April 21, 2016

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

Re: Environmental Impact Statement; Introduction of the Products of Biotechnology (Docket No. APHIS-2014-0054)

Dear Administrator Shea,

Center for Food Safety (CFS) submits these comments on the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service's (APHIS or the Agency) notice and request for public input on the scope of an Environmental Impact Statement (EIS) for new regulations regarding Introduction of the Products of Biotechnology, 81 Fed. Reg. 6225 (Feb. 5, 2016).

CFS is a nonprofit, public interest organization with a mission to empower people, support farmers, protect the earth from the harmful impacts of industrial agriculture, and promote sustainable agriculture. As a membership organization, CFS represents over 750,000 farmer and consumer members who reside in every state across the country, and who support sustainable food systems. For over two decades, CFS has been the leading U.S. public interest organization working on the issue of genetically engineered (GE) organisms. CFS staff are recognized experts in the field and intimately familiar with the issue of GE organisms, the inadequacy of APHIS oversight, their risks, and their adverse impacts.

It has long been CFS's position that APHIS's current GE regulations under the Plant Protection Act of 2000 (PPA) at 7 C.F.R. Part 340 are woefully inadequate to address the realities of GE crop systems, insects, and trees in U.S. agriculture. A regulatory update was overdue long ago; indeed, APHIS began the revision process in 2004, issued a draft programmatic EIS in 2007 and a proposed rule in 2008, and then abandoned the effort. As APHIS is aware, the single most necessary change is for the Agency to apply the full scope of its statutory authority under the PPA to GE organisms, unlike the pre-PPA regulations that it currently applies, and use that authority to responsibly address and regulate the significant environmental and socioeconomic impacts of GE crop systems, insects, and trees.

Further, in evaluating each of the four alternatives proposed, the National Environmental Policy Act (NEPA) requires APHIS in the programmatic environmental impact statement (PEIS) to analyze the full spectrum of reasonably foreseeable impacts based on current, real-world practices and information, with the purpose of protecting the environment from unnecessary and

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irreversible impacts—*not* the biotechnology industry's bottom line. Accordingly, CFS submits the following comments on and recommendations for the scope of APHIS's PEIS. We also make reference below to APHIS's abortive, four-year exercise in revising its GE organism regulations—in particular the never-finalized, draft PEIS issued in 2007[1]--and incorporate by reference our prior comments in that connected rulemaking process.

Make Genetic Engineering the Trigger for Regulation

APHIS states that a major reason for this regulatory revision is to address "advances in biotechnology," understood as newer genetic engineering techniques that do not involve plant pest sequences. Indeed, at least 30 GE organisms have been exempted from APHIS regulatory review because, although genetically engineered, they did not involve the use of plant pests.[2] APHIS foresaw this gap in its 2007 draft PEIS, and proposed to close it by making genetic transformation the trigger for regulation and assessing GE organisms for noxious weed as well as plant pest risks.[3] In doing this, APHIS was following the recommendation of a National Academy of Sciences' National Research Council (NRC) committee that had conducted an exhaustive review of APHIS GE plant regulation.[4] This NRC committee had recommended that USDA regulate all GE plants, because those that did not involve use of plant pests could also cause harm to public health or the environment, and because there is no scientific basis on which to forecast which ones might pose risk.[5] APHIS agreed that a simple GE trigger would result in "a reduced potential for significant adverse impacts to the environment as compared to the current system."[6]

Besides offering a greater degree of environmental protection, a simple GE trigger is also more transparent than the current system, in that it conforms to the public's and many GE crop, insect, and tree developers' expectations that USDA regulates GE organisms—not, as at present, only those that are developed with the use of certain plant pest organisms (or bits of DNA derived from them) that are enumerated at 7 C.F.R. Part 340. Using genetic transformation as the trigger for regulation would also be more efficient administratively, eliminating the *ad hoc*, individual correspondence and evaluation that presently occurs when GE organism developers (often confused by the current, byzantine system) seek APHIS determinations on whether their GE organisms fall under the scope of regulation.[7]

Despite the many advantages a GE trigger would have over the current system—namely, closing what APHIS itself has long characterized as a "regulatory gap"[8] and providing superior environmental protection and greater transparency and efficiency—APHIS inexplicably fails to incorporate it in any of the four alternatives discussed in its scoping notice.

Choosing genetic transformation as the trigger for regulation does not imply, as APHIS seems to insinuate in the scoping notice, that it is "inherently dangerous," and it would be consistent with the Coordinated Framework. APHIS's past proposal of a GE trigger as its preferred alternative demonstrates this. Further, as APHIS once understood, the real danger is the current system's "narrow definition of a regulated article," which leads to the release of GE organisms into the environment "without regulatory oversight," potentially resulting in "negative impacts on agriculture" due to GE traits that "increase plant susceptibility to disease or insect pests," increase pesticide usage to effect the eradication of a GE organism that becomes persistent in the environment, or similar adverse impacts.[9] APHIS once understood that while GE organisms that

escape regulation under the current system "may very well not pose a significant danger," they still require regulation as potentially hazardous due to "lack of familiarity" or the difficult-to-predict environmental impacts resulting from "innovations in genetic engineering technology."[10] Absent following the NAS's recommendation and its own past views, if it fails to include any alternative in which GE is the trigger for regulation, APHIS has failed to provide sufficient regulatory alternatives for responsible future regulation of GE organisms.

Comments on APHIS's Proposed Definitions

As explained above, APHIS should regulate all GE organisms as posing potential "plant pest risks" or "noxious weed risks." This would make the definition of "regulated organism" equivalent to that of "product of biotechnology," making the latter term superfluous. As noted above, this would accord with the recommendation of the NAS National Research Council committee, that use of genetic engineering be the trigger for APHIS regulation. In this context, "genetically engineered" means produced from an organism or organisms in which the genetic material has been changed through the application of: Vector-based recombinant deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) techniques; direct introduction of DNA or RNA into cells, protoplasts, or organelles; or other *in vitro* nucleic acid techniques. For the purposes of this definition, "in vitro nucleic acid techniques" means preparation of DNA or RNA outside of organisms and then introduction of the prepared nucleic acid into a recipient cell, protoplast, organelle or organism in such a way that the genetic material of the recipient is changed.

Comments on Scope of Impacts that APHIS Must Consider at the Programmatic Level

APHIS's notice specifies broad categories of impacts that APHIS plans to assess in this PEIS. In addition, APHIS must analyze:

- Agricultural production impacts, including and not limited to: the burden from GE contamination (or the risk of it) on GE-sensitive markets, such as organic, non-GE, and many export and domestic markets; other impacts to traditional agricultural production from GE crop production;

- Socioeconomic impacts, such as: transgenic contamination and its economic effects on domestic and export markets and contaminated farmers, including both non-GE and organic farmers, as well as consumers and farmers' right of choice; changes in seed industry market concentration and its impacts; impacts on farm size through any labor-saving effects of GE crops; and effects on the methods and costs of weed control.

- Environmental impacts, including but not limited to: gene flow from GE crops to compatible varieties and any resulting increase in weediness; changes in herbicide use patterns and associated harms to non-target organisms, such as reduction in floral resources for pollinators and degradation of habitat for animals; and impacts on soil health such as increased erosion from altered tillage practices, for instance to control herbicide-resistant weeds.

- Public health impacts, such as: effects of herbicide use, including impacts on farm workers; and safety of food products.

- Livestock health impacts, such as: effects of herbicide use; and safety of animal feed.

- Effects on threatened and endangered species, such as: effects of herbicide use on habitat; and quality of crop components as food sources.

- Disease and pest impacts, such as increased susceptibility to diseases or pests from herbicide applications to an herbicide-resistant crop.

- Transgenic contamination. This impact is particularly significant and deserves careful consideration in the PEIS. Transgenic contamination is the unwanted presence of transgenic material in conventional or organic crop or food supplies. It occurs when GE crops cross-pollinate their conventional or organic counterparts, or wild relatives, in the field, or when GE seeds become admixed with non-GE seeds at various stages of the crop and food production processes.[11] Hundreds of unique GE contamination episodes have been documented involving corn, rice, wheat, alfalfa, flax, canola, and other crops.[12] Collectively, transgenic contamination has cost U.S. farmers billions of dollars in rejected sales, lost exports, and closed agricultural markets.[13] These contamination episodes have resulted in the rejection by foreign markets of GE-contaminated supplies; farmers' loss of GE-contaminated seed stocks for planting purposes; removal of potentially hazardous GE-contaminated food items from supermarket shelves; and loss of valuable grain export markets to other nations capable of providing the GE-free supplies demanded by foreign markets.[14] Domestic GE-sensitive markets are harmed by contamination as well: organic growers are at particularly great risk of losing their customers and markets, and potentially their organic certification, since USDA organic standards prohibit use of GE seed, and require that all inputs in organic production be 100% organic. More crucially, organic consumers buy organic specifically to avoid GE crops, and reject GE-contaminated products, costing organic growers their reputation and customers. The risk of contamination alone creates costly burdens for organic and conventional farmers and businesses, such as the need for DNA testing or crop buffer zones.

Comments on Assessment and Impacts of GE Herbicide-Resistant Crops

APHIS should give particular attention to GE herbicide-resistant (HR) crops in preparing the PEIS, for several reasons. Herbicide-resistance is the dominant application in biotechnology, with over 90% of GE crops, by acreage, containing one or more HR traits (alone or in combination with insect-resistance). Based on the continuing large number of field trials and recent deregulations of HR crops with resistance to multiple herbicides, this class of GE crops will also dominate the future of agricultural biotechnology. HR crops have had a host of negative impacts, including many that were not anticipated and have not been addressed by APHIS; these impacts are among the most important of the "issues raised by a range of stakeholders" that APHIS purports to address with this revision of its regulations. Thus, it is particularly important to assess all regulatory alternatives in terms of their efficacy in addressing and mitigating the current and foreseeable future adverse impacts caused by this class of GE crop.

First and foremost, HR crops must be analyzed and overseen as weed control systems to improve regulation in a meaningful way. HR crops are "crop systems" comprising the herbicide-resistant crop itself and post-emergence application of the associated herbicide(s). Monsanto describes its glyphosate-resistant crops as "Roundup Ready crop/cropping systems." Dow describes its 2,4-D-resistant crops as the "Enlist weed control system." "System" is defined as "a set or arrangement of things so related or connected as to form a unity or organic whole,"[15] meaning there is no need for elements not included in the system to accomplish its purpose. This tight nexus between GE crop and system herbicide(s) has many implications that APHIS must consider, most basically a substantial shift in farmer weed control practices.

For all practical purposes, HR crops eliminate the severe biological constraint—crop injury—on use of the "system herbicide(s)" that otherwise obtain for similar non-HR crops. Elimination of crop injury concerns drives fundamental shifts in weed control practices. In general, a mix of weed control practices is replaced by exclusive reliance on the system herbicide(s); the timing of herbicide use shifts from early to later in the season; the herbicide is sprayed "over the top" of the growing crop rather than near planting time; herbicide rates rise; and overall herbicide use increases.

Some of the specific impacts that APHIS must analyze and regulate include:

- **Increased use of herbicides:** HR GE crops have led to a massive increase in the amount of weed killers applied in U.S. agriculture: 527 million pounds more than would otherwise have been used over the 16 years from 1996 to 2011.[16] Over 280 million pounds of glyphosate were applied to U.S. farm fields in 2012, ten-fold more than was used in the mid-1990s, before Roundup Ready crops were introduced.[17] Future HR crops are likely to spur similar increases.

- **Effects on threatened, endangered, or other non-target species and their habitat.** Intensive spraying of glyphosate has practically eliminated milkweed from America's corn and soybean fields. Because monarch butterflies require milkweed for reproduction, this GE crop-driven eradication of milkweed from cropland is the leading factor in the catastrophic decline in monarch butterfly populations over the past two decades.[18] This example highlights the potential for increased herbicide use triggered by an HR crop system to cause serious non-target damage to native flora, and fauna that depend on it.

- **The herbicide-resistant weed epidemic and associated economic and environmental harm.** HR crop systems are responsible for an epidemic of weeds that have evolved resistance to glyphosate on 70 million acres in the U.S. By one estimate, the current resistant weed epidemic has cost U.S. farmers approximately $1 billion in damages to crops.[19] In order to kill them, farmers apply herbicide cocktails, resort to soil-eroding tillage, and/or hire weeding crews to hoe the weeds by hand,[20] leading to increased erosion of valuable topsoil and up to six-fold increases in the cost of weed control for farmers,[21] as well as environmental impacts. APHIS must assess the potential for HR crop systems to increase soil erosion by generating HR weeds that are controlled with tillage.

HR crop systems are thus no "solution" to herbicide-resistant weeds, but will increase the use of toxic herbicides to new heights, and generate still more intractable weeds resistant to multiple weed killers in a spiral of increasing resistance and herbicide applications.[22] The mere existence of "best management practices" (BMPs) with HR crops that purport to reduce the likelihood of HR weed evolution cannot be invoked as mitigation. Experience shows these BMPs are for the most part not utilized, and not necessarily effective when used.

In addition, APHIS must investigate how pricing strategies influence farmer weed management decisions in such a way as to contribute to evolution of weed resistance. Companies charge fees for HR traits that are substantial enough to create a strong incentive for the farmer to make full use of the trait(s) through total reliance on the associated herbicide(s).[23] APHIS should find or develop studies that explore the extent to which pricing strategies for HR crop systems (e.g. high-priced seed, low-cost herbicide) reinforce herbicide use patterns that foster resistance.

- **Impact of HR crop systems on sustainable weed control.** HR crop systems are based on an herbicide-only weed *eradication* paradigm that panders to some farmers' desire for cosmetically weed-free fields rather than income optimization, and thereby exerts superfluous selection pressure for resistant weeds. Sustainable weed control approaches seek to manage rather than eradicate weeds, utilizing a diverse array of cultural techniques supplemented by herbicides as needed, thereby exerting much less selection pressure for herbicide resistance without loss of income. APHIS has acknowledged that approval of 2,4-D & glyphosate-resistant corn and soybeans will slow adoption of sustainable weed management practices, and should assess this issue for all HR crops.

- **HR crop volunteers as weeds.** Glyphosate-resistant crop volunteers have been repeatedly noted as problematic weeds, particularly glyphosate-resistant corn; and especially where glyphosate-resistant crops are rotated. APHIS should assess the increased weediness of HR crop volunteers. Since one aspect of a noxious weed is difficulty of control, and resistance to herbicides makes control more difficult, HR crop volunteers should be assessed as noxious weed risks. In general, the more herbicides a crop (volunteer) is resistant to, the more difficult and costly it is to control, and the more likely to be noxious.

- **Feral HR crops as weeds**. Crops like GE alfalfa, GE canola and GE creeping bentgrass that can spread outside of agricultural fields and persist there over years as weeds in feral (wild) form become more difficult, costly, and environmentally damaging to control when they harbor herbicide-resistance traits. These impacts become even more serious when the GE crop has the ability to spread great distances, and/or has wild relatives that it can cross-pollinate, thus transferring the property of herbicide resistance. Such feral GE crops (or their progeny) can serve as conduits to transfer herbicide-resistance traits to crops. Contamination can be irreparable, because it becomes difficult or impossible to contain once it occurs.[24] Unlike chemical pollution, transgenic contamination can propagate itself over space and time via gene flow.[25]

- **Interplay between HR traits and Bt resistant pests**. HR corn and cotton are today offered primarily in stacks with Bt traits. Research shows that HR corn volunteers produce lower levels of Bt toxin and thereby promote Bt resistance in corn rootworm; the more HR traits in the corn volunteers, the less likely they will be managed adequately, and hence the more likely they will contribute to evolution of Bt resistance in pests.

- **Herbicidal drift injury to sensitive plants and other non-target organisms.** Glyphosate is also a leading culprit in herbicidal drift injury to sensitive crops,[26] and injures wild plants that many other organisms depend upon for food and/or habitat. Glyphosate is frequently detected in the air, rain, and water bodies of the Midwest and South.[27] Glyphosate-containing Roundup formulations are extremely toxic to tadpoles and frogs, and likely have contributed to the worldwide decline in frog populations.[28]

  In general, HR crop systems entail a pronounced shift in herbicide use to much later in the season, which increases herbicide drift damage to crops and other plants for several reasons. First, later-season post-emergence herbicide use occurs when neighboring crops have leafed out and are more vulnerable to drift damage (versus early season herbicide use when crops have not or only barely emerged). Second, temperatures become considerably higher as spring gives way to summer, and spraying under hot conditions fosters vapor drift of volatile herbicides. For both reasons, herbicide drift damage to susceptible crops will continue to rise as more HR crops are introduced, representing a threat to "agricultural plants." In short, an HR crop virtually eliminates the potential for the system herbicide to damage it, while the HR crop system increases damage to neighboring crops. In some cases, the fact or even the threat of increased drift damage would simplify agricultural landscapes, as growers of susceptible crops shut down their operations, or shift to the HR crop itself or others that are more tolerant of the pertinent herbicide. For instance, broadleaf plants are killed or damaged by herbicides like 2,4-D and dicamba, while grass-family crops (cereals) and plants are tolerant. HR crop systems involving resistance to these herbicides pose risks to broadleaf crops like soybeans, cottons, vegetables and fruits, especially grapes; and could encourage shifts from these crops to corn or other cereal crops.

  The high potential for drift damage with Roundup Ready (RR) crop systems has demonstrably led to "defensive adoption" of crops with the RR trait (e.g. RR corn) by farmers seeking to defend themselves against drift damage, even if they have no desire to use the trait for weed control. APHIS should consider the extent to which HR crops will be adopted for defensive reasons; and the extent to which defensive adopters go on to make use of the trait for weed control once they have adopted it; the increased costs borne by defensive adopters in purchasing traits they do not want (at least initially); and the impacts of this additional (more extensive) selection pressure in terms of promoting evolution of weed resistance to the system herbicide(s).

- **Public health impacts of exposure and air and water contamination.** Because the World Health Organization has determined that glyphosate is "probably carcinogenic to humans,"[29] and it is widely found in the atmosphere, rainfall, surface waters, crops, food and human urine,[30] the vast amounts now used in GE crop production systems may pose a

risk to public health as well. Some herbicides are hazardous to human health despite the fact that they are chemicals that target plants. APHIS should assess the human health impacts of increased herbicide use with HR crop systems, particularly farmers and farmworkers.

- **Socioeconomic factors associated with HR crops.** Herbicide-resistant crop systems reduce labor for and simplify weed control (at least in the short term, before resistant weeds emerge). These closely intertwined "benefits" facilitate increased farm size, since more land can be managed for weeds with the same labor, and labor needs for weed control are a major limiting factor on farm size. This is why USDA economists have found that HR crops are one factor contributing to consolidation of farmland,[31] which primarily benefits already large growers who are in a better financial position to lease or purchase additional land than smaller growers. HR crops are thus one factor contributing to the decline of family farms in the U.S.

Implementation of PPA Noxious Weed Authority

One further key issue is how APHIS will apply and implement the PPA's noxious weed authority in its forthcoming post-PPA GE regulations. This question is not explicitly addressed in the notice. The answer is that, as we have explained in the past, the PPA has a broad definition of noxious weed harms, which expressly includes direct and indirect injury and damage to crops, livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.[32] In integrating and applying the authority to GE organisms, APHIS must apply this definition and statutory authority coherently, applying it in a meaningful and logical way to address GE organisms' adverse environmental and agronomic impacts, which are expressly cognizable under the PPA's definition.

APHIS has previously recognized the broad noxious weed definition and authority mandated by the PPA. This is evidenced by the following passage from the agency's 2007 draft PEIS:

"There are many instances in which the noxious weed authority would allow APHIS to assess risks beyond plant pest risks. Many developers are combining multiple GE traits in a single plant variety, and these gene combinations may have noxious weed effects but no plant pest effects. For example, a plant could be genetically engineered with genes to increase its fitness to the point where the plant could become invasive in the wild. This situation could be exacerbated if the plant had weedy wild relatives. Alternatively, a plant could be engineered to produce a substance with the potential to be toxic, allergenic, or otherwise biologically active in humans, and its unconfined release could pose risks to public health. Some plants engineered to produce pharmaceutical or industrial compounds might be examples. GE plants may also be developed with transgenes of unknown function, and it would be important for APHIS to be able to look at the broadest range of possible impacts resulting from releasing the plant in the environment."[33]

As APHIS's examples above show, there are many risks posed by GE organisms that are encompassed by the PPA's definition of noxious weed. APHIS thus previously proposed applications of its noxious weed authority that would protect the environment and public health as well as agriculture, and understood the importance of examining "the broadest range of possible

impacts" to address uncertainties. In any new Part 340 regulations, such an application of the authority is a necessity for responsible and lawful regulation of GE organisms.

Comments on APHIS's Proposed Alternatives

Alternatives 1 and 4 would exacerbate the known harms of GE crop systems, insects, and trees, and fail to adequately protect conventional farmers, the environment, or public health. Alternative 1—the no action alternative—would allow the current inadequate regulatory scheme to continue, including the deficiencies thoroughly explained in CFS's comments to the Office of Science and Technology Policy (OSTP) regarding Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology,[34] which are incorporated here by reference. The number of GE organisms that escape regulation—at least 30 at present—would gradually increase as GE organism developers shift away from use of plant pest material. The likely result is an effective end to USDA regulation of GE organisms. Similarly, for the reasons outlined in CFS's comments to OSTP, Alternative 4 would allow the biotechnology industry to regulate itself, amounting to an impermissible abdication of APHIS's statutory duties under the PPA, and an end to USDA regulation of GE organisms.

At a minimum, APHIS must require that all GE organism producers supply information necessary for meaningful risk assessments, including the information currently required under 7 C.F.R. § 340.6(c), or, better yet, undertake appropriate research to fill in the gaps. In the case of GE HR crop systems, in addition to data needs suggested above, APHIS should also require and make available to the public information on:

- Proposed herbicide application regime: herbicide rate(s), how often applied, window of application.
- Expression of transgene and degree of herbicide resistance conferred by the transgene in different plant parts and at stages of development.
- Expression of the transgene in pollen, nectar; levels of herbicide residues and metabolites in pollen and nectar.

APHIS should also collect information relevant to its regulatory decision-making from the independent scientific literature.

In both Alternatives 2 and 3, APHIS proposes to eliminate 7 C.F.R. § 340.6, the process whereby companies petition for non-regulated status for a GE organism, and § 340.3, which regulates field trials of most GE crops, insects, and trees. Section 340.6 requires submission to APHIS of specified information that serves as the basis for APHIS's environmental reviews and regulatory decision-making. Because APHIS does not propose an alternate means of gathering this information, it must have decided to make regulatory decisions in the absence of these data. Because each GE organism is unique, its potential impacts can only be fully assessed on a GE organism-by-organism basis, with scientifically grounded information about specific GE organisms—information that APHIS would no longer collect with elimination of 7 C.F.R. § 340.6. It is entirely unclear what APHIS means by terms like "documented" plant pest and noxious weed risks, when the documentation necessary to assess these risks would not be collected.

Eliminating the regulations for notification field trials (§ 340.3) would leave APHIS as well as state regulatory officials entirely ignorant of the circumstances of most experimental GE crop, insect, and tree cultivation—that is, of GE organisms not regulated under the schemes proposed in Alternatives 2 and 3. APHIS would not know the identity of the GE organisms, where or when or how extensively it was grown or released, etc. Developers of experimental GE organisms would no longer be under any obligation to prevent inadvertent mixing of the GE organism with other non-regulated plants, insects, or trees (§ 340.3(c)(2)), or to take measures to ensure that the GE organism does not persist in the environment (§ 340.3(c)(5), or to submit field test reports to APHIS concerning any deleterious effects of the GE organism on plants, non-target organisms, or the environment (§ 340.3(d)(4)), among other lapsed requirements. APHIS must assess the consequences of eliminating these field trial regulations on the agricultural economy, since transgenic contamination is likely to increase substantially, with increased potential for rejection of contaminated supplies by foreign and domestic buyers.

More specifically, with regard to Alternative 2, APHIS's proposed "analyze first" process is unworkable unless there are adequate experimental data to determine whether the engineered organism could cause the many potential kinds of harm enumerated in the PPA as relevant, especially under the noxious weed provisions, and as acknowledged by APHIS in its list of direct and indirect possible harms to the environment and public health. Importantly, the interactions between genes, organisms, environments, and society are complex and often not predictable without adequate test data. This alternative improperly puts the decision cart before the scientific analysis horse, and APHIS should reject it.

APHIS's suggested criteria are only hypothetical at this time, since genomic editing methods currently have uncertainties that may go beyond what can be done through historically non-regulated methods such as mutagenesis. APHIS has not supplied other criteria for GE organisms that might be waived from the regulatory process under this option, but from a practical perspective, those organisms would likely be difficult to determine *a priori*. Therefore, APHIS should instead continue to regulate any GE organisms (i.e. using the process of genetic engineering as the trigger), which will ensure that any possibly harmful GE organism will be evaluated to protect the public. This alternative should include the ability to restrict the use of GE organisms to mitigate risk; contain a proactive, active management approach to evaluate the organism on a continuing basis; and provide a robust means of enforcement when new risks are encountered in permitted GE organisms. These should include independent expert review, rather than reliance on industry-supplied data alone. Additionally, pharmaceutical products should not be produced in food crops, and in non-food plants only under contained conditions. This should also be the case for industrial products that are not approved for food use.

Alternative 3 would subject GE organisms captured by the plant pest or noxious weed analysis triggers to ongoing regulatory oversight. As discussed above, proper application and integration of the statutory definitions of plant pest harms and noxious weed harms easily cover the adverse impacts of GE organisms—GE crops, especially, as CFS has discussed repeatedly—and that must be the proper scope of this alternative. How effective this alternative would be in large part depends on APHIS's application of the proper scope of those statutory definitions of harm, applying them to address GE organisms in the logical and proactive way, which would necessarily be inclusive of

existing and future GE organisms. Absent such application, the alternative might not improve and could worsen existing regulation. More fundamentally, like Alternative 2, this alternative suffers from the lack of a simple GE trigger. Absent using the NAS's recommended regulatory trigger, like with Alternative 2, APHIS would have to make a judgment about the likelihood of plant pest or noxious weed risks prior to collecting adequate, GE organism-specific data according to clearly laid out experimental criteria; without such data, it is not possible to assess risks—including delayed or indirect risks, which are very difficult to predict without experimental research. Since APHIS is silent about whether and how much of such research would be required at the point where the Agency carried out its assessment of whether the GE organism trips the trigger, there remains a strong possibility that some risky organisms could entirely escape APHIS regulation. Again, all GE organisms should be regulated by APHIS.

Among those listed, CFS prefers Alternative 3, but with the addition of a much more simple and straightforward GE trigger. In that instance, and again, assuming that APHIS integrates forward-looking applications of its robust PPA statutory authority that properly include the current adverse impacts of GE organisms discussed above, Alternative 3 appears to provide for regulation under permit and without deregulation, which allows for mitigation of risks throughout the life of the organism. However, this Alternative will only be effective if APHIS maintains an ongoing active management process, with a mandatory period of regulation, thorough review, and robust, proactive enforcement, and a commercial permit system. To protect against transgenic contamination and other GE harms, which APHIS can regulate as noxious weed harms, CFS supports crop exclusion zones and isolation distances that are considerably larger and therefore more protective than standard seed purity isolation distances. For some GE organisms, mitigation measures of any kind will be insufficient to prevent contamination; these organisms should be prohibited from commercialization unless or until APHIS can show that contamination will not occur. In all cases the GE organism developer and/or farmer should bear liability for transgenic contamination.

Thank you for the opportunity to provide comments on this important issue.

Sincerely,
Center for Food Safety

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[1] USDA Animal and Plant Health Inspection Service. *Introduction of Genetically Engineered Organisms: Draft Programmatic Environmental Impact Statement*, July 2007, https://www.aphis.usda.gov/brs/pdf/complete_eis.pdf.

[2] U.S. Government Accountability Office. *Genetically Engineered Crops: USDA Needs to Enhance Oversight and Better Understand Impacts of Unintended Mixing with Other Crops*. GAO-16-241, March 2016, p. 17.

[3] USDA Animal and Plant Health Inspection Service, op. cit., p. 168.

[4] National Academy of Sciences, National Research Council. *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*. National Academy Press, Washington, DC, 2002.

[5] USDA Animal and Plant Health Inspection Service, op. cit., p. 20.

[6] USDA Animal and Plant Health Inspection Service, op. cit., p. 168. APHIS inexplicably failed to finalize this PEIS, then in the following year (2008) issued a proposed rule that not only dropped its preferred alternative of using GE as the regulatory trigger, but would have allowed GE crop developers to decide whether their crops fell under APHIS regulatory jurisdiction in a scheme that resembles the current Alternative 4. APHIS has never explained this sudden and unjustifiable about-face. CFS suspects that APHIS allowed itself to be influenced by industry stakeholders who wished (and wish) to throw off APHIS regulation altogether and instead regulate themselves.

[7] U.S. Government Accountability Office, 2016, op. cit., pp. 17-18.

[8] USDA Animal and Plant Health Inspection Service, op. cit., p. 168. APHIS described its preferred alternative for "scope of regulatory oversight" that involves the process of genetic transformation as the trigger for regulation as follows: "This alternative would eliminate potential gaps that may occur as genetic engineering technologies continue to advance."

[9] USDA Animal and Plant Health Inspection Service, op. cit., p. 132.

[10] USDA Animal and Plant Health Inspection Service, op. cit., p. 133.

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