caused if the seed containing a noxious weed were distributed and planted."[93] This begs the question, would contamination of non-GE food crops, such has occurred in the StarLink, LL601, and LL604 cases, trigger the direct or indirect injury standard?

Under the noxious weed authority under the PPA, APHIS must clarify that indirect effects, such as economic injury due to biological contamination, be evaluated and regulated in the final regulations. To limit the new regulations otherwise would be arbitrary, capricious, an abuse of discretion, and not in accordance with the PPA.[94]

2. APHIS Should Address Economic Impacts Under Noxious Weed Authority

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."[95] In fact, seven of nine introductory findings of the PPA focus on preventing burdens on commerce and the economy.[96] Additionally, the definition of noxious weed provides authority to the agency to

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[91] *See e.g., Geertson Seed Farms,* 2007 WL 518624 at *7- 10 (holding that biological contamination, interrelated economic impacts, and the development of herbicide-resistant weeds are significant environmental impacts).
[92] 73 Fed. Reg. 60014.
[93] Id.
[94] Administrative Procedure Act ("APA"), 5 U.S.C. § 706.
[95] 7 U.S.C. § 7701(1) (emphasis added). The ultimate goal – contained in the second half of the first finding – is the protection of US agriculture and economy. Id. The means to this goal – contained in the first half of the first finding – is the prevention and spread of plant pests. Id.
[96] The findings state, for example: "detection . . . of plant pests . . . is necessary for the protection of the . . . economy," 7 U.S.C. § 7701(1); "decisions affecting imports, exports, and interstate commerce in agricultural products . . . shall be based on sound science," 7 U.S.C. § 7701(4); "the smooth movement of . . . plant products . . . is vital to the United State's economy," 7 U.S.C. §

assess a GEO's ability to "directly or indirectly injure or cause damage to crops … other interests of agriculture, . . . the public health, or the environment ."[97] As a result, to properly assess any GEO under its noxious weed authority, APHIS must thoroughly assess how a GEO may "damage" U.S. agricultural interests.[98] This should include a mandatory review of how the commercial introduction of a GEO or possible low-level contamination of any commodity with the GEO from a proposed field trial will impact the U.S. agricultural economy. A number of such contamination events – StarLink corn, LL 601 rice, and Bt10 corn for example – have already caused significant damage to the US agricultural economy. Analysis of this potential impact should be completed before allowing any planting, and should be used as part of the agency's assessment of whether or not to issue a field trial permit for, and if so under which particular gene containment standards (more or less rigorous), or deregulate, a GEO. Failure to do so would violate the intent and plain meaning of the PPA, and would be arbitrary, capricious, an abuse of discretion, and not otherwise in accordance with the PPA.[99]

3. APHIS Should Comprehensively Address Human Health Impacts Under Noxious Weed Authority In Order to Protect Public Health and the Economy of the United States

Under its noxious weed authority, APHIS must address human health impacts, but fails to sufficiently do so under its newly proposed regulations. One of the main goals of the PPA is "the control . . . of noxious weeds [] necessary for the protection of the agriculture, environment, and economy of the United States."[100] Under the noxious weed authority, the PPA further defines the PPA's goals to include the protection of human health, by defining a noxious weed as "any plant or plant product that can directly or indirectly injure or cause damage to . . . the public health."[101] Thus, APHIS must affirmatively investigate potential adverse health effects of newly proposed GE crops under the noxious weed authority. Additionally, given that GE crops have the potential to negatively affect the economy, particularly where they may be found to have adverse health effects, it is incumbent on APHIS to require evaluation of potential human health effects of new GE crops before they are released into the environment, either through permits or deregulation. Moreover, the definition of a noxious weed as any plant that can "injure or cause damage to .... the public health" indicates that for the first time the U.S. should require human

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7701(5); export markets could be severely impacted by the introduction or spread of plant pests or noxious weeds," 7 U.S.C. § 7701(6).

[97] "The term 'noxious weed' means any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment" 7 U.S.C 7702(10).

[98] Id.

[99] 5 U.S.C. § 706. In *Geertson Seed Farms*, the court held that economic impacts from biological contamination be considered when conducting environmental review. 2007 WL 518624 *7-8.

[100] 7U.S.C. 7701(1).

[101] "The term 'noxious weed' means any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment" 7 U.S.C 7702(10).

health safety testing prior to the introduction of any GEO into the environment or commerce. APHIS acknowledged this when it announced the Draft EIS in preparation for these rules:

> The noxious weed provision would allow oversight of genetically engineered plants by explaining the scope of what is regulated and by allowing a broader consideration of potential risks, including risks to public health. This would allow APHIS to consider what is known about the potential hazards of the introduced proteins and other substances to humans for animals, if inadvertently consumed or released.[102]

APHIS further stated in the DPEIS that utilizing the noxious weed authority would allow it to consider human health effects before deregulating a GEO.[103] The newly proposed regulations fall short, however. While APHIS indicates that it must evaluate adverse human health effects – "When evaluating whether a particular GE plant may be a noxious weed because it poses a public health risk when growing in the environment, APHIS considers toxicity and other food safety information" – it rejects the notion of evaluating food safety – "APHIS would not assess the safety of the GE plant for human or animal consumption."[104]

Without evaluating human health effects, APHIS fails to comply with its noxious weed authority.[105] Such a limitation would be arbitrary, capricious, an abuse of discretion, and not in accordance with the PPA.[106] This is all the more true because, while FDA may have more expertise in assessing and implementing a system to evaluate the human health safety of new GEOs, the agency has failed to do so and only provides limited voluntary safety oversight.[107] Given this situation, USDA should revise its proposed regulations to clarify that a mandatory human health safety assessment be a part of evaluating whether newly proposed GE crops. This regulation and review process should be no less stringent than the most stringent of the safety assessment procedures for any particular test or procedure established by joint consultations of the Food and Agriculture and World Health Organizations or by Codex Alimentarius.[108]

4. APHIS Should Apply Its Noxious Weed Authority To Herbicide Tolerant Crops

As CFS argued in comments on the DPEIS, the most prevalent category of GE plants – herbicide-tolerant ("HT") crops engineered to survive direct application of one or more herbicides – are appropriately assessed only in conjunction with the herbicide that is invariably

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[102] DEIS, 72 Fed. Reg. 39023.
[103] DPEIS at 21.
[104] 73 Fed. Reg. 60014.
[105] 7 U.S.C. 7702(10).
[106] 5 U.S.C. § 706.
[107] 57 Fed. Reg. 22984 (May 29, 1992).
[108] FAO/WHO (2000). "Safety Aspects of Genetically Modified Foods of Plant Origin," Food and Agriculture Organization and World Health Organization, 2000, Geneva, Switzerland; FAO/WHO (2001). "Evaluation of Allergenicity of Genetically Modified Foods," Food and Agriculture Organization and World Health Organization, January 2001, Geneva, Switzerland; "Codex Alimentarius Commission (2003). "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants," CAC/GL 45-2003.

used with them, that is, as HT crop systems. We urge APHIS to regulate HT crop systems under its noxious weed authority for their potential to harm the interests of agriculture, the environment, and public health.[109]

HT crop systems exhibit considerable and growing adverse effects on the interests of agriculture, the environment, and possibly public health. These effects include:

1) Dramatically increased use of the major HT crop-associated herbicide, glyphosate;
2) The extremely rapid emergence of weeds resistant to this herbicide, which experts agree is directly attributable to widespread and unregulated use of this HT crop system, known as the Roundup Ready crop system, on over 148 million acres (2008);
3) Increasing use of toxic herbicides other than glyphosate to control resistant weeds directly attributable to unregulated use of the Roundy Ready crop system;
4) Increased soil erosion from use of mechanical tillage as another means to control resistant weeds;
5) Increased costs to growers from measures required to control resistant weeds; and
6) Increased residues of one or more herbicides on HT crops.

In our DPEIS comments, we cited leading agronomists and weed science experts to document these effects, and their serious nature. We also noted that APHIS's treatment of GE herbicide-tolerant plants in the DPEIS was completely inadequate, barely more than two pages in length for a class of GE crops that comprises roughly 80% of all GE crops presently grown. In particular, APHIS arbitrarily and capriciously ignored the growing harms to American agriculture from glyphosate-resistant weeds. Rather than discuss even a single study from the vast literature published since the year 2000 on this topic, when the rapid emergence of herbicide-resistant weeds began, APHIS referred only to a handful of studies authored from 1993 to 1998, before the threat emerged.

Since providing our comments on the DPEIS, there is updated information concerning herbicide use in US agriculture. In Appendix 2 of these comments, we provide updated information on the USDA National Agricultural Statistics Service's (NASS) survey of pesticide use on cotton for 2007, which found a dramatic 24% increase in the overall amount of herbicides applied per acre of upland cotton from 2005 to 2007 (2.07 lbs/acre to 2.56 lbs./acre). This dramatically increased herbicide use is likely attributable to the need to control glyphosate-resistant weeds. In just the past year, a glyphosate-resistant version of a particularly nasty weed (pigweed) originally identified in Georgia has rapidly emerged in cotton and soybean fields in mid-South cotton-growing states like Arkansas and Tennessee, a development that weed expert Larry Steckel of the University of Tennessee fears could "run us out of [growing] cotton."[110] Eminent North

[109] We incorporate by reference our extensive discussion of HT crop systems from our comments on the DPEIS CFS Comments at 5-34. Additionally, in Appendix 1 we provide corrections to those comments.

[110] Bennett, D (2008). "Resistant pigweed 'blowing up' in mid-South," Delta Farm Press, July 30, 2008.

Carolina weed scientist Alan York has called glyphosate-resistant weeds "potentially the worst threat [to cotton] since the boll weevil."[111]

One major risk factor for more rapid spread of resistant weeds is the skyrocketing use of GE corn varieties with the Roundup Ready (glyphosate-tolerance) trait. This is because over 90% of soybean and cotton acres in the US are already planted to Roundup Ready varieties, corn is often grown in rotation with soybeans, and continual heavy use of glyphosate year after year on both soybeans and corn generates additional "selection pressure" that accelerates the development and spread of glyphosate-resistant weeds, as well as weed shifts to types of weeds naturally more resistant to glyphosate.

According to Monsanto's "trait acreage" figures, the area planted to Roundup Ready corn in the US increased from just 7.8 million acres in 2002 to 32.7 million acres in 2006. Just two years later, in 2008, US Roundup Ready corn acreage more than doubled to 68.2 million acres.[112] Overall in 2008, acreage planted to Roundup Ready crops (corn, soybean, cotton and canola) reached 148.7 million acres, up a massive 30% from 114 million acres in 2006.

Recent information indicates that the incidence of herbicide tolerant weeds is rapidly increasing, and therefore APHIS must take action to assert its regulatory authority to prevent the increasing associated risks. Glyphosate-resistant weeds continue to spread thanks to the unregulated expansion of Roundup Ready crop systems. Of the 38 reports of documented glyphosate-resistant weeds in the US since 1998, seven (18%) were reported in 2007 or 2008.[113] Significantly, these seven included two reports of weed species for which glyphosate-resistant biotypes had never been reported before in the US: glyphosate-resistant hairy fleabane in California in 2007, and glyphosate-resistant Johnsongrass in Arkansas and Mississippi in 2008.

Glyphosate-resistant Johnsongrass is especially concerning. Johnsongrass is a perennial plant that is already (even without resistance to glyphosate) considered the world's sixth worst weed.[114] It has been listed as a "noxious weed" or given similar status in 19 states.[115] A single Johnsongrass plant can produce up to 80,000 seeds and 212 fee of rhizomes (reproductive root parts) per season. Johnsongrass can spread not only by seed, but by rhizome. Tillage to kill the weed cuts up its extensive underground rhizome network and thus propagates it. Johnsongrass has been reported to reduce the yield of corn from 80-100 bushels to 20 bushels per acre, and sometimes causes complete crop failure. Under certain environmental conditions, Johnsongrass can produce toxic quantities of prussic acid, which is hazardous to foraging livestock.[116]

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[111] Unfortunately, USDA NASS did not report herbicide use on soybeans or corn for 2007.
[112] "Monsanto Biotechnology Trait Acreage: Fiscal Years 1996-2008," updated October 8, 2008. Note that one must add up the acreage planted to different forms of Roundup Ready corn.
[113] At www.weedscience.com, see Glycines (i.e. glyphosate) list under Herbicide Mode of Action.
[114] Franz, JE, Mao, MK and JA Sikorski (1997). "Glyphosate: A Unique Global Herbicide," American Chemical Society Monograph 189, Washington, DC, 1997, p. 14. The authors are listed as Monsanto employees.
[115] http://plants.usda.gov/java/profile?symbol=soha.
[116] Franz et al (1997) at 3-5.

In Missouri and many other states, Johnsongrass has been declared a noxious weed by state law, and there is a duty imposed on every owner of lands to eradicate this weed and to prevent seed production.[117]

Arkansas weed scientist Bob Scott identifies the heavy use of Roundup Ready crop systems (Roundup Ready crop and linked use of Roundup herbicide) as the cause for development of a glyphosate-resistant version of this already noxious weed in his state:

> We're not trying to push resistance in these weeds," says Bob Scott, Arkansas Extension weed specialist. "But there's close to 5 million acres of Roundup Ready crops that get two or three applications of Roundup every season. Plus, we're using Roundup as a burndown. It's inevitable that such weeds are produced. It's hardly a surprise.[118]

Glyphosate-resistant Johnsongrass was first identified in Argentina in 2005, and was reported on 120,000 hectares (300,000 acres) in 2006. Agronomists there predict that the spread of glyphosate-resistant Johnsongrass could increase agricultural production costs by $160 million to $950 million per year.[119] The rapid spread of glyphosate-resistant Johnsongrass is clearly linked to the massive and unregulated use of Roundup Ready sobyeans in Argentina, where they comprise nearly 100% of the soybeans grown there. Very similar conditions obtain in the US, where over 90% of soybeans are Roundup Ready, plus large percentages of cotton and corn. Thus, glyphosate-resistant biotypes of this noxious weed will likely spread in the United States as well.

We emphasize that glyphosate-resistance will render this already noxious weed still more noxious – more difficult and expensive to control, more damaging to the interests of American agriculture, and also in certain circumstances pose a threat to foraging livestock. The advent of the first glyphosate-resistant noxious weed in the US, directly attributable to the unregulated use of Roundup Ready crop systems, is still another reason for APHIS to exercise its noxious weed authority to assess, and regulate as needed, HT crop systems for noxious weed risk.

NEW CONDITIONAL EXEMPTION PROCESS CREATES END-RUN AROUND DEREGULATION

The process concerning the new conditional exemption creates a potential legal end-run around the deregulation process. The legal requirements under both provision are literally identical (compare §§ 340.5 & 340.6), with the exception that proposed process for "petition for new conditional exemptions from the requirement for a permit" requires a description of proposed conditions associated with the 'exemption', (§ 340.5(b)(1)(iv)), and includes a process to amend those conditions (§ 340.5(d)). Furthermore, the legal standards for evaluating a petition for

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[117] Id. at 3.

[118] Bennett, D. (2008). "Glyphosate-resistant johnsongrass in Mid-South, Delta Farm Press, March 19, 2008. http://deltafarmpress.com/soybeans/johnsongrass-scott-0319/.

[119] Romig, S. (2007). "Roundup resistant weeds spreading in Argentina," Dow Jones Newswire, Sept. 26, 2007. http://www.lasojamata.org/?q=node/77.

deregulation and a petition for conditional exemption are functionally the same.[120]

Furthermore, once a GEO has been granted a conditional exemption under § 340.5, the exemption and its conditions may be amended at any time, apparently **without any further notice and comment or public process** (§ 340.5 (d)). Thus, the conditional exemption process, as set up, stands to become a legal end-run around the deregulation process set up in § 340.6. For example, an applicant could choose to pursue a conditional exemption under proposed § 340.5 instead of a full deregulation under § 340.6, and then later have the conditions eliminated, or changed to an extent that they become meaningless, through the amendment process provided in § 340.5 (d). Although this section requires that "[t]he amendment conditional exemption and the reasons for it will be published in the **Federal Register**,"[121] there is not public process for farmers, consumers, or consumer advocacy groups to review and comment on the changes before they happen.

From a policy standpoint, adopting the newly proposed conditional exemption would be absurd. Applicants could obtain a conditional exemption with rigorous conditions, only to later downgrade those conditions under the radar screen of public scrutiny, and achieve the same lack of regulatory oversight achievable through the deregulation process. Legally, adoption of such a system would be a plain violation of fundamental tenants of American administrative law by short-circuiting the clear statutory notice and comment requirements of the Administrative Procedures Act.[122]

APHIS'S PREEMPTION PROVISION MUST BE CLARIFIED TO NOT INTERFERE WITH STATE AND LOCAL LAWS REGULATING GEOS GENERALLY

On November 10, 2008, APHIS proposed a last minute change to its proposed rules concerning the preemption of state and local laws, just two weeks before the original comment deadline.[123] After reviewing this last minute proposed rule change, CFS submitted a letter to Charles D. Lambert, Acting Under-Secretary for Marketing and Regulatory Programs, on November 14, 2008, requesting an extension of the comment period so that CFS could analyze the potential affect of this rule change. CFS received no response to this letter.

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[120] The legal standard for determining whether to deregulate a GEO under proposed § 340.6(b)(4) – "whether the GE organism is unlikely to be a plant pest or noxious weed" – is substantively no different than the legal standard for determining whether to approve a conditional exemption under § 340.5(b)(4) – whether the GE organism "would be unlikely to result in the introduction or dissemination of a plant pest or noxious weed." While the proposed standard for deregulations under § 340.6(b)(4) appears more direct, the proposed standard for conditional exemption approval under § 340.6(b)(4) is functionally equivalent, because in order to evaluate whether a conditional permit exemption "would be unlikely to result in the introduction or dissemination of a plant pest or noxious weed," APHIS must consider whether the species in question is in fact "unlikely to be a plant pest or noxious weed." Thus functionally they are the same.

[121] 73 Fed. Reg. 60046.

[122] 5 U.S.C. § 553.

[123] 73 Fed. Reg. 66563.

CFS requests APHIS to clarify that this preemption provision, which states that "all State and local laws and regulations that are inconsistent with this rule will be preempted,"[124] does not and will not preempt state and local laws designed to protect existing agricultural markets, and will not prevent enactment of GEO ordinances or rules that govern the planting of GE crops beyond the PPA's plant pest or noxious weed context. For example, California adopted the Rice Certification Act of 2000 (HB2622) to regulate rice that has "characteristics of commercial impact." The purpose of the act is to protect California rice from to protect from characteristics that "may adversely affect the marketability of rice in the event of commingling" with rice varieties "that create a significant economic impact in their removal from commingled rice, and those characteristics whose removal from commingled rice is infeasible."[125] Similarly, the state of Arkansas has adopted the Arkansas Rice Certification Act (HB2574) to regulate rice with "characteristics of commercial impact." These characteristics include those "that may adversely affect the marketability of rice in the event of commingling with any other rice [and]…that cannot be identified without the aid of specialized equipment or testing."[126] Additionally, several counties in California and Hawaii, and several cities across the United States have adopted GE crop restrictions.[127] Some of these laws have been in place and enforced since 2004 and should similarly not be preempted.

Under the PPA, APHIS is given narrow jurisdiction to regulate the movement of "plant pests"[128] and "noxious weeds."[129] The PPA does not regulate GE crops generally, and in fact there is no reference to "genetically engineered" organisms or equivalent terms in the PPA at all. The preemption provision contained in the PPA is similarly narrow, applying only where the Secretary of the USDA "has issued a regulation or order to prevent the dissemination of the biological control organism, plant pest, or noxious weed."[130] Furthermore, when this issue was

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[124] Id.

[125] The Act provides for regulation and potential certification of GE rice varieties. Cal. [Food & Agric.] Code § 55000 to 55108.

[126] The Act allows the State Plant Board to prohibit or place restrictions on the "selling, planting, producing, harvesting, transporting, storing, processing, or other handling" of such rice. Ark. Code Ann. §2-15-201 to 2-15-208 (2005), available at http://www.arkleg.state.ar.us/ftproot/acts/2005/public/act1238.pdf.

[127] See e.g., Trinity County Health and Safety Code § 8.25.030 ("It is unlawful for any person to propagate, cultivate, raise, or grow genetically engineered organisms in Trinity County); Mendocino County Code § 10A.15.020 ("It shall be unlawful for any person, firm, or corporation to propagate, cultivate, raise, or grow genetically modified organisms in Mendocino County"); Marin County Code § 6.92.020 ("It is unlawful for any person or entity to propagate, cultivate, raise, or grow genetically modified organisms in Marin County"); Hawaii County Bill 361.

[128] 7 U.S.C. § 7711.

[129] 7 U.S.C. § 7712.

[130] 7 U.S.C. § 7756(b)(1) ("no State or political subdivision of a State may regulate the movement in interstate commerce of any article, plant, biological control organisms, plant pest . . . **if the Secretary has issued a regulation or order** to prevent the dissemination of the biological control organism, plant pest, or noxious weed with the United States." (emphasis

brought to the Congressional Research Service ("CRS") in 2004, when the state of Vermont was considering legislation to restrict the use of GE crops, CRS issued a legal opinion concluding that such a restriction on GE crops would not be preempted by federal law, finding that such a moratorium would not interfere with any federal legislation: "**It does not appear that Congress has directly spoken on the issue of GE seeds or particularly the prohibition of their planting. Nor does it appear that any federal agency has regulated the planting of GE seeds**."[131]

Thus, APHIS's federal authority under the PPA is narrowly applicable to whether whether GEOs are plant pests or noxious weeds, and should not preempt state laws designed to protect the marketability of crops or to protect a state or local jurisdiction from imposing general GEO restrictions. APHIS must be explicit about the scope of its proposed preemption provision to avoid confusion and/or legal conflict in the future.

APHIS' PROPOSED REGULATIONS MUST COMPLY WITH 2008 FARM BILL REQUIREMENTS

With the passage of the 2008 Farm Bill, Congress mandated APHIS to make specific regulatory changes to "improve the management and oversight of certain regulated articles."[132] While the newly proposed regulations governing 'Certain GE Organisms' include some of the required improvements, such as a record retention requirement, the new rules fail to incorporate many of the required improvements.

Farm Bill Section 10204 (a)(1) requires APHIS "to take action on each issue identified in the document entitled 'Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework,' dated October 4, 2007. "Lessons Learned" was prepared in the wake of the 2006 'Liberty Link' rice contamination incident, and suggests new measures that APHIS should included in its regulations to avoid the pitfalls it discovered during the rice investigation.[133] Farm Bill Section 10204 (b) requires the Secretary to take nine actions to make the improvements suggested in 'Lessons Learned.' Farm Bill Section 10204 (c) requires the Secretary to consider ten additional improvements. The following is list of actions addressed in 'Lessons Learned' and/or required by Farm Bill Section 10204 that APHIS failed to incorporate into the newly proposed regulations. Adoption of final rules that fail to comply with Farm Bill

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added).)

[131] Congressional Research Service, Memorandum: Constitutionality of a State-Wide Moratorium of the Planting of Genetically Engineered Seeds, February 6, 2004 (emphasis added) (Attached hereto).

[132] Food, Conversation, and Energy Act of 2008, Pub. L. No. 110-246, § 10204, 122 Stat 1651 (June 18, 2008) (Hereinafter "Farm Bill Section 10204").

[133] USDA, "Lessons Learned and Revisions under Considerationfor APHIS' Biotechnology Framework," (Hereinafter "Lessons Learned") available at http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/LessonsLearned10-2007.pdf.

Section 10204 would be arbitrary, capricious, an abuse of discretion, and not in accordance with the law.[134]

1. Availability of Representative Samples:

In the rice investigation, the effort to test for biological contamination was hampered by the unavailability of representative seed samples. Thus, USDA suggested "Revising 7 CFR 340 to require that representative samples of events introduced must be retained by permit and notification holders for a designated period of time."[135] Farm Bill Section 10204(b)(2) requires inclusion of "representative samples." Farm Bill Section 10204(c)(1)(B) requires the Secretary to consider establishing a means to identify regulated articles (including retention of seed samples). The newly proposed regulations do not contain such an improvement and therefore violate the plain meaning of Farm Bill Section 10204.

2. Contingency Plan

In its rice investigation, APHIS found that researchers and developers were unclear about their responsibilities in the event of unauthorized releases. Thus, USDA suggested, "requiring that the applicant submit a contingency plan with their permit application that addresses the unauthorized release of regulated articles to include dispersal, commingling, and persistence due to climate, animal incursion, or human error."[136] The newly proposed regulations merely require permits to include a "Description of the contingency plans associated with the release" (7 CFR 340.2(c)(3)(iii)(F)). However, this requirement is vague, overbroad. It fails to even describe what contingencies the plan is to be formulated for. It also fails to include the specifics outlined in "Lessons Learned," namely that such a plan address dispersal, commingling, and persistence due to climate, animal incursion, or human error.

3. Gene-Specific Testing Procedures; Molecular Forensics

Due to difficulties in determining proper testing procedures during the rice investigation, USDA stated that APHIS should consider "whether a permit holders . . . have gene-specific testing procedures needed to identify regulated articles in the event of an unauthorized release."[137] USDA also stated that it must "assure that the sampling and testing of all physical seed samples meet scientifically sound sampling and testing protocols."[138] Furthermore, Farm Bill Section 10204(b)(5) requires inclusion of "protocols for conducting molecular forensics." However, the newly proposed regulations do not contain any gene-specific testing protocols for any requirements whatsoever concerning molecular forensics.

4. Corrective Action Plan

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[134] APA, 5 U.S.C. § 706.
[135] Lessons Learned at 2.
[136] Id.
[137] Id.
[138] Id. at 3.

In past unauthorized release events, APHIS claims it was delayed in responding because it did not have the technical expertise that researchers and developers possess. Thus, USDA explored revising 7 CFR 340, "requiring applicants to submit a comprehensive action plan for any incident in which viable regulated articles could persist in the environment or in the seed, food, or feed supply following an incident."[139] Farm Bill Section 10204(b)(4) requires the Secretary to take actions to enhance "corrective actions in the event of an unauthorized release." The newly proposed regulation merely permits the Administrator "to require corrective action plans" as an enforcement measure, but fails to make the requirement a mandatory part of the permitting process (Proposed § 340.7(e)(2))

5. Contractual Relationships

USDA acknowledged that APHIS investigations have been hindered by incomplete access to agreements made between researchers/developers and other parties. Thus, APHIS has explored "revisions to 7 CFR 340 to require certain business agreements made among GE technology researchers or developers and other parties regarding regulated articles to be in writing," with provisions including "duration of the agreement, ownership of regulated materials, genetic events involved, and other items that ma be deemed critical as BRS revises this regulation."[140] Additionally, Farm Bill Section 10204(b)(6) requires the Secretary to take actions that enhance "clarity in contractual agreements." The newly proposed regulations, however, fail to include these requirements.

6. Isolation Distances

During recent investigations, APHIS continues to confront the critical issue of isolation distances between experimental crops and nearby field crops to prevent biological contamination. USDA stated that it is "essential to incorporate the latest scientific information into APHIS' regulatory requirements to maximize confinement of regulated articles."[141] Farm Bill Section 10204(b)(7) requires the Secretary to take actions that enhance "the use of the latest scientific techniques for isolation and confinement distances." Farm Bill Section 10204(c)(1)(C) requires the Secretary to consider establishing "standards for isolation and containment distances." The newly proposed regulations fail to include any such requirements. The regulations merely require that permit holders follow required isolations, but do not set any standards whatsoever to establish what those isolations might be (Proposed 7 CFS 340.3(a)(4)(i)(C)).

APHIS MUST FULLY IMPLEMENT KEY RECOMMENDATIONS OF USDA'S OFFICE OF INSPECTOR GENERAL TO PREVENT CONTAMINATION EPISODES

The Office of Inspector General (OIG) made 28 recommendations to improve APHIS's operations, in particular to improve gene containment and so prevent the unauthorized presence of GE crops in commercial seeds, grain and food products to the greatest extent possible.[142] The

[139] Lessons Learned at 2.
[140] Id. at 3.
[141] Id.
[142] OIG (2005). "Audit Report: Animal and Plant Health Inspection Service Controls Over

OIG refused to accept, in full or in part, APHISs' responses to 9 of the 28 recommendations.[143] Below, we describe these disputed recommendations, and also examine whether APHIS has complied with them in the proposed rule.

1. Permit Conditions

Three OIG recommendations (10, 11 and 12) urged APHIS to require submission (10), APHIS review (11) and distribution to inspection officers (12) of written protocols for all field trials of regulated GE crops. APHIS disagreed with these recommendations, maintaining that it "does not feel it is warranted to require or review written protocols prior to approval of field tests." OIG did not accept APHIS's position, and insisted that APHIS comply.

In the proposed rule, APHIS requires submission of a "description of the site management practices and control procedures designed to make it unlikely that there will be unauthorized introduction or dissemination of the GE organism beyond the proposed area and the permit time frame of the release" (340.2(c)(3)(iii)). More specificity would be desirable to fully comply with OIG's recommendation 10 for submission of "written protocols" prior to approval of the field test. More importantly, APHIS should set "zero tolerance" of contamination as its management goal, rather than procedures designed to make contamination merely "unlikely." One can set high standards, while recognizing they will never be fully achieved in practice. Making the "unlikely" standard the **bar** to which APHIS aspires has thus far not proven adequate to achieve adequate containment of experimental GE crops.

APHIS has complied with OIG recommendation 11 requiring review of permit conditions (340.2(d)(3)). However, APHIS does not propose to "distribute written [field trial] protocols to PPQ [inspection] officers to use in conducting inspections of field test sites…" as per OIG recommendation 12. Instead, APHIS merely notes that inspectors have the right of inspection (340.2(d)(5)) and that inspectors shall "have access to" records maintained by the permit holder (340.7(b)). OIG pointedly rejected APHIS's explanation that inspectors already have access to records, and demanded instead that APHIS provide them with written protocols before the inspection, as a prerequisite for conducting a thorough inspection.

a. Reporting Requirements

Four OIG recommendations (6, 23, 24 and 26) related to reporting issues. OIG recommended that APHIS require field trial operators to submit planting notices, 4-week/28-day reports and harvest/termination reports (6) for all field trial notifications and permits; impose sanctions for missing or late progress reports (23); require applicants to report planned date of disposal of pharma crop harvests (24); and require reporting of the date, amount and final disposition of pharma crop harvests (26). APHIS did not agree with these recommendations; OIG rejected APHIS's objections and insisted that APHIS comply.

Issuance of Genetically Engineered Organism Release Permits," Office of Inspector General, Southwest Region, USDA, Audit 50601-8-Te, December 2005.

[143] Id. (Recommendation Nos. 5, 6, 10, 11, 12, 15, 23, 24 and 26).

In the proposed rule, APHIS does not comply with many of the OIG's recommendations. For instance, APHIS does not require permit holders to submit planting notices for the majority of field trials (permit categories A and B), but rather only for those few that fall under categories C and D (340.3(a)(4)(iii)(F)).[144] Likewise, APHIS does not comply with OIG's recommendation that termination (i.e. harvest) reports be submitted in a timely manner. APHIS does not require submission of a termination report by any particular date (340.3(a)(4)(iii)(E)), while OIG had expressly stated that termination reports submitted 6 months after harvest were not timely. While APHIS does ostensibly comply with OIG's recommendation that all field trial operators submit 28-day reports with the location and number of GE organisms planted, it is important to note that this requirement only applies to the first GE plants released (i.e. planted) under the permit.

340.3(a)(4)(iii)(D) states: "Within 28 days after the ***initiation*** of the release, the responsible person shall report to APHIS in writing the final release site coordinates; number of GE organisms actually released; ***any information related to the expected date(s) and quantities of GE organisms for <u>subsequent</u> planned releases to be done under this permit.***"[145]

Since a single permit often applies to several or even dozens of separate releases of the GE plants in several to dozens of different states, ***in many cases APHIS will lack basic information concerning the precise location and number of GE plants released in some or even the great majority of field trial locations.*** We note also that the phrase "any information" suggests that even information on "***expected*** dates and quantities of GE organisms for subsequent planned releases" need not be supplied if the responsible person does not have it available. This is clearly unacceptable. APHIS should specify that permit holders provide precise information on location and number of GE organisms for ALL releases done under the permit, not just the initial one.

APHIS fails to comply with two OIG recommendations specific to pharma crops. Nothing in the proposed rule requires that pharma crop permit holders report the planned date of disposal of pharma crop harvests (24), or report the date, amount and final disposition of pharma crop harvests (26). The OIG made these recommendations because of the sensitive nature of drug-containing crop material, and its audit discovery that APHIS had been completely ignorant of the disposition (and even existence) of a total of two tons of pharma crop harvests that had been in storage for over a year in two separate locations. Instead, APHIS merely reserves the right to assign additional permit conditions to address "nonliving materials associated with or derived from GE plants when such conditions are needed to make it unlikely that the nonliving materials would pose a noxious weed risk" (340.3(b)). If the pharmaceutical crop harvest is comrpised of unprocessed seeds, it might be considered live material and thus not even subject to this optional permit condition process. This obviously does not comply with OIG's recommendations. Instead, APHIS should specifically require submission of the reports requested by OIG, at least for category C and D permits that will most often be applied to pharma crop field trials.

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[144] Note that APHIS has likened the least stringent permit category (A) in the proposed rule to notification field trial permits issued under current regulations, which comprise upwards of 90% of field trial permits.

[145] 73 Fed. Reg. 60044 (emphasis added).

Similarly, APHIS's generic compliance and enforcement provisions (340.7) contain no specific provision to comply with OIG's recommendation (23) that APHIS impose sanctions for missing or late progress reports. This is a serious deficiency given the massive non-compliance with reporting requirements discovered by the OIG in its audit.

b. Other OIG recommendations

APHIS appears to have taken no action in the proposed rule on OIG recommendation 5 to restrict public access to edible GE crops, based on the risk posed by the type of crop. We also find no provisions in the proposed rule to address OIG recommendation 15, relating to development of written policies on risk-based selection of field test sites for inspection. APHIS could perhaps comply with this latter recommendation by prioritizing inspections of field trials conducted under higher-risk category permits (C and D).

APHIS SHOULD MAINTAIN THE PRESCRIPTIVE CONTAINER REQUIREMENT SYSTEM

The newly proposed regulations change the container requirements for shipment of regulated GE organisms from the current prescriptive system to performance-based standards. The newly proposed rules now merely require that containers are "of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation."[146]

The purpose of prescriptive container requirements is to prevent environmental release of regulated GEOs. If APHIS had a track record of successfully verifying that applicants were meeting such performance standards, then such performance based standard may be acceptable. A performance-based system without oversight, as proposed here, amounts essentially to "self-certification" by applicants as to the adequacy of their containers, and APHIS has a track record of failing to verify such self-certification systems, thus it should not and enforce such performance based

The USDA Office of the Inspector General criticized USDA for just such "self-certification" of compliance with performance standards in the context of APHIS' notification permit system.

> "Performance-based regulatory standards set objectives and desired outcomes without specifying how they are to be achieved, thus giving approved applicants the flexibility to determine how these objectives/outcomes can be met. ***APHIS is relinquishing its regulatory responsibility in favor of self-certification by the notification applicants—namely the applicants merely certify in their notification applications that they will meet the performance standards. Yet, in 2001, APHIS' own survey of notification protocols found that some protocols may not be adequate to meet the field test performance standards.*** Without documented approved protocols, APHIS has no basis to determine if the applicant's procedures meet the performance standards. To reach

[146] 73 Fed. Reg. 60039.

> management decision, APHIS needs to provide its science-based support for its policy that written protocols will not be required or reviewed prior to approval of field tests."[147]

The situation here is exactly analogous. "Self-certification" is unacceptable, and therefore APHIS's proposed performance based standards for containers should not be adopted. APHIS should therefore adopt Alternative 3 from the DPEIS, and maintain the prescriptive system, with the proviso that it should reject variance requests where they are an excessive burden on its staff resources.

APHIS SHOULD REGULATE BIOLOGICAL CONTROLS

CFS applauds APHIS decision to regulate biological control organisms not already regulated by EPA, such as the pink bollworm and future GE plant BCOs.[148] Regulating GE biological control organisms is critical because they may harm the environment. Biological control species typically harm some organisms, in particular their target pests, but also may harm non-target species. The properties that make biological control organisms effective may increase the likelihood that they will also harm some non-target organisms. Genetic engineering to enhance the virulence, aggressiveness, or survival of biological control organisms may cause harm by unintentionally increasing host or geographic range.[149] Also, many biological control organisms can survive and reproduce in the environment. It is therefore crucial that APHIS maintains this provision to regulate BCOs under the newly proposed rules.

CHANGES TO DEFINITIONS

The newly proposed regulations contain definition that are vague, or have been altered to make their application less effective. We urge APHIS to make the following definitional corrections to clarify ambiguity and to maintain strong regulatory oversight.

Contained facility, contained structure. As proposed, contained facility or contained structure would be defined as "A physical structure designed to minimize release into the outdoor environment."[150] This definition is overly vague, and hinges on the performance standard "minimize release." The definition should be more specific about the physical nature of such a facility or structure to explicitly state that it is a "fully enclosed" structure designed to minimize release.

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[147] APHIS Audit, p. 22, emphasis added.
[148] 73 Fed. Reg. 60015.
[149] Chet I. and Inbar J. (1994) Biological control of fungal pathogens. Appl Biochem Biotechnol. 48(1):37-43; Maeda S., Volrath S.L., Hanzlik T.N., Harper S.A., Majima K, Maddox D.W., Hammock B.D., and Fowler E. (1991) Insecticidal effects of an insect-specific neurotoxin expressed by a recombinant baculovirus. Virology 184(2):777-80; St. Leger R.J., Lokesh, J., Bidochka M.J., and Roberts D.W. (1996) Construction of an improved mycoinsecticide overexpressing a toxic protease. Proc. Natl. Acad. Sci. U S A. 93:6349-6354.
[150] 73 Fed. Reg. 60039

Release into the environment. The newly proposed definition of "release into the environment" is "Dispersal beyond the constraints of a contained facility or secure shipment." The term "dispersal" is vague and over narrow. The current § 340.1 definition of defines "release into the environment" as "the use of a regulated article outside the constraints of physical confinement..." The current definition is also overly narrow because it limits "release" to "use." The newly proposed definition, however, is overly vague because the term "dispersal" is unclear. Thus, APHIS should modify the definition of "release into the environment" should include the following action words to prevent a narrow or vague definition: "use," "dispersal," and "movement." Thus, APHIS should revise the definition to read: "release into the environment" is "dispersal, use and/or movement beyond the constraints of a contained facility or secure shipment."

CHANGES TO PERMIT REQUIREMENTS AND DEREGULATIONS

The newly proposed informational requirements to obtain permits for GEOs fail to include key informational requirements currently in place in 7 CFS 340. We urge APHIS to include the following requirements to keep the regulatory oversight and informational requirements at least as robust as current regulations: a description of the molecular biology of the GEO (7 CFR 340.4(6)), country or locality of donor/recipient organism or vector (7 CFR 340.4(7)), and purpose of GEO (7 CFR 340.4(8)). Crucially, the description of the final disposition of the regulated article (7 CFR 340.4(14)) is not included in the newly proposed regulations. However, this is crucial information that must be added back into the proposed regulations.

While the newly proposed informational requirements for deregulation of GEOs includes a detailed description of the phenotype of the GEO (proposed 7 CFR 340.6(b)(1)(iii)), it fails to require a detailed description of the genotype of the GEO as currently required (7 CFR § 340.6(C)(3)). This is crucial information to enable parties to track unintentional releases and contamination, and therefore must be included in the final regulations.

CONCLUSION

As discussed herein and in CFS comments on the Draft Programmatic EIS, the Center for Food Safety urges APHIS to reconsider its regulatory approach taken in the proposed rule and formulate a final rule that adequately protects the environment, the interests of agriculture, and public health in compliance with the Plant Protection Act, the Administrative Procedures Act, and the 2008 Farm Bill, and in accord with the Office of the Inspector General and National Academy of Science recommendations concerning the regulation of genetically engineered organisms.

Respectfully Submitted,

Kevin Z. Golden	Bill Freese
Staff Attorney	Science Policy Analyst

APPENDIX I - CORRECTIONS

We miscalculated the amounts of several herbicides used on major crops in the U.S. We reproduce the relevant sections of our comments with the corrected figures below. We note that these figures are based on the highest-quality data available on pesticide use in the U.S., collected by USDA's National Agricultural Statistics Service ("NASS").

"In 2006, 96.7 million lbs. of glyphosate were applied to soybeans alone, an astounding 28% increase from the previous year. Glyphosate use on corn has also increased rapidly, rising more than five-fold from 5.1 million lbs in 2002 to 26.3 million lbs in 2005, the latest year for which USDA statistics are available."[151]

USDA statistics on herbicide use demonstrate that farmers are in fact using both more glyphosate (see above) as well as increased amounts of other herbicides. For instance, 2,4-D is the second most-heavily used herbicide on soybeans (after glyphosate). From 2002 to 2006, while glyphosate use on soybeans increased by an astounding 29 million lbs (43% rise), 2,4-D use on soybeans more than doubled from 1.39 to 3.67 million lbs (a 164% increase). Clearly, glyphosate is not displacing 2,4-D.

Atrazine is the most heavily applied herbicide on corn, followed by acetochlor, S-metolachlor and metolachlor. At the same time that glyphosate use on corn climbed five-fold from 2002 to 2006, atrazine use rose by nearly 6.7 million lbs. (12% increase). While the use of acetochlor decreased by 8%, the amount of metolachlor/S-metolachlor applied rose by just over 6%. Use of the top four herbicides combined rose by nearly 6 million lbs (4.9%). Clearly, glyphosate is not displacing use of the top four corn herbicides. Such increased herbicide use constitutes a significant environmental impact that must be addressed in the PEIS."[152]

[151] CFS Comments at 16.
[152] Id. at 19.

Appendix 2

Genetically Modified (GM) Crops and Pesticide Use[153]

May 2008

Worldwide GM Crop Acreage By Trait or Trait Combination[154]

(expressed as % of total international GM crop acreage)

Trait(s)	1999	2005	2006
Herbicide tolerance (HT)	71%	71%	68%
Insect resistance (IR)	22%	18%	19%
HT and IR	7%	11%	13%
TOTALS	100%	100%	100%
HT alone or HT/IR	78%	82%	81%

- Herbicide-tolerance lends crops the ability to survive direct application of a broad-spectrum herbicide to kill nearby weeds. HT crops encourage greater and more indiscriminate use of weedkillers, and likely have higher levels of herbicide residues than conventional crops[155]
- 4 of every 5 acres of GM crops worldwide (81%) are modified for herbicide-tolerance
- Biotechnology companies have failed to introduce a single GM crop with increased yield potential, enhanced nutrition, drought-tolerance or salt-tolerance. Disease-resistant GM crops are practically non-existent.

[153] This is a revised and updated version of comments delivered at the August 1, 2007 meeting of the USDA's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21).

[154] International Service for Acquisition of Agri-biotech Applications (ISAAA). Note that biotechnology and agricultural chemical companies are major funders of ISAAA, and its statistics and analysis particularly with respect to GM crops in developing countries have been criticized for inaccuracies (see, for example, "Who Benefits from GM Crops?" Friends of the Earth International, 2006, at http://www.foei.org/en/publications/pdfs/gmcrops2006full.pdf). For 2006, see: http://www.isaaa.org/resources/publications/briefs/35/executivesummary/default.html

[155] For instance, EPA increased the tolerance for glyphosate residues on sugarbeet roots from 0.2 to 10 ppm at the request of Monsanto in 1999, the same year Monsanto gained USDA approval for commercial cultivation of glyphosate-tolerant sugarbeets. See "Glyphosate; Pesticide Tolerance," EPA Final Rule, Federal Register Vol. 64, No. 71, 18360-67, 4/14/99. For other examples, see Center for Food Safety's comments on USDA's Programmatic Environmental Impact Statement on GM crops, p. 60. http://www.centerforfoodsafety.org/pubs/USDA%20PEIS%20Comment%20Master%20FINAL%20-%209%2011%2007.pdf.

The 12 GM Crops Pending Deregulation (Commercial Approval) by USDA

(as of December 13, 2007)

Trait	No.	Notes
Tolerate 1 herbicide	3	All glyphosate (Roundup) tolerant: cotton (Bayer CropScience), alfalfa & creeping bentgrass (Monsanto)
Tolerate 2 herbicides	**2**	**Soybeans and corn that tolerate glyphosate and ALS inhibitor herbicides,[156] both DuPont-Pioneer**
Insect-resistant	3	Corn (2 – Syngenta & Monsanto), cotton (1 – Syngenta)
Virus-resistant	1	New version of old papaya trait
Enzyme added	1	Syngenta, corn w/ alpha-amylase enzyme derived from deep sea microorganisms for processing into ethanol. First GE industrial crop. Some alpha amylase enzymes cause respiratory allergies. South Africa has refused import clearance on grounds that Syngenta has not provided an adequate analysis of potential health impacts from consumption of this corn.
Oil alteration	1	High oleic acid soy for processing (DuPont-Pioneer)
Color alteration	1	Carnation (Florigene)

Source: Petitions of Nonregulated Status Granted or Pending by APHIS as of December 13, 2007 (last accessed January 7, 2008). See: http://www.aphis.usda.gov/brs/not_reg.html.

- Herbicide-tolerant crops are not only dominant now. They represent the near- and longer-term future of biotech agriculture
- Nearly one-half (5 of 12) of near-future GM crops are herbicide-tolerant; all five are tolerant to glyphosate
- Two of the five HT crops are each modified for tolerance to two herbicides (glyphosate and ALS inhibitors) rather than one, a novel development driven by the dramatic increase in glyphosate-resistant weeds
- In the U.S., an estimated 99% of GM HT crops are glyphosate-tolerant (Roundup Ready)[157]
- Cultivation of Roundup Ready soybeans, cotton and corn is associated with:
    - Large and accelerating increases in the use of glyphosate (see Table 1)
    - An epidemic of weeds with resistance to glyphosate (see footnote 3, pp. 11-19)
    - Constant or rising use of older, more toxic, herbicides such as 2,4-D and atrazine (often in combination with glyphosate), to control resistant weeds (Table 2)
- The longer-term future of GM crops is also dominated by herbicide-tolerance. Over one-third of ongoing GM crop field trials involve HT crops; these field trials encompass 18 plant species and tolerance to 8 or more different herbicides (see footnote 3, p. 9).

[156] The USDA lists the dual herbicide-tolerant corn as tolerant to glyphosate and "imidazolinones" – imidazolinones are one class of the acetolactate synthase (ALS) inhibitor group of herbicides. DuPont-Pioneer refers to this dual herbicide-tolerance as "Optimum GAT" in both soybeans and corn.

[157] Freese, B. (2007). "Cotton Concentration Report: An Assessment of Monsanto's Proposed Acquisition of Delta and Pine Land," February 2007, International Center for Technology Assessment/Center for Food Safety, Section 3.6.2. http://www.centerforfoodsafety.org/pubs/CFS-CTA%20Monsanto-DPL%20Merger%20Report%20Public%20Release%20-%20Final%20_2_.pdf

GM Crops Increase Pesticide Use

- Pesticides are chemicals designed to kill pests, whether weeds (herbicides), insects (insecticides) or other pests such as fungi. According to the most comprehensive, independent analysis of the subject, based on exhaustive analysis of USDA data, GM crops increased pesticide use in the U.S. by 122 million pounds from 1996-2004[158]

+ Herbicide-tolerant:	+ 138 million lbs. more herbicides
+ Insect-resistant:	- 16 million lbs. less insecticides
+ NET:	+ 122 million lbs. more pesticides

The Myth of Reduced Pesticide Use

- Selective reference to and illegitimate extrapolation from the pesticide use impacts of GM crops in the early years of adoption, before herbicide-resistant weeds led to steadily increasing herbicide use[6]

+ 1996 – 1998:	- 20.6 million lbs
+ 1999 – 2004:	+ 143.1 million lbs
+ 1996 – 2004:	+ 122.5 million lbs

- Pesticide use reductions from Bt corn sometimes greatly exaggerated by assuming all current Bt corn growers would use insecticides to control European corn borer (ECB) if they switched back to conventional corn. In fact, only 5.2% of corn acreage was sprayed for ECB prior to availability of Bt corn. According to the National Academy of Sciences:

"… the European corn borer, which is the major target of transgenic Bt field corn, has not commonly been controlled with insecticides. A survey of the literature (Gianessi and Carpenter 1999) indicates that across the corn belt only 5.2% of the acreage is sprayed annually for corn borers and in Iowa only 2.6%. Some of the reasons for the lack of chemical control are that the perceived yield loss has always been considered small (estimated at about 4%), the cost of pesticides is high relative to the crop's value, and typical insecticides have not been very efficient at killing the pest after it bores into the plant." [159]

[158] Benbrook, C. (2004). "Genetically Engineered Crops and Pesticide Use in the United States: The First Nine Years," Technical Paper No. 7, October 2004, available at: http://www.biotechinfo.net/technicalpaper7.html. Dr. Benbrook is the former chair of the Board on Agriculture of the National Academy of Sciences.

[159] "Genetically Modified Pest-Protected Plants: Science and Regulation," Board on Agriculture and Natural Resources, National Research Council, National Academy of Sciences, 2000, Section 3.1.2. http://books.nap.edu/catalog/9795.html.

Herbicide-Tolerant Crops Increase Pesticide Use

- **USDA data show clearly that glyphosate use on soybeans, cotton and corn in the U.S. has increased 15-fold (from 7.9 million lbs. to 119.1 million lbs.) from 1994 to 2005.** This dramatic increase in glyphosate use has been driven by the rapid adoption of Roundup Ready versions of these crops, which are engineered for use with glyphosate (brand name: Roundup). Roundup Ready (RR) crops were introduced by Monsanto in 1996 (RR soybeans), 1997 (RR cotton and canola) and 1998 (RR corn). See Table 1.

- Increasing glyphosate use is also being driven by a growing epidemic of weeds that have become partially resistant to the chemical. Farmers apply heavier doses of glyphosate to kill resistant weeds, which now infest up to 2.4 million acres of U.S. cropland. For instance, **USDA data show that glyphosate use on soybeans has increased from 0.52 lbs./acre in 1994 to 1.33 lbs./acre in 2006, a more than 2.5-fold increase.**

- Another strategy to control resistant weeds is to apply other herbicides in addition to or in combination with glyphosate. **Table 2 documents increasing use of other leading soybean and corn herbicides.** For instance:

    - Use of 2,4-D on soybeans has increased by more than 2.6-fold from 2002 to 2006. 2,4-D is the second most heavily used soybean herbicide (after glyphosate)
    - Use of atrazine on corn has increased by 12% from 2002 to 2005, even as glyphosate use on corn increased 5-fold. Atrazine is the most heavily used herbicide on corn.
    - Combined use of the top four corn herbicides increased by 5% from 2002 to 2005.

- **The intensity of overall herbicide use on soybeans, corn and cotton (lbs./acre) has also increased in tandem with rising adoption of Roundup Ready versions of these crops.**

    - Total herbicide use per acre on soybeans and cotton began rising in 2002, after a decade-long trend of declining herbicide intensity on these crops (Chart 1).

    - Adoption of Roundup Ready soybeans is clearly correlated with substantially increased use of herbicides, from 0.97 lbs./acre in 2001 to 1.42 lbs./acre in 2006 (Chart 2).

    - Adoption of herbicide-tolerant cotton is also correlated with increased herbicide intensity: from 1.66 lbs/acre in 2001 to 2.56 lbs/acre in 2007 (Chart 3).

    - Adoption of herbicide-tolerant corn has lagged behind that of RR soybeans and herbicide-tolerant cotton. However, herbicide intensity has begun to rise here as well, from 1.87 lbs/acre in 2002 to 2.07 lbs/acre in 2005 (Chart 4).

Table 1: Adoption of Herbicide-Tolerant GM Crops vs. Quantity of Glyphosate Applied in the U.S.

Year	Soybeans		Corn		Cotton		Soybeans, corn, cotton	Notes
	Glyphosate applied[1]	% = HT[2]	Glyphosate applied[1]	% = HT[2]	Glyphosate applied[1]	% = HT	Glyphosate applied	
1994	4,896,000	0%	2,248,000	0%	789,189	0%	**7,933,189**	The first HT crop, Roundup Ready soybeans, were introduced in 1995.
2002	67,413,000	75%	5,088,000	11%	n.a.	74%[3]	n.a.	
2003	n.a.	81%	13,696,000	15%	14,817,000		n.a.	
2005	75,743,000	87%	26,304,000	26%	17,024,000		**119,071,000**	More than 15-fold increase in glyphosate use on soybeans, corn and cotton from 1994 to 2005.
2006	96,725,000	89%	n.a.	36%	n.a.	86%[4]	n.a.	More than 19-fold increase in glyphosate use on soybeans, the most widely planted Roundup Ready crop, from 1994 to 2006.
2007	n.a.	91%	n.a.	52%	18,572,000	92%[5]	n.a.	

[1] Pounds of active ingredient. Source for all crops: "Agricultural Chemical Usage: Field Crops Summary," USDA National Agricultural Statistics Service, for the respective years. Accessible from: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1560. The figures represent sum of all versions of glyphosate, including sulfosate. USDA pesticide usage figures cover only a certain percentage of the nationwide acreage planted to the given crop, a percentage which varies from year to year. In order to obtain the best estimate of nationwide use, we have corrected by dividing total reported glyphosate use by the percentage of the nationwide crop acreage for which pesticide usage data was reported. n.a. = not available, note that USDA does not report pesticide usage for all crops in all years.

[2] Percentage of overall crop acreage planted to herbicide-tolerant varieties. From USDA's Economic Research Service (ERS), see: http://www.ers.usda.gov/Data/BiotechCrops/alltables.xls. Figures are the sum of percentages listed for "herbicide-tolerant only" and "stacked gene varieties." As defined by ERS, stacked gene varieties always contain an HT trait. All HT soybeans are Roundup Ready. In 2006, 96% of HT cotton was Roundup Ready, 4% was tolerant to glufosinate (LibertyLink). Most HT corn is Roundup Ready; a small but unknown percentage is tolerant to glufosinate (LibertyLink).

[3] May, O.L., F.M. Bourland and R.L. Nichols (2003). "Challenges in Testing Transgenic and Nontransgenic Cotton Cultivars," *Crop Science* 43: 1594-1601. http://crop.scijournals.org/cgi/reprint/43/5/1594.pdf. Figure calculated by adding all HT varieties in Table 1. Based on USDA AMS data, see next footnote.

[4] From USDA's Agricultural Marketing Service (AMS), which has more reliable statistics on cotton than USDA's ERS. See: "Cotton Varieties Planted: 2006 Crop," USDA AMS. Figure calculated by adding percentages of all HT varieties (those with designations R, RR = Roundup Ready or RF = Roundup Ready Flex and LL for LibertyLink). Note that most HT cotton is Roundup Ready (Flex); LL cotton varieties comprised only 3-4% of US cotton in 2006.

[5] From "Cotton Varieties Planted: 2007 Crop," USDA AMS, at: http://www.ams.usda.gov/mnreports/cnavar.pdf.

Table 2: Usage of Leading Herbicides Other Than Glyphosate on Corn and Soy in the U.S.: 2002 to 2006

Crop	Soy	Corn				Notes
Active ingredient	2,4-D[1] (lbs.)	Atrazine[2] (lbs.)	Acetachlor (lbs.)	Metalachlor/ S-metalachlor (lbs.)	Top 4 corn herbicides (lbs.)	
2002	1,389,000	55,018,000	34,702,000	25,875,000	115,595,000	
2003	n.a.	60,480,000	39,203,000	27,535,000	127,218,000	
2005	1,729,000	61,710,000	32,045,000	27,511,000	121,266,000	From 2002 to 2005, atrazine use on corn increased by 12%. Use of the top four corn herbicides increased 4.9%. The 5-fold increase in glyphosate use on corn over the same time span (see Table 1) has clearly not displaced any of the leading corn herbicides.
2006	3,673,000	n.a.	n.a.	n.a.	n.a.	Use of 2,4-D on soy rose by more than 2.6-fold from 2002 to 2006. Over the same period, glyphosate use on soy rose 43% (see Table 1). Glyphosate is clearly not displacing use of 2,4-D.

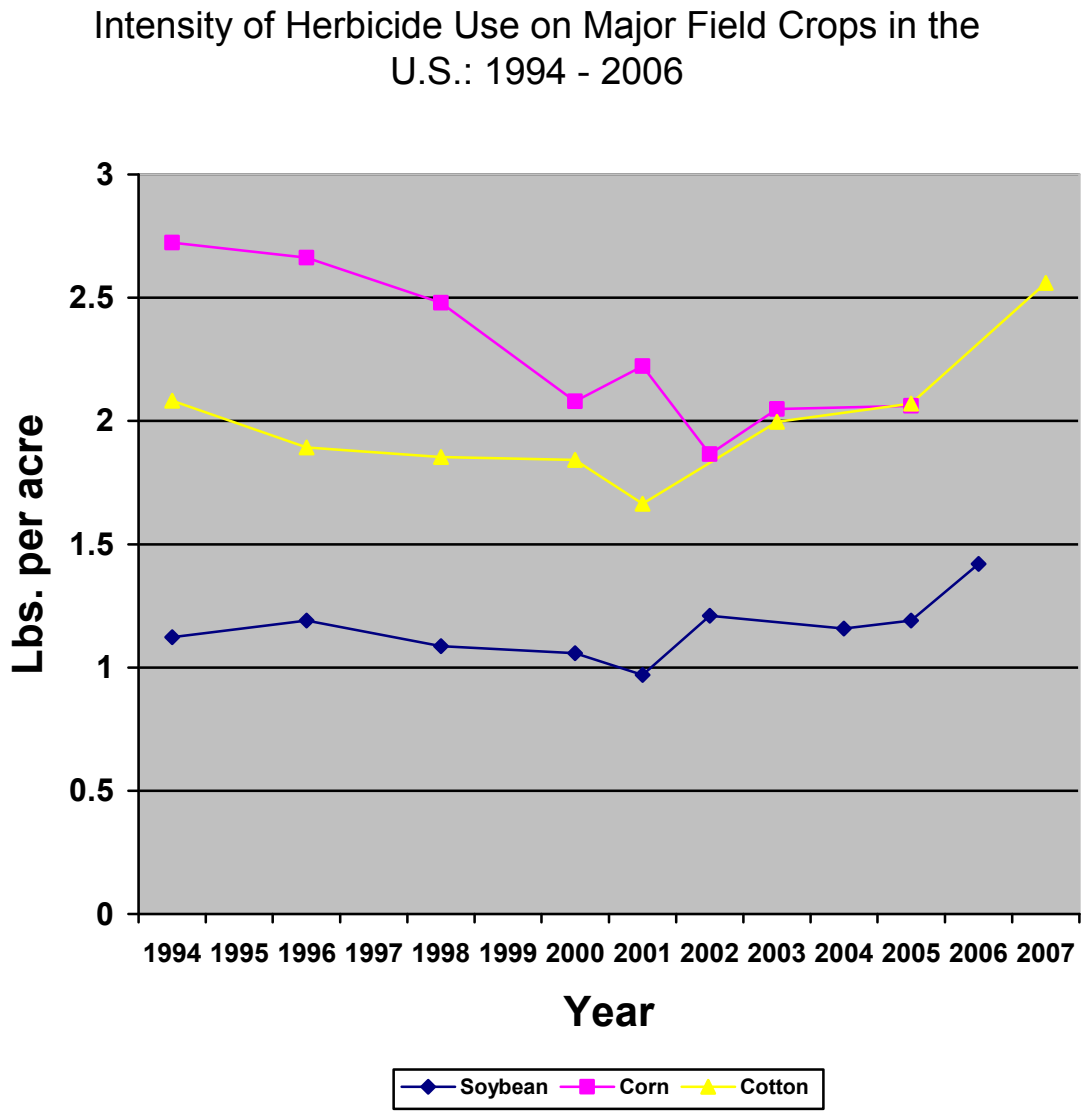
Figures = pounds of active ingredient. Source: "Agricultural Chemical Usage: Field Crops Summary," USDA National Agricultural Statistics Service for the respective years. Accessible from: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1560. USDA pesticide usage figures cover only a certain percentage of the nationwide acreage planted to the given crop, a percentage which varies from year to year. In order to obtain the best estimate of nationwide use, we have corrected by dividing total reported use of the respective herbicide by the percentage of the nationwide crop acreage for which pesticide usage data was reported. n.a. = not available, note that USDA does not report pesticide usage for all crops in all years.

[1] 2,4-D, the second-most heavily used herbicide on soybeans (after glyphosate), is a phenoxy herbicide that formed part of the Vietnam War defoliant Agent Orange. 2,4-D has been associated with a number of adverse health impacts on agricultural workers who apply it: increased risk of cancer, particularly non-Hodgkin's lymphoma, and increased rate of birth defects in children of men who apply the herbicide. 2,4-D is also a suspected endocrine disruptor. For more, see http://www.beyondpesticides.org/pesticides/factsheets/2,4-D.pdf. For restrictions on residential use of 2,4-D in various countries, see: http://en.wikipedia.org/wiki/2,4-D. Figures cited are the sum of all forms of 2,4-D.

[2] Atrazine, the most heavily used herbicide on corn, has been linked to endocrine disruption, neuropathy and cancer (particularly breast and prostate cancer). Atrazine is regularly detected in drinking water supplies in the Midwest, and has been associated with low sperm counts in men. Exposure to extremely low levels of atrazine can cause sex change and/or deformities in frogs, fish and other organisms. Based on this evidence, and the widespread presence of atrazine in drinking water supplies, the European Union announced a ban on atrazine in 2006. The U.S. EPA re-registered atrazine in 2003 despite objections from scientists and environmental groups. See http://www.beyondpesticides.org/pesticides/factsheets/Atrazine.pdf and http://www.loe.org/shows/segments.htm?programID=06-P13-00016&segmentID=1.

- When biotechnology companies are forced to admit that GM crops do in fact increase rather than decrease overall pesticide use, they often fall back on a second claim – that increased use of glyphosate is good, because it displaces more toxic herbicides. However, recent trends show that this is decidedly not the case for several widely used and toxic herbicides. Use of both atrazine on corn and 2,4-D on soybeans has increased substantially since 2002.
- Increasing use of 2,4-D on soy (and perhaps atrazine on corn) is largely attributable to the need to control glyphosate-resistant weeds.

Chart 1

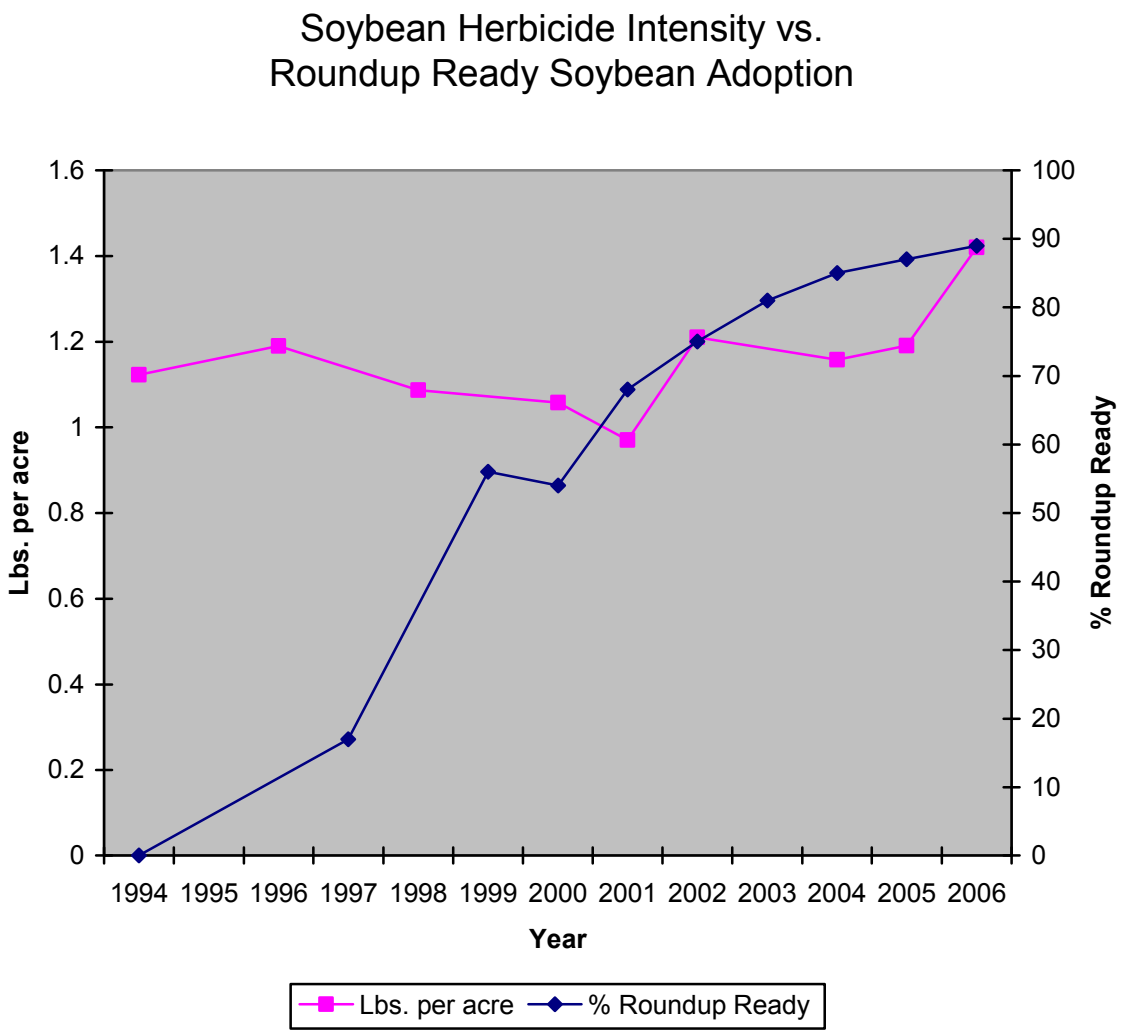


Notes: Intensity of herbicide use began rising in 2002 for soybeans and cotton, and in 2003 for corn, as herbicide-tolerant versions of these crops became prevalent.

Sources: "Agricultural Chemical Usage: Field Crops Summary," USDA National Agricultural Statistics Service, for the respective years. Accessible from: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1560. The figures represent total herbicide use on the respective crop in the "Program States" included in USDA's survey, divided by the number of acres planted to that crop in the Program States. The Program States surveyed by USDA represent a high percentage of nationwide acreage planted to the crop (usually more than 80%, often more than 90%). The only assumption made here is that the amount of herbicides applied per acre covered by the survey is equal to that applied on acres not included in the survey. This is accepted practice for calculation of pesticide intensity. For instance, see Table 3.3.3 in Section 3.3: "Biotechnology and Agriculture," in: "Agricultural Resources and Environmental Indicators, 2006 Edition," USDA Economic Research Service, Economic Information Bulletin 16, July 2006, accessible from: http://www.ers.usda.gov/Publications/AREI/EIB16/. In this 2006 report, USDA for some

unexplained reason plotted pesticide intensity on major field crops only up through 2001 or 2002, despite the availability of data for later years.

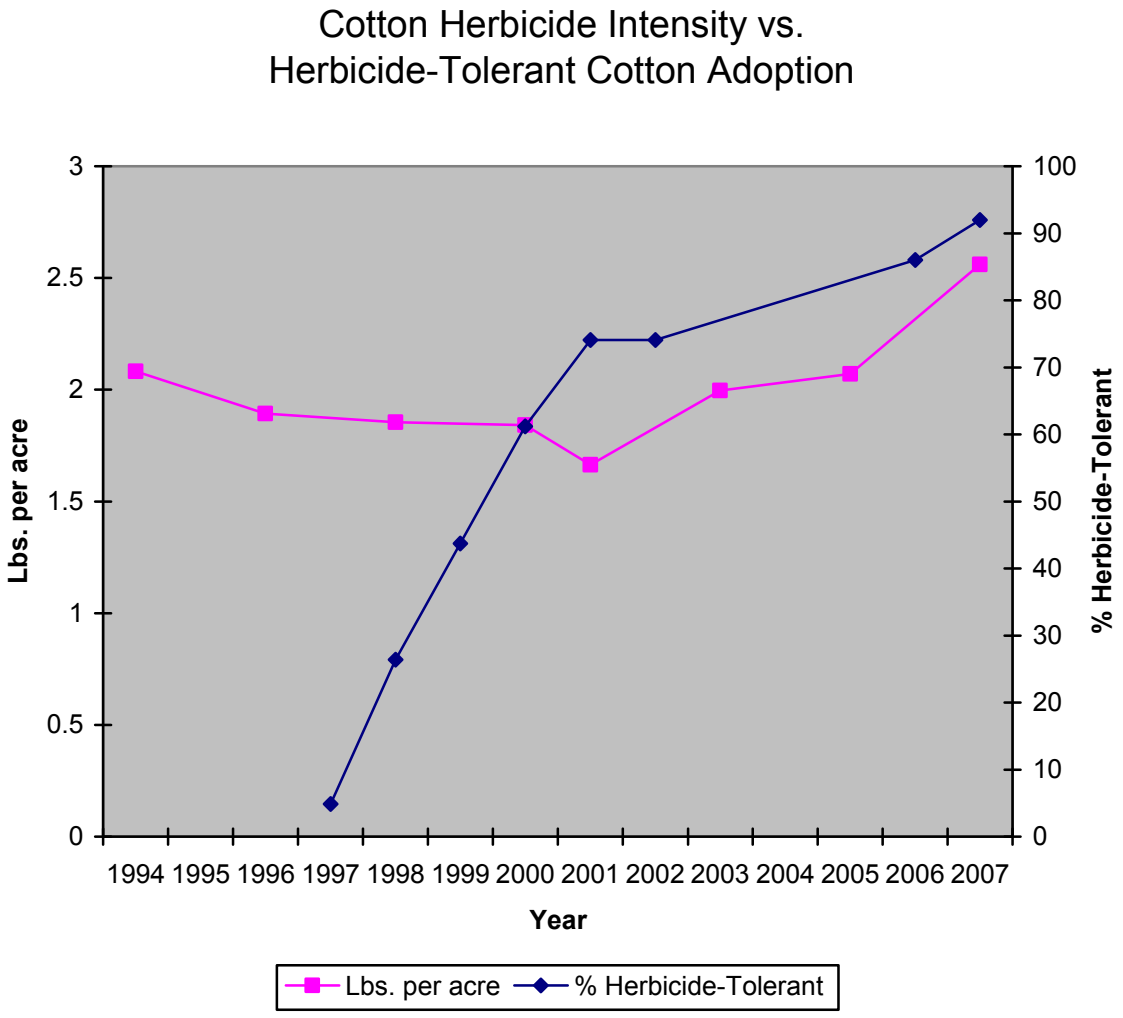
Chart 2



Notes: All herbicide-tolerant soybeans are Roundup Ready. RR soy represents by far the most widely planted HT crop. Note the large spike in herbicide intensity beginning in 2002, as Roundup Ready soybean adoption grew to exceed 70% of all soybean acres planted. While correlation is not causation, this large spike in herbicide intensity corroborates the findings of Benbrook (2004) presented on page. 3.

Sources: For herbicide use, see: "Agricultural Chemical Usage: Field Crops Summary," USDA National Agricultural Statistics Service, for the respective years. Accessible from: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1560. See notes under "Sources" on page 7 for details. For percentage of overall soybean acreage planted to herbicide-tolerant soybeans (all Roundup Ready), see: USDA's Economic Research Service (ERS), see: http://www.ers.usda.gov/Data/BiotechCrops/alltables.xls.

Chart 3

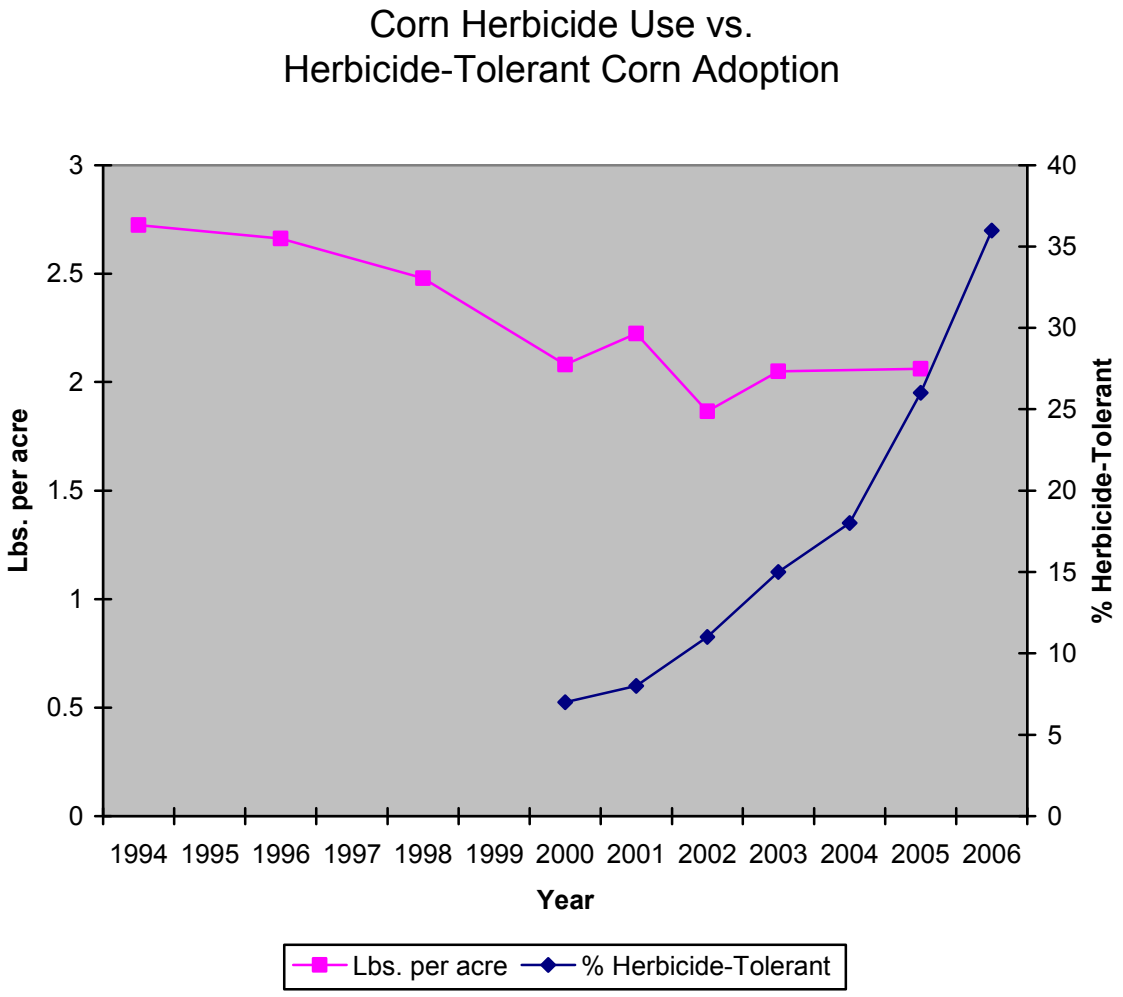


Notes: Note the substantial spike in herbicide intensity beginning after 2001, as herbicide-tolerant upland cotton adoption rose to exceed 70% of all upland cotton planted. While correlation is not causation, this substantial spike in herbicide intensity corroborates the findings of Benbrook (2004) presented on page 3. In 2006, 96% of HT cotton was Roundup Ready, 4% was tolerant to glufosinate (LibertyLink).

Sources: For herbicide use, see: "Agricultural Chemical Usage: Field Crops Summary," USDA National Agricultural Statistics Service, for the respective years, accessible from: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1560. See notes under "Sources" on page 7 for details. Percentage of overall upland cotton acreage planted to herbicide-tolerant cotton from USDA's Agricultural Marketing Service (AMS), which has more reliable statistics on cotton than USDA's ERS. For 1997-2002, see AMS data cited in: May, O.L., F.M. Bourland and R.L. Nichols (2003). "Challenges in Testing Transgenic and Nontransgenic Cotton Cultivars," *Crop Science* 43: 1594-1601. http://crop.scijournals.org/cgi/reprint/43/5/1594.pdf. Figures calculated by adding all HT varieties in Table 1. For 2006, see: USDA AMS data in: "Cotton Varieties Planted: 2006 Crop" http://www.ams.usda.gov/cottonrpts/MNXLS/mp_cn833.xls. This figure was calculated by adding percentages of

all HT varieties (those with designations R, RR = Roundup Ready or RF = Roundup Ready Flex and LL for LibertyLink). Note that in 2006, 96% of HT cotton was Roundup Ready (Flex); 4% was LibertyLink.

Chart 4



Notes: Herbicide intensity in corn began to rise modestly in 2003, but is expected to continue increasing as adoption of herbicide-tolerant corn (mainly Roundup Ready corn, though some LibertyLink corn is also grown) continues its dramatic rise. While correlation is not causation, this increase in herbicide intensity corroborates the findings of Benbrook (2004) presented on page. 3.

Sources: For herbicide use, see: "Agricultural Chemical Usage: Field Crops Summary," USDA National Agricultural Statistics Service, for the respective years. Accessible from: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1560. See notes under "Sources" on page 7 for details. For percentage of overall corn acreage planted to herbicide-tolerant corn, see: USDA's Economic Research Service (ERS), at: http://www.ers.usda.gov/Data/BiotechCrops/alltables.xls. Figures are the sum of percentages listed for "herbicide-tolerant only" and "stacked gene varieties." As defined by ERS, stacked gene varieties always contain an HT trait.