CENTER FOR FOOD SAFETY

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U.S. Department of Agriculture
Regulatory Analysis and Development, PPD, APHIS
Station 3A–03.8
4700 River Road Unit 118,
Riverdale, MD 20737–1238

Re: Proposed Rule on Movement of Certain Genetically Engineered Organisms, 7 CFR Parts 340 and 372, Docket No. APHIS-2018-0034

Center for Food Safety (CFS) submits the following comments on APHIS's proposed for regulating genetically engineered (GE) organisms and its accompanying documentation.

INTRODUCTION

CFS is a nonprofit, public interest organization with a mission to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture, while also promoting and protecting regenerative, sustainable agriculture. CFS represents over 950,000 farmer and consumer members who reside in every state across the country. For over two decades, CFS has been the leading U.S. public interest organization working on the issue of GE organisms and their oversight. CFS has a major program area specific to GE organism oversight and numerous staff members—scientific, policy, campaign, and legal—whose work encompasses the topic. CFS staff are recognized experts in the field and intimately familiar with the issue of GE organisms, the inadequacy of their oversight, their risks, and their adverse impacts.

CFS has a long history of participation in APHIS's GE regulatory process, including its ongoing and longstanding process of revising its GE organism regulations under the Plant Protection Act (PPA). CFS has submitted several rounds of comments on the prior stages of APHIS's rulemaking,[1], all of which are incorporated here by reference, and resubmitted to the current docket.

COMMENTS

As consistently recognized by CFS, other commenters and APHIS itself throughout prior stages of APHIS's rulemaking, new rules are necessary. However, APHIS's latest proposal (Proposal or Proposed Rules) is the opposite of regulation. Rather than exercising its broad PPA authority to regulate GE crops and provide better regulatory oversight, under the Proposal, developers of GE technologies will have free rein to self-determine whether or not their GE experiments should be subject to regulations, and the vast majority of GE plants would be exempted from any meaningful

[1] *See* Docket Nos. 03-031-02 (Apr. 13, 2004); APHIS–2006–0112 (Sept. 11, 2007); APHIS-2008-0023 (Nov. 24, 2008); 2008-0023 (Mar. 20, 2009); 2008-0023 (June 29, 2009); APHIS-2014-0054 (Apr. 26, 2016).

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regulatory oversight. For the limited number of GE plants that would continue to be regulated, the Proposal will enable these GE plants to be commercialized and planted without any regulation or monitoring based only on a streamlined review that does not capture the myriad of biological, agricultural, socioeconomic, and environmental harms of new GE technologies, falling woefully short of APHIS's duties to prevent noxious weed risks and plant pest harms under the PPA. The Proposed Rules do not set up a rigorous regulatory scheme, but rather a "deregulatory scheme" that is arbitrary and capricious and contrary to sound science. The Proposal also runs counter Congressional mandates in the 2008 Farm Bill, and APHIS's own prior acknowledgments of the recommendations in the 2005 and 2015 reports of the USDA's Office of Inspector General (OIG). APHIS's latest Proposal is arbitrary and capricious, and not accordance with the law, and must be rejected.

The Scope of the Proposed Rules

APHIS's Proposal gives the impression that it broadly regulates genetically engineered organisms, in fact a multitude of exemptions drastically shrink the scope of regulation to a small subset of them.

APHIS proposes to exempt four broad categories of GE plants from any regulation because they purportedly could have been generated by traditional breeding methods. The exemption categories comprise GE plants for which: (1) the genetic modification is solely a deletion of any size; (2) the genetic modification is a single base pair substitution; (3) the genetic modification is solely introducing nucleic acid sequences from within the plant's natural gene pool or from editing nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool; or (4) the plant is an offspring of a GE plant and does not retain the genetic modification in the GE plant parent. These GE plants "would not be regulated or subject to a regulatory status review."[2] Thus, the GE plant developer would self-determine whether its GE plant is exempted under one of these four exemption categories, without consulting APHIS.

This exemption scheme is arbitrary and capricious, and contrary to sound science, because as APHIS itself concedes, it is impossible to determine whether a specific GE modification in a specific plant could in fact have been effected by means of traditional breeding techniques.[3] First, APHIS lacks proper basis for the proposed changes. APHIS claims the Proposal would align its regulatory scheme with a press statement made by the USDA Secretary, but a press statement, without legal or scientific basis, is not a proper rational for a major deregulatory initiative such as this one. In any case, these proposed exclusions would allow GE organisms that could pose plant pest risks to entirely escape review and regulation by APHIS (discussed infra).

[2] 84 Fed. Reg. 26519 (Proposed 7 CFR § 340.1(b)(1) through (4).
[3] 84 Fed. Reg. 26519.

APHIS also proposes to exempt from review GE plants with plant-trait-mechanism of action (MOA) combinations that have previously undergone APHIS review in some form.[4] Here, too, the GE plant developer is given the option to make a self-determination as to whether his or her GE plant qualifies for this exemption.[5] GE plants exempted under this provision could also entirely escape review and regulation by APHIS, despite the fact that they could pose plant pest risks. As detailed below, these exemptions are arbitrary and capricious, and contrary to sound science.[6]

The Proposed Rules Unlawfully Subdelegates APHIS's PPA Statutory Authority to Developers.

In passing the PPA, Congress delegated to APHIS the responsibility to, among others, prevent "the risk of dissemination of plant pests or noxious weeds."[7] Yet, under the Proposed Rules, for the majority of GE plants, APHIS will no longer make any such determinations. Instead, APHIS will leave it entirely up to GE developers to self-determine and apply the exemptions. As a result, developers will have free rein to determine whether their GE products fall within the scope of APHIS's regulation, without any approval or confirmation from APHIS. Thus, under the Proposed Rules, the majority of GE plants would be exempt from any regulation, without the determination from APHIS that such GE plants carry no plant pest or noxious weed harms, as those terms are broadly defined under the PPA. This is arbitrary and capricious, and contrary to sound science. In this way, the Proposed Rules also impermissibly subdelegate APHIS's duties under the PPA to private third parties.

APHIS claims that developers may voluntarily seek APHIS's affirmation for their self-determinations, but are not required to. However, as APHIS acknowledges, that process is entirely voluntary. Nor is it likely that GE developers would voluntarily consult APHIS to confirm whether a GE organism is exempt from further regulatory oversight, because the proposed regulatory criteria are explicit enough that in most cases they will be enabled to make their own regulatory determinations. Thus, for the many GE organisms that a developer self-determines meet the exemptions discussed above, developers would have little or no reason to consult with APHIS. These GE plants could be grown and commercialized not only in the absence of regulation, but without APHIS's knowledge. This is undesirable for many reasons, not least because it would likely complicate remediation of GE contamination episodes with market impacts too big for APHIS to ignore.

Aside from unlawful subdelegating its duties to private parties, authorizing industry self-determined exemptions also makes the Proposed Rules exceedingly non-transparent, and insulates APHIS from determinations that Congress intended to have been made with the benefit of

[4] 84 Fed. Reg. 26537 (Proposed 7 CFR § 340.1(c)).
[5] 84 Fed. Reg. 26517.
[6] *See infra*.
[7] 7 U.S.C. §7701(3).

democratic accountability. The public, the scientific community and America's trading partners, among others, would be given the false impression that "GE organisms" are under APHIS regulation (absent explicit determination of "nonregulated status"), when under the Proposed Rules, the majority of them will be exempted from review altogether, without even any public record/reporting of their use. In contrast, a clean regulatory trigger based on the use of genetic engineering, as detailed below, would make APHIS's regulatory regime just what the public perceives it to be—building trust in the honesty and legitimacy of APHIS's regulatory program.

In addition to broadly exempting the majority of GE plants from any regulation at all, under the Proposed Rules, the only GE plants that would be subject to regulation are those which have a plant-trait-mechanism of combination that has been evaluated by APHIS under its cursory regulatory review process, or those which meet the proposed definition of a plant pest.[8] As CFS explained previously, the first criteria is likely to be the effective trigger for APHIS regulation, since genetically engineering is seldom if ever used to render plant pests.[9]

APHIS is thus proposing to end its current event-based regulation[10] in favor of a narrower system based on novel trait-and-organism combinations. Every event is unique, and thus potentially has a novel phenotype[11] that must be assessed to determine appropriate regulation.[12] As CFS previously commented, the proposed approach is contrary to sound science, in violation of the PPA.[13] APHIS had conceded that event-based regulation is more protective than a trait-and-organism approach, and would "eliminate potential gaps that may occur as genetic engineering technologies continue to advance."[14] Similarly, as explained *infra* and in past comments, the National Academy of Sciences has also advocated the use of genetic engineering [i.e. transformation] as "both a useful and scientifically justifiable regulatory trigger" because "there is no scientific basis" on which to exclude

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[8] 84 Fed. Reg. 26537 (Proposed 7 CFR § 340.2).
[9] *See* Attachment A, CFS 2017 Comments (and appendices therein).
[10] "Currently, APHIS regulates GE organisms as "transformation events." An event is a single successful insertion of a gene or gene fragment into a cell's genetic material or a successful deletion of a gene or gene fragment from a cell. Each event can be genetically unique, even if the event results from a single transformation experiment in which many individual cells were treated under identical conditions. Biotechnology techniques allow scientists to regenerate entire organisms, such as whole plants, from a single cell. A plant produced from one transformed cell may also be called an event." (USDA APHIS 2007 Draft PEIS GE Organisms at 22)
[11] *Phenotype* means "[t]he visible and/or measurable characteristics of an organism (i.e., how it appears outwardly and physiologically) as opposed to its genotype, or genetic characteristics." NASEM 2017 at 129.
[12] Montero M, Coll A, Nadal A, Messeguer J, Pla M. 2011. Only half the transcriptomic difference between resistant genetically modified and conventional rice are associated with the transgene. Plant Biotechnology Journal 9: 693-702. doi: 10.1111/j.1467-7652.2010.00572.x.
[13] *See* Attachment A, CFS 2017 Comments (and appendices therein).
[14] USDA APHIS (2007), pp. 133-134; 168. *See also* Jupe F, Rivkin AC, Michael TP, Zander M, Motley ST, Sandoval JP, et al. 2019. The complex architecture and epigenomic impact of plant T-DNA insertions. PLoS Genet 15(1): e1007819. https:// doi.org/10.1371/journal.pgen.1007819.

GE organisms from regulatory review prior to evaluation of data on the interactions between "trait, organism and environment."[15] CFS strongly opposes APHIS's proposal to exclude GE organisms from regulations based on the loopholes discussed above.

Plant Pests and Plant Pest Risks

Under the Proposed Rules, APHIS will continue to exercise regulatory authority over GE organisms that meet the definition of plant pest or GE plants that have a plant-trait-mechanism of action combination not previously evaluated by APHIS,[16] provided of course that the GE plant has not already been excluded from Part 340 regulation under proposed 340.1(b)(1) to (4), discussed above.

APHIS proposes to define "plant pest" using the PPA's definition of the term, which includes "any article similar to or allied with [any living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infections agent or other pathogen], that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[17]

As for the "plant pest" trigger, APHIS's assessment must go beyond simply determining whether the GE organism is one of the specific plant pest organisms enumerated in the plant pest definition at proposed 340.3. Such a narrow interpretation would automatically exclude all GE plants from regulation under this provision, since the only type of plant listed in the definition is "parasitic plant," and it is difficult to imagine an application of genetic engineering that would create such a plant. APHIS must use the full definition—which gives wide scope to APHIS's regulatory authority by encompassing "any article similar to or allied with" a plant pest organism—as needed to fulfill its duties under the PPA. Failure to do so would be arbitrary and capricious.

Second, the novel plant-trait-mechanism of action regulatory trigger is unscientific, since as described further below, GE transformation events are unique, and even those with the same plant-trait-mechanism of action combination may differ in potentially important ways that have plant pest risk implications. Excluding a novel GE plant from any regulatory review whatsoever simply because a prior one with the same plant-trait-MoA combination has been found not to pose a plant pest risk would be arbitrary and capricious, and contrary to sound science.

[15] NRC (2002), p. 79.
[16] 84 Fed. Reg. 26537 (Proposed 7 C.F.R. § 340.2(b)).
[17] 84 Fed. Reg. 26538; *see* 7 U.S.C. § 7702(14) (definition of plant pest).

APHIS also proposes, for the first time, to formally define "plant pest risk" as distinct from "plant pest."[18] APHIS proposes defining "plant pest risk" as "[t]he possibility of harm to plants resulting from introducing or disseminating a plant pest or exacerbating the impacts of a plant pest."[19]

While a formal definition of this term is needed, as an initial matter, to properly align the definition under the PPA, the proposed definition must consider the possibility of harm to not just plants, but also plant products, since the PPA statutory definition of "plant pest" includes those "that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[20]

Secondly, as CFS argued in past comments, the proposed definition of "plant pest risk" as "[t]he possibility of harm to plants resulting from introducing or disseminating a plant pest or exacerbating the impacts of a plant pest"[21] is far too narrow, and represents a radical departure from current regulations. Under the current Part 340, plant pest risk is construed much more broadly than in the proposed definition. Criteria APHIS has used to evaluate GE organisms for potential plant pest risks in the past include:

> the potential of the GE organism to create pest or disease problems, the potential for nontarget effects that might affect organisms beneficial to agriculture, changes in agricultural practices that might exacerbate pest or disease problems, the potential for a GE organism to become a weed or increase its weediness or that of sexually compatible species, and the potential of the GE organism to transmit the introduced trait to organisms with which it does not interbreed.[22]

While past APHIS assessments of GE organisms have mostly failed to apply some or all of these criteria rigorously, it is critical that any formal definition of "plant pest risk" in a new Part 340 encompass them, so that future GE organism assessments become more rigorous so as to comply with the provisions of the PPA. The proposed definition, for instance, omits nontarget harms to organisms beneficial to agriculture, changes in agricultural practices associated with the GE organism, and weediness of the GE organism or that of species with which it interbreeds.

APHIS's exclusion of any weediness impacts from the definition is particularly concerning in light of the agency's failure to implement any aspect of its noxious weed authority in the Proposed Rules. While retaining a "weediness" component in the plant pest risk definition would by no means be a substitute for implementing the agency's noxious weed authority in Part 340, its proposed elimination would dramatically weaken APHIS's ability to regulate GE plants for this serious issue.

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[19] 84 Fed. Reg. 26523.
[20] 7 U.S.C. § 7702(14) (definition of plant pest).
[21] 84 Fed. Reg. 26538. [refer to the official 340.3 "definitions" section of proposed rule]
[22] 84 Fed. Reg. 26524, summarizing plant pest risk criteria in current Part 340.6.

APHIS's stated intent to continue assessing GE plants for weediness in its proposed regulatory review process[23] is unconvincing, since that process is explicitly keyed to assessment of "plant pest risks" and the definition lacks any reference to weediness.

It is also critical that the plant pest risk definition include effects resulting from changes in agricultural practice associated with the GE organism, and nontarget harms to organisms beneficial to agriculture. GE plants may be specifically intended to alter agricultural practices in ways that increase pest or disease susceptibility or harm beneficial organisms. The proposed definition must be broadened to assess and regulate such potential plant pest risks. For instance, GE herbicide-resistant (HR) crops are designed for direct application of an herbicide that would kill or severely damage, and thus cannot be applied to, its non-GE counterpart. Thus, GE HR crops are explicitly intended to change agricultural practice. Herbicide application to a GE crop can increase the crop's susceptibility to plant disease pathogens. For instance, glyphosate application to GE glyphosate-resistant crops results in exudation of glyphosate from the crop's roots, which in turn fosters colonization of the roots by *Fusarium* fungi as well as other changes in rhizosphere-associated microbial poulations.[24] Several studies have shown that glyphosate treatment increases the incidence and severity of sudden death syndrome, a disease caused by the plant pest organism *Fusarium virguliforme* (formerly *F. solani* f. sp. *glycines*), in glyphosate-resistant soybeans.[25] Glyphosate is also harmful to organisms beneficial to agriculture. For instance, glyphosate is toxic to *Bradyrhizobium japonicum*, an important nitrogen-fixing symbiont that colonizes soybean roots, due to the sensitivity of its EPSPS enzyme to inhibition by glyphosate.[26] Suppression of this important symbiont is likely related to the finding that glyphosate application to glyphosate-resistant soybeans reduces foliar nitrogen content, seed nitrogen content, biomass and yields, especially under conditions of water stress, early application of glyphosate, and high application rates.[27]

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[23] 84 Fed. Reg. 26526-27.
[24] Kremer RJ and Means NE (2009). Glyphosate and glyphosate-resistant crop interactions with rhizosphere microorganisms. European Journal of Agronomy 31(3): 153-161.
[25] Sanogo S, Yang XB, Scherm H (2000). Effects of herbicides on *Fusarium solani* f. sp. *glycines* and development of sudden death syndrome. Phytopathology 90(1): 57-66. Sanogo S, Yang XB, Lundeen P (2001). Field response of glyphosate-tolerant soybean to herbicides and sudden death syndrome. Plant Disease 85(7): 773-779. Navi SS, Jing L, Yang XB (2013). Effects of glyphosate application rates and frequency of soybean sudden death syndrome. Plant Pathology Presentations and Posters. 4. http://lib.dr.iastate.edu/plantpath_conf/4.
[26] Zablotowicz, R.M. and K.N. Reddy (2007). "Nitrogenase activity, nitrogen content, and yield responses to glyphosate in glyphosate-resistant soybean," *Crop Protection* 26: 370-376.
[27] Zablotowicz et al (2007), op. cit.; King, C.A., L.C. Purcell and E.D. Vories (2001). "Plant growth and nitrogenase activity of glyphosate-tolerant soybean in response to foliar glyphosate applications," Agron. J. 93: 179-186.

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Assessments of plant pest risk must also account for unintended as well as intended effects of the GE modification. For instance, GE glyphosate-resistant crop systems were not introduced with the intention of harming N-fixing symbionts, but as noted above can do so. A second example also illustrates this point. The genetic engineering of Arctic apple to resist browning (the intended purpose) involved the silencing of a family of genes that generate enzymes – polyphenol oxidases – that are critical to plant defense against disease and insect pests in some plants. Thus, their silencing may well have the unintended effect of rendering Arctic apple trees more susceptible to disease or insect pests, creating plant pest risks.[28] This is true even though the engineering of Arctic apple trees was not intended to make them more susceptible to pest attack.

Another change in agricultural practice initiated with introduction of GE HR crops is profoundly altered herbicide use patterns, and increased overall herbicide use, that have given rise to rapid evolution of herbicide-resistant weeds. These impacts, too, can and must be assessed under APHIS's broad plant pest authority under the PPA, and/or under the PPA's noxious weed authority.

The Proposal must be structured so as to regulate and assess such potential plant pest risks, whether intentional or unintended, direct or indirect, from the GE crops that APHIS is charged with regulating. APHIS does not have the requisite experience to dismiss such risks, *a priori*, particularly with respect to advanced techniques, such as the RNA interference technique that was used in the development of the Arctic apple. One major purpose of the Proposed Rules is to respond to challenges presented by advances in genetic engineering. Failure to so make this change would be contrary to that need and purpose of the proposed new rules.

For these reasons, we urge APHIS to adopt the definition of "plant pest risk" that CFS proposed in comments on APHIS's January 2017 proposal:

Plant pest risk: A GE organism poses a plant pest risk when, relative to the unmodified organism from which it was derived, it has greater susceptibility to disease or non-vertebrate pests, adverse non-target effects on organisms beneficial to agriculture, weediness, capacity to impart weediness to sexually compatible relatives or transmit the introduced GE trait to organisms with which it does not interbreed, or indirect plant pest effects on other agricultural products; promotes changes in agricultural practices that exacerbate pest or disease problems; or there is reason to believe a GE organism might pose such plant pest risks.[29]

In sum, the impacts and risks of GE crops, such as transgenic contamination, the creation of superweeds, and the massive increase in pesticide use, can and do fall within the PPA's broad plant

[28] CFS (2013). Comments to USDA/APHIS on plant pest risk assessment and environmental assessment for determination of nonregulated status of apples genetically engineered to resist browning. Docket No. APHIS-2012-0025, Center for Food Safety, Dec. 16, 2013.
[29] *See* Attachment A (CFS 2017 comments).

pest harm authority. APHIS should not try and nullify that authority, but rather must apply it in the GE crop context, taking account of their differences from traditional plant pests.

Noxious Weed Authority

The latest proposal fails to incorporate (or even meaningfully mention) assessment of GE plants for noxious weed risks, despite past recognition by the agency as well as OIG that such assessments are critically necessary.[30] The original impetus to this revised rulemaking process was the PPA of 2000 and the need to align APHIS's pre-PPA regulations with its new, broader statutory authority. APHIS has repeatedly proposed to integrate the noxious weed authority into Part 340 in past proposals. APHIS's changed position to not incorporate noxious weed risk assessments into its proposed regulations is a fatal error of its latest proposal, is arbitrary and capricious, and contrary to sound science.

Congress specified a broad definition of noxious weed harms in the PPA, 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, and which encompasses harms caused by non-viable 'plant products' as well as plants.[31] APHIS is statutorily obligated to integrate and apply this authority to GE crops. In doing so, APHIS must apply the 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 must define and apply its statutory noxious weed authority in a manner that is consistent with the statute's language, and which encompasses the broad types of noxious weed harms as defined by the PPA. APHIS must also recognize that the types of harms posed by GE organisms are dynamic and evolving as the technology evolves; APHIS must apply its noxious weed authority in a manner that reflects this changing nature. Consideration of noxious weed risks cannot be blind to the specific context of GE crops, and should take those differences into account. This includes accounting for both direct and indirect harms, including socioeconomic harms. It is wholly arbitrary and capricious for APHIS to only continue to apply its plant pest authority (albeit in a neutered, unlawful way) but then choose not to apply its noxious weed authority at all.

APHIS previously acknowledged that it must evaluate GE plants for noxious weed risk."[32] APHIS also recognized the broad noxious weed definition and authority mandated by the PPA.[33] Yet, in its current proposal, APHIS fails to incorporate its statutory noxious weed authority as part of a

[30] *See, e.g.,* 82 Fed. Reg. 7009 ("Advances in genetic engineering have also made the need to evaluate GE plants for noxious weed risk more pressing.")
[31] 7 U.S.C. § 7702(10).
[32] 82 Fed. Reg. 7008, 7010 (Jan. 19, 2017); 73 Fed. Reg. 60007-48 (Oct. 9, 2008).
[33] 82 Fed. Reg. at 7009-10.

comprehensive regulatory scheme for GE plants. Instead, the entire proposal is only focused on assessing plant pest risks, and APHIS's regulatory approach is one that, according to the agency, would regulate "GE organisms that post a plant pest risk," with no mention of its noxious weed authority.[34] APHIS's selective application of its PPA authority is arbitrary and capricious, and violative of Congressional intent in passing the PPA.

As we have detailed in our past comments, which are resubmitted concurrently, there are many current adverse impacts and risks posed by GE organisms that are encompassed by the PPA's definition of noxious weed harms. APHIS's refusal to regulate these harms falls short of its statutory duty under the PPA, is contrary to sound science, and constitutes arbitrary and capricious agency action.[35]

APHIS's claim, that any noxious weed harms of GE plants would continue to be regulated under the Part 360 regulations, contradicts the agency's prior position, is arbitrary and capricious, and contrary to sound science. APHIS previously detailed ways that the Part 360 regulations are limited in their applicability to GE organisms today.[36] APHIS also admitted that it cannot "properly identify all risks" of GE plants without utilizing its statutory authority to regulate noxious weed harms, as those harms are broadly defined under the PPA.[37] Most significantly, under the Proposal, APHIS is unlawfully deferring the decision of whether a GE plant would be regulated at all to the private developers, and to only conduct a cursory regulatory review of the very small number of GE plants that developers themselves determine not to be under the agency's purview, giving away any noxious weed authority the agency may have over the vast majority of GE plants.

Proposed Exemptions

APHIS's proposed exemptions of GE plants are also contrary to sound science, and unacceptably narrow the regulatory scope of APHIS's regulation of GE plants, in violation of APHIS's duties under the PPA.[38]

As discussed above, APHIS's proposal to exempt GE organisms that purportedly could have been produced with traditional breeding has no basis in science or law. The proposed exclusions would also allow GE organisms that could PPA risks to entirely escape review and regulation by APHIS. Such a decision would be contrary to sound science and arbitrary and capricious.

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[34] 84 Fed. Reg. at 26516, 26525 (regulatory status review process only mentions plant pest risks).
[35] *See* Attachment A, CFS 2017 comments, Appendix B.
[36] 82 Fed. Reg. 7010.
[37] *Id.*
[38] 84 Fed. Reg. 26537 (Proposed 7 C.F.R. § 340.1).

1) GE organisms that are produced using genome editing techniques that cause a deletion in a gene, or substitute one nucleotide base pair for another, would be improperly exempted from regulation.

A priori exemption of GE organisms that have loss-of-gene-function or small changes in a nucleic acid sequences is contrary to sound science. Any type of change in a gene sequence can potentially cause phenotypic changes[39] that have significant consequences, whether the change could occur naturally or not.[40] Moreover, genome editing methods are still in early development, and risks of their use are not well-enough known to predict impacts *a priori*.[41]

For example, genome editing can result in alterations at unintended sites in the genome with potentially harmful results, and the use of such technologies, in plants[42] and also in animals[43], are too new and diverse to accurately predict or reliably prevent such off-target effects. Unlike largely random, genome-wide mutations that result from chemical mutagenesis and irradiation, current research on the off-target mutations caused by genome editing indicates they are more likely to be non-random, presenting unique, uncharacterized risks.

Further, genome editing can be done sequentially, to intentionally alter one gene after another. Presumably, each intermediate organism with just one new intentional change could be exempt from the proposed definition, cumulatively resulting in a final GE organism with many intended changes, that would also be exempt. Additionally, plants produced by almost every GE method are regenerated from single cells in tissue culture at some point in their development, a process well

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[39] NASEM 2016 at 387: "Phenotype/Phenotypic - The visible and/or measurable characteristics of an organism (i.e., how it appears outwardly and physiologically) as opposed to its genotype, or genetic characteristics".

[40] NASEM 2016 at 331: "A few changes in an endogenous plant gene can confer an agronomic trait, such as herbicide resistance. Thus, small changes in gene sequence in an endogenous gene can result in large phenotype and fitness changes"; e.g., Xiong L, Lee H, Huang R, Zhu J-K (2004) A single amino acid substitution in the Arabidopsis FIERY1/HOS2 protein confers cold signaling specificity and lithium tolerance. The Plant Journal 40: 536–545; Doyle MR, Amasino RM (2009) A single amino acid change in the enhancer of zeste ortholog CURLY LEAF results in vernalization-independent, rapid flowering in Arabidopsis. Plant Physiology 151: 1688–1697

[41] Kadam US, Shelake RM, Chavhan RL, Suprasanna P. 2018. Concerns regarding 'off-target' activity of genome editing endonucleases. Plant Physiology and Biochemistry. 131:22-30. https://doi.org/10.1016/j.plaphy.2018.03.027. See also: Ahmad N, Rahman M-u, Mukhtar Z, Zafar Y, Zhang B. 2019. A critical look on CRISPR-based genome editing in plants. Journal of Cell Physiology 2019: 1–17. https://doi.org/10.1002/jcp.29052.

[42] Wolt JD (2017) Safety, Security, and Policy Considerations for Plant Genome Editing. Progress in Molecular Biology and Translational Science. http://dx.doi.org/10.1016/bs.pmbts.2017.03.005

[43] Schaefer KA, Wu WH, Colgan DF, Tsang SH, Bassuk AG, Mahajan VB (2017) Unexpected mutations after CRISPR-Cas9 editing in vivo. Nature Methods 14(6): 547-548; Shin HY, Wang C, Lee HK, Yoo KH, Zeng X, Kuhns T, Yang CM, Mohr T, Liu C, Hennighausen L.(2017) CRISPR/Cas9 targeting events cause complex deletions and insertions at 17 sites in the mouse genome. Nature Communications 8:15464.

known to introduce genetic and epigenetic changes that result in somaclonal variation with unpredictable consequences.[44]

2) GE organisms made by "introducing only naturally occurring nucleic acid sequences from a sexually compatible relative" are improperly excluded.

Nucleic acids with sequences found naturally in closely related, sexually compatible organisms do not necessarily have acceptable risks when introduced into other species. For example, the introduced nucleic acids can direct the synthesis of toxins, change metabolism in harmful ways, turn on or off genes and metabolic pathways in the genetically engineered host, make the genetically engineered organism more susceptible to pests and pathogens, or more fit in the wild and more weedy.[45] Adding nucleic acid sequences derived from related organisms using genetic engineering results in the same unintended genome alterations from transformation-induced[46] and tissue-culture associated mutagenesis and epigenetic changes (see above footnote) as does adding nucleic acid sequences from unrelated sources, with risks that must be assessed.[47]

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[44] NASEM 2016 at 44: "Plants regenerated in tissue culture sometimes vary widely in phenotype (appearance) from the source plant and from each other, and the term *somaclonal variation* was established to refer collectively to such phenotypic variation…"; at 260: "…the construction of GE plants commonly relies on in vitro plant tissue culture, transformation, and plant regeneration. Among the complications often associated with the regenerated plants is that they can be variable in phenotype and fertility because of somaclonal variation rather than the genetic-engineering event itself…. Many factors—including crop, culture media, length of time in tissue culture, and genotype—can affect the frequency and severity of somaclonal variation. Altered gene expression can result from changes in chromosome number or structure, in DNA sequence, in epigenetic status—for example, DNA methylation…or in all the above…."; NASEM 2016 at 241; Neelakandan AK, Wang K (2012) Recent progress in the understanding of tissue culture-induced genome level changes in plants and potential applications. Plant Cell Reports 31: 597 – 620; Miguel C, Marum L (2011) An epigenetic view of plant cells cultured in vitro: somaclonal variation and beyond. Journal of Experimental Botany 62: 3713–3725.

[45] NRC (2002), p. 43.

[46] Wilson AK, Latham JR, Steinbrecher RA (2006) Transformation-induced mutations in transgenic plants: Analysis and biosafety implications. Biotechnology and Genetic Engineering Reviews 23: 209 – 234; Latham JR, Wilson AK, Steinbrecher RA (2006) The mutational consequences of plant transformation. BioMed Research International 2006: 1 – 7; Van Leeuwen W, Ruttink T, Borst-Vrenssen AWM, Van der Plas LHW, Van der Krol AR (2001) Characterization of position-induced spatial and temporal regulation of transgene promoter activity in plants. Journal of Experimental Botany 52: 949 – 959; Liu Z, Li Y, Zhao J, Chen X, Jian G, Peng Y, Qi F (2012) Differentially Expressed Genes Distributed Over Chromosomes and Implicated in Certain Biological Processes for Site Insertion Genetically Modified Rice Kemingdao. International Journal of Biological Sciences 8: 953 - 963.

[47] Zsögön A, Cermak T, Voytas D, Peres LE (2016) Review: Genome editing as a tool to achieve the crop ideotype and *de novo* domestication of wild relatives: case study in tomato. Plant Science, http://dx.doi.org/doi:10.1016/j.plantsci.2016.12.01.

3) The progeny of GE organisms is excluded when the nucleic acid sequences introduced into or changed in the parents have been removed by subsequent breeding to make "null segregants."

Bringing null segregants into the APHIS regulatory system to verify that any inserted or altered genes have indeed been fully removed, and are not present as partial, multiple, or scrambled versions somewhere in the genome, is necessary for assessment of risks. Also, having gone through the process of genetic engineering, the null segregants may still harbor somaclonal variation or off-target mutations with risks that must be assessed.

4) GE plants that have plant-trait-mechanism of action combinations that APHIS has already reviewed are exempted from regulation

APHIS is proposing to end its current event-based regulation[48] in favor of a narrower system in which GE plants with plant-trait-mechanism of action combinations that APHIS has already reviewed for plant pest risk are exempted from regulatory review.[49] Every transformation event is unique, and thus potentially has a novel phenotype[50] that must be assessed to determine appropriate regulation. As CFS previously commented, APHIS's proposed approach is contrary to sound science, in violation of the PPA.[51] APHIS has conceded that event-based regulation is more protective than a trait-and-organism approach, and would "eliminate potential gaps that may occur as genetic engineering technologies continue to advance."[52] Similarly, as explained *infra* and in past comments, the National Academy of Sciences has also advocated the use of genetic engineering [i.e. transformation] as "both a useful and scientifically justifiable regulatory trigger" because "there is no scientific basis" on which to exclude GE organisms from regulatory review prior to evaluation of data on the interactions between "trait, organism and environment."[53] CFS strongly opposes APHIS's proposal to exclude GE organisms from regulations based on the loopholes discussed above.

<u>Plants that Produce Pharmaceutical and Industrial Compounds (PMPI Plants)</u>

[48] "Currently, APHIS regulates GE organisms as "transformation events." An event is a single successful insertion of a gene or gene fragment into a cell's genetic material or a successful deletion of a gene or gene fragment from a cell. Each event can be genetically unique, even if the event results from a single transformation experiment in which many individual cells were treated under identical conditions. Biotechnology techniques allow scientists to regenerate entire organisms, such as whole plants, from a single cell. A plant produced from one transformed cell may also be called an event." (USDA APHIS 2007 Draft PEIS GE Organisms at 22)
[49] 84 Fed. Reg. 26525.
[50] *Phenotype* means "[t]he visible and/or measurable characteristics of an organism (i.e., how it appears outwardly and physiologically) as opposed to its genotype, or genetic characteristics." NASEM 2017 at 129.
[51] *See* Attachment A, CFS 2017 Comments.
[52] USDA APHIS (2007), pp. 133-134; 168.
[53] NRC (2002), p. 79.

CFS strongly opposes APHIS's proposal to effectively end its long-standing regulation of PMPI plants. It has long been recognized by the scientific community and by APHIS itself that PMPI plants produce potentially hazardous compounds that merit stringent regulation.[54] The risks posed by PMPI plants to the food system, public health, and agriculture fall well within APHIS's broad PPA authority. APHIS admits that these crops are not regulated by either FDA or EPA, and recognizes that its current proposal would leave PMPI plants unregulated. In light of their recognized risks and harms, it would be irresponsible and unlawful to halt PMPI regulation by APHIS, violative of APHIS's statutory duties to protect agriculture and the public health, contrary to sound science, and arbitrary and capricious.

Rather than proposing meaningful regulatory oversight of PMPI plants pursuant to its broad PPA authority, APHIS simply brushes the risks associated with these plants aside, claiming that it could either regulate PMPI under some other regulatory authority, or under some new statutory authority issued by Congress.[55] APHIS cannot kick this can down the road with uncertain proposals and imaginary Congressional actions that are entirely outside the agency's control. Together all of APHIS's PPA authority, over both plant pest and noxious weed harms, encompass these PMPI plants, and APHIS can and should regulate them to prevent dangerous contamination of the food supply.[56] Instead APHIS has proposed to leave this hazardous class of GE crops, which pose clear risks to agriculture, the environment, and the food supply, unregulated, in violation of the PPA's mandates.

Field-Testing of GE Plants with Pesticidal Substances on 10 Acres or Less

Under current regulations, APHIS is solely responsible for regulating field tests of GE crops that produce pesticidal substances (plant-incorporated protectants, or PIPs) for plantings of 10 acres or less. APHIS currently regulates these plants because they are engineered with plant pest components or with the aid of plant pests. The Environmental Protection Agency jointly regulates GE PIP plants with APHIS when plantings exceed 10 acres.

Under the Proposed Rules, APHIS would abdicate responsibility for regulating most GE PIP plant field tests when plantings are 10 acres or less, leaving them entirely unregulated. The only exceptions would be PIP plants that represent novel plant-trait-mechanism of action combinations,

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[54] USDA APHIS (2007). Introduction of Genetically Engineered Organisms: Draft Programmatic Environmental Impact Statement. USDA Animal and Plant Health Inspection Service, July 2007, p. 35: ("…some of these substances [pharmaceutical or industrial compounds produced by GE plants] may be allergenic, toxic or otherwise biologically active in humans and APHIS requires extraordinary safeguards to ensure that they are not found in commodity food or feed channels.")
[55] 84 Fed. Reg. 26518.
[56] *See also* Attachment A, CFS 2017 Comments, App. B.

and even these GE plants would most likely go unregulated following a cursory regulatory status review that would "generally not require data from outdoor plantings."[57]

CFS opposes APHIS's attempt to delegate its statutory duties to other agencies, without meaningful assurance or certainty that those agencies will effectively regulate these organisms. Shifting responsibility over these organisms to another agency amounts to an unlawful abdication of APHIS's statutory duties, which constitutes arbitrary and capricious agency action.

GE plants expressing PIPs pose potential plant pest or noxious weed risks. PIPs increase the plant's resistance to certain insect pests and/or disease pathogens. A PIP plant itself, or a sexually compatible plant to which it transfers the PIP trait(s), would be immune or less susceptible to the target pest(s)/pathogen(s), potentially increasing its ability to establish populations in the wild. Such populations of PIP-containing plants could become weedy. Even if PIP-containing GE plants do not persist in nature or become weedy, their cultivation over years imposes selection pressure on target pests, potentially leading to evolution of PIP-resistant plant pests. A number of insect pests have evolved resistance to PIPs in commercially-grown GE plants. The same could occur with PIP plants grown in field trials. PIP-containing crops could also transfer their GE trait(s) to other crops of the same species, resulting in GE contamination of crop supplies and subsequent potential market disruptions if the GE PIP trait is rejected by downstream markets. Without oversight by APHIS or EPA, such impacts would go not only unregulated, but potentially unobserved, since the PIP plant developer would never even inform a regulator that such plants are being field-tested in plantings up to a substantial 10 acres in size. The lack of any required confinement measures for such plantings would dramatically increase the potential for contamination episodes.

Sharing regulation of field trials between APHIS and EPA is necessary and should continue. Under the Proposal, risks from field trials of less than 10 acres would be left arbitrarily unregulated, unless EPA assumes oversight. Yet, EPA's regulatory authority focuses on the PIP itself, while APHIS currently regulates the GE PIP plant. Any plant pest and/or noxious weed risks properly falls within APHIS' PPA authority because each event is a novel organism, and field trials of any size are capable of causing harm to the environment or human health. APHIS is already positioned to oversee field trials, whereas it is entirely uncertain whether EPA would be in a position to assume regulation of GE PIP plant field plantings of 10 acres or less.

In sum, the impacts and risks of GE crops can and do fall within the PPA's broad plant pest harm authority, and APHIS should not try and nullify that authority in any new proposed rule, but rather apply it in the GE crop context, taking account of their differences from traditional plant pests.

<u>Regulatory Status Review</u>

[57] 84 Fed. Reg. 26518-59.

APHIS is proposing to modify the current permit and notification system, and eliminate the current petition for nonregulated status entirely. The proposed regulatory status review process is impermissibly narrow, not based on sound science, and is arbitrary and capricious.

Rather than utilizing its statutory authority to regulate both plant pest and noxious weed harms, APHIS is proposing to evaluate GE plants for plant pest risks only, with an impermissibly narrow definition of "plant pest risk," and under a streamlined "regulatory status review" process.

The scope of the proposed regulatory status review process is impermissibly narrow. The proposed review process would only encompass "novel" GE plants that developers self-determine are not exempted from regulation entirely.[58] And for those GE plants that do need regulatory status review, APHIS cabins the review to only examining plant pest (but not noxious weed) risks, by seeking only preliminary information on "(1) [t]he basic biology of the plant prior to modification; (2) the trait that resulted from the genetic modification; and (3) the mechanism of action".[59] The information on the GE plant to be submitted in support of a regulatory status review is impermissibly narrow, as it involves exclusively characterization of the GE plant's genotype, together with a description of the ***intended*** trait(s) conferred by the GE modification, and any ***expected*** changes in metabolism, physiology, and development due to the trait/genetic modification.[60] The GE plant developer need not submit experimental data from any field trials or other testing it may have conducted, as is required under current regulations, and is necessary to detect unintended phenotypic changes and unexpected changes in the GE plant.

As discussed infra (Plant Pests and Plant Pest Risks), APHIS suggests that its initial regulatory status review would cover weediness issues as well as harms to beneficial nontarget organisms as "plant pest risks," but these promised elements of the review process do not align with the excessively narrow, formal definition of "plant pest risk," nor with the scope of review in current Part 340.6, and thus would not be required elements of the review. Nor is there any consideration given to changes in agricultural practice associated with cultivation of the GE plant, which can profoundly influence the risks it poses.

APHIS explains that if the agency does not identify any plant pest risk base on its initial review, APHIS would post the findings on its website without any further analysis, and that it would only conduct a Plant Pest Risk Assessment (PPRA) if the deficient initial review detects potential plant pest risks. The proposed process is entirely silent on further process for complying with the National Environmental Policy Act (NEPA), which applies to every major federal action that may significantly affect the human environment. Yet, under APHIS's latest proposal GE plants would no

[58] *See supra.*
[59] *See* 84 Fed. Reg. 26517.
[60] *See* 84 Fed. Reg. 26525 (emphasis added).

longer be regulated after either initial preliminary reviews or a review of only the GE plant's plant pest risks. This process is contrary to sound science, and in violation of the agency's broad statutory duties under the PPA, as well its statutory obligations under NEPA. APHIS must comply with NEPA's obligations whenever it takes such actions, regardless of where in the process the action may fall for a particular GE organism.

Instead of the streamlined regulatory review process proposed, APHIS should take a more proactive role in plant pest risk and noxious weed risk assessments. APHIS should not rely entirely on developer-submitted information, and give developers the discretion to omit or downplay contrary information. Simply put, APHIS cannot subdelegate out its statutory duties to the regulated entities. APHIS should conduct comprehensive literature searches to uncover any potential unintended effects of the genetic modification, or of changes in agricultural practices associated with the genetic modification, that are potentially relevant to the plant pest or noxious weed risk assessment. Targeted testing should be undertaken to confirm or rule out such effects, whether or not they are intended or reported by the GE crop developer.

1. Field Trial Data

The elimination of the field trial data requirement as part of APHIS's review constitutes a "significant departure" from the current rules, which specify that a petition for nonregulated status must contain "field reports for all trials conducted under permit or notification procedures … including …. methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment."[61]

This proposed change must be rejected, as contrary to sound science. APHIS cannot perform scientifically sound assessments without field trial data, and its proposal to do so will likely result in widespread cultivation of GE crops that pose unexamined plant pest and noxious weed risks. This is particularly true with respect to unintended or unexpected effects of the genetic engineering process, which are unlikely to be detected from genotypic data or a description of "intended" traits and "expected" changes required by APHIS under the proposed regulatory review process.

APHIS justifies the elimination of a field trial data requirement by claiming that it has not received from GE plant developers any reports of field trial data indicating "unintended or deleterious effects on plants, non-target organisms, or the environment."[62] As discussed in our prior comments on the January 2017 Proposed Rule (pp. 16-17), this is due to the unscientific nature of the field trial reports, which involve only "observations" rather than controlled tests, and APHIS's lax assessment process. As examples, we discuss there how APHIS missed potential plant pest impacts of the Arctic

[61] 84 Fed. Reg. 26525.
[62] 84 Fed. Reg. 26525.

apple and glyphosate-resistant soybeans by not requiring appropriate data from their developers, and by failing to consult relevant scientific literature.

It is also disingenuous of APHIS to suggest that GE field trials have never given rise to harms cognizable under the PPA. These include, prominently, many episodes in which supposedly "confined" GE plant field trials have resulted in contamination of commercial crops, causing significant economic losses and injury to U.S. agriculture. CFS has documented such episodes and their impacts in past comments to APHIS in the previous rounds of rulemaking. For example, field trials of GE LL601 LibertyLink rice led to contamination of 30% of U.S. long-grain rice supplies in 2006 and 2007, resulting in massive export market rejection of contaminated shipments, and huge losses estimated at up to $1.3 billion to 11,000 American rice farmers and others in the rice food chain.[63] APHIS's regulatory failure forced farmers to sue the GE crop's developer, Bayer CropScience, which denied all responsibility. Only after five years of litigation did farmers obtain at least partial compensation. Similarly, in late 2010, contamination stemming from a 2005 field trial of Roundup Ready bentgrass was discovered in Ontario, Oregon, four miles from the field trial location in Idaho.[64] The agency's reliance on an outdated 1989 NRC report to support its assertion that field trial data are unnecessary is similarly flawed. At the time of this report, extremely few data were available to the authors of this report, since field tests of GE organisms began in very small numbers only in the late 1980s.

2. Petitions for Deregulation

CFS strongly opposes the proposal to end petitions for deregulation, and instead replacing it with a regulatory scheme that would end regulated status for the vast majority of GE organisms. GE organisms must be subjected to a nonregulated status review process, based on sound science and in compliance with other federal statutory duties, such as those under NEPA and the ESA, before they can be commercialized. A contrary decision violates sound science principles and is arbitrary and capricious. An agency needs adequate data to assess risks, and the proposed streamlined regulatory review process would dramatically narrow current data requirements, which are already insufficient, in that they do not provide adequate grounds for assessing GE crops' actual impacts under real-world production conditions and constraints. APHIS must make clear that all GE organisms begin at minimum as regulated organisms. APHIS must regulate and assess each GE organism on an individual basis, and must include an assessment of their actual direct and indirect harms.

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[63] Harris and Beasley (2011). Bayer agrees to pay $750 million to end lawsuit over gene-modified rice. Bloomberg, 7/2/11. CFS (2011). Legal settlements and awards for Bayer contamination of U.S. rice with experimental, genetically engineered LibertyLink rice. Center for Food Safety, April 2011.
[64] Mitch Lies, *GMO bentgrass found in Eastern Oregon*, CAPITAL PRESS, Nov. 9, 2010, *available at* http://www.capitalpress.com/oregon/ml-gmo-bentgrass-111210.

As mentioned above, the Proposal will leave APHIS without the data and information necessary to make a meaningful risk assessment. It is simply illogical for APHIS to claim that it can conduct risk assessments prior to receiving data based on properly conducted experiments at the field trial stage. Moreover, it would be unlawful and contrary to the PPA for APHIS to make such assessments without necessary data. For these reasons, the Proposal with respect to deregulation petitions is contrary to sound science, arbitrary and capricious agency action, contrary to the evidence before the agency, and an improper delegation of APHIS's statutory authority to private parties.

3. Permits and Notifications

CFS theoretically supports the proposal to eliminate notifications in favor of permits, because permits are stricter and provide APHIS with greater means of enforcing safeguards and control over GE crops. CFS also supports establishing and strengthening the general reporting requirements for all permits.

However, as detailed above, the practical effect of APHIS's Proposal would be to allow the majority of GE plant field trials to occur without any permits or notifications, and for GE crops to be commercialized without meaningful review. Because permits will only apply to those GE crops where the developer opts to apply for a permit, or those that APHIS determines carry plant pest risks on impermissibly narrow grounds, the Proposal would result in permits for only a small minority of currently-regulated GE plant field trials, and would not encompass the broad range of risks that must be regulated under the PPA. Instead, genetically engineered organisms exempted at the outset by APHIS from regulation would be field-tested by developers as part of their private research and development, without reporting to or oversight by APHIS. Such a decision is arbitrary and capricious and contrary to sound science, and an improper delegation of APHIS's duties to industry.

And it would have dramatically negative effects. Ending regulation of many experimental GE crops, as proposed, would sharply increase harms to farmers, markets, and the environment from GE escapes and contamination, as detailed in these comments and CFS's prior comments. This would also be directly contrary to the 2008 Farm Bill mandates that APHIS claims it is implementing in the Proposal, as discussed below. APHIS's contrary conclusions are belied by evidence and past history of GE crops. APHIS assumes that GE crops exempted from its regulatory regime under the proposed rule would not cause contamination-related harms for two main reasons: GE crop developers would of their own accord employ rigorous gene containment measures; and economic losses would not occur if the contaminating GE crop were exempted from APHIS oversight. Neither assumption is valid.

Moreover, as detailed in CFS's 2017 comments and in our comments on the current draft Programmatic Environmental Impact Statement (Draft PEIS), because APHIS-exempted GE crops would continue to be regulated in most of our export markets, which have stricter regulatory

regimes, and thus export shipments contaminated by them would likely be rejected. There have already been numerous costly episodes in which export markets rejected shipments contaminated with GE crops that had been officially granted nonregulated status by APHIS, but were not approved in the receiving country; known losses reach the many billions of dollars.[65] Domestically as well, organic and non-GE farmers already incur substantial costs from GE contamination. Such episodes and their costs would likely increase dramatically under the proposed rule, with most GE crops either never-regulated, or subject only to perfunctory "regulatory status reviews." APHIS provides no projection of the costs associated with such episodes, despite recognizing that they would cause market disruptions, the costs of which, as usual, would be borne chiefly by American farmers.

Additionally, CFS also opposes APHIS's proposal to list requirements for permit applications on the internet or through guidance, rather than in federal regulations with the force of law.[66] Permit information should be made public and easily accessible; however, it must be codified with the force of law and implemented or changed through notice-and-comment rulemaking procedures. If APHIS intends to treat these requirements as legally binding, it cannot issue them through a process that does not guarantee public participation and accountability.

2015 OIG Reports, 2008 Farm Bill

The Proposal is also arbitrary and capricious, and not in accordance with the law. APHIS claims that the proposed regulatory changes are reflective of the changes mandated by Congress under the 2008 Farm Bill, and the 2005 and 2015 OIG reports. The 2008 Farm Bill contained provisions that explicitly directed APHIS to *strengthen* its regulation of GE crop field trials to forestall GE contamination events. These provisions were enacted by Congress in response to thousands of rice farming constituents who were victimized by an extremely costly GE contamination episode involving an unapproved, experimental GE rice variety known as LLRICE601, discussed earlier and in prior CFS comments.[67]

APHIS's claim that its Proposal, which exempts most GE plants from regulation and eliminates regulatory oversight of most GE field trials, vastly increasing the potential for similar episodes in the future, is responsive to the 2008 Farm Bill is entirely without merit. Neither does the Proposal

[65] For instance, see: Durison and Wilson (2014). U.S. grain losses seen up to $6.3 billion on China ban. Bloomberg, 4/16/14. Newman J (2014). China's hard line on biotech burns U.S. hay. Wall Street Journal, 12/15/14.
[66] *See* 84 Fed. Reg. 26525.
[67] Blue EN (2007). Risky Business: economic and regulatory impacts from the unintended release of genetically engineered rice varieties into the rice merchandizing system of the US. Neal Blue Consulting and Greenpeace, 2007.

respond to the USDA OIG's 2005 and 2015 reports, which detailed the numerous regulatory deficits that enabled GE contamination to occur, particularly but not solely with respect to PMPI plants.

In sum, APHIS's Proposed Rules are contrary to the evidence before the agency in this rulemaking and in prior dockets that have led to the current proposal, where the records are replete with evidence of harms that stem from APHIS's repeated failures to prevent escapes and contamination from field trials. This course of proposed action is also contrary to sound science, arbitrary and capricious, and a direct violation of the 2008 Farm Bill.

New Rules Are Necessary

APHIS first contemplated a regulatory change more than a decade ago, in 2004, drafted a programmatic Environmental Impact Statement in 2007, and issued a proposed rule in 2008, in which it recognized that new regulations were necessary to effectively regulate GE organisms[68] under its statutory authority, the Plant Protection Act (PPA) of 2000. APHIS subsequently withdrew the proposal, and published a new proposal in 2017 (the 2017 Proposal).[69] Concurrent with the Federal Register notice for this Proposal, APHIS has now withdrawn the 2017 Proposal.

As APHIS itself has repeatedly acknowledged, new, effective regulations are long overdue and sorely needed due to the reality of GE crops in the United States and their adverse environmental and agronomic impacts. APHIS's constrained application of its plant pest authority to date has allowed GE crops to proliferate, to sometimes devastating effect. To summarize: APHIS oversight to this point has been an abysmal failure. Transgenic contamination episodes cost U.S. farmers, including organic and conventional farmers, billions of dollars as the result of a variety of economic consequences that flow from contaminated crops, including 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. Herbicide-resistant crops have had a host of negative impacts, including increased use of herbicides; effects on threatened, endangered, and other non-target species and their habitats; an herbicide-resistant weed epidemic and its associated economic and environmental harms, including soil erosion; its negative impact on sustainable weed control; herbicidal drift injury to sensitive plants and other non-target organisms; and public-health and socioeconomic impacts of air and water contamination. Further, beyond GE crops, newer GE

[68] Throughout, "GE organisms" refers to all GE life forms, as defined *infra* and "GE crops" refers to GE organisms, mainly plants, that are domesticated and/or cultivated, including GE seeds, crops and crop systems, perennial grasses and trees.
[69] 82 Fed. Reg. 7009.

organism types including GE grasses and GE trees pose their own novel risks that APHIS must regulate and analyze.[70]

Unfortunately, as detailed in our comments, the Proposal is significant step backward, and the proposed scheme falls woefully short of APHIS's statutory duties with respect to GE organisms under the Plant Protection Act (PPA), and is contrary to Congress's mandates in the 2008 Farm Bill, as well as the recommendations of the USDA's Office of Inspector General (OIG). Rather than applying it statutory authority under the PPA broadly to provide meaningful oversight of GE organisms, APHIS's latest proposal sets up a "deregulatory" scheme whereby the vast majority of GE plants can be experimented on and commercialized without any federal oversight. APHIS is proposing to abdicate its responsibilities, and instead leave it solely up to the agrichemical companies and developers of GE technologies to self-regulate.

APHIS had previously acknowledged that it must incorporate its noxious weed harm authority in order to carry out its duties under the PPA with respect to GE organisms. Nothing has changed. APHIS's decision to abdicate its statutory authority is contrary to sound science, arbitrary and capricious, and constitutes an unlawful subdelegation of the agency's regulatory authority.

The Scope of USDA oversight: Genetic engineering must be the trigger.

APHIS currently regulates only those GE organisms that were engineered using genetic sequences or vectors that were derived from plant pests such as pathogenic viruses and bacteria, even though it knew at least by the early 1990s that these plant pest components themselves were highly unlikely to turn crops into actual plant pests.[71] As CFS has long contended, using plant pest components in order to bring GE organisms into the USDA regulatory net is not related to risks, and is thus arbitrary and contrary to sound science. Almost any crop can be genetically engineered using old or new methods that do not involve plant pest components and thus evade USDA regulation. Examples of GE crops that have gone unregulated because of not being engineered using plant pest components include herbicide-resistant turf grasses, fast-growing grasses and trees for biofuels, and disease-resistant rice and grapes.[72] There are now dozens of GE crops that APHIS has agreed with the crop developers can make an end-run around its current regulatory process, and are thus presumably in some stage of commercial development, without any monitoring or

[70] NASEM 2019. National Academies of Sciences, Engineering, and Medicine: Forest Health and Biotechnology: Possibilities and Considerations. Washington, DC: The National Academies Press. https://doi.org/10.17226/25221.
[71] USDA APHIS 1992, FLAVR SAVR tomato deregulation decision, Petition Number 92-196-01p, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status
[72]USDA APHIS "Regulated Article Letters of Inquiry," https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/Regulated_Article_Letters_of_Inquiry; accessed June 11, 2017.

oversight. From field trials through commercialization, companies and researchers are free to plant most of these never-regulated GE crops anywhere.[73] This irresponsible practice must be halted, and the loophole closed, one of many reasons why new regulations are needed.

Rather than exercising its statutory authority to responsibly regulate GE plants, APHIS instead proposes to expand the loophole by excluding most of GE plants entirely form any regulatory oversight. APHIS must use its broad authority under the PPA to regulate all GE crops for the myriad risks they pose, to protect our health, environment, and agricultural economy in a scientifically sound way. Genetic engineering, broadly defined, should be the unambiguous trigger for bringing GE organisms into the regulatory system.

Using GE, broadly defined, as the trigger for regulation is supported by the recommendation of a National Academy of Sciences committee, which conducted an exhaustive review of APHIS GE plant regulation and 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.[74] 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."[75]

Further, in order to be scientifically sound, the definition of genetic engineering must be robust and include all methods that use *in vitro* manipulation of nucleic acids and proteins to alter genetic material or its expression, including methods on the horizon, so that the proposed rule will be inclusive and durable. Based on this proper definition, all GE organisms should begin and stay regulated and not be eligible for commercialization absent APHIS analysis, affirmative approval, and continued monitoring and conditions.

Recently, the National Academies of Sciences, Engineering, and Medicine (NASEM) produced reports that dealt in part with the future landscape of genetically engineered plants and other kinds

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[73] Depending on their particular traits, a few of the crops that are not being regulated by USDA will be regulated later by EPA or FDA, when releases are over 10 acres, and when the GE crops are grown commercially for food.

[74] NRC (2002). Environmental Effects of Transgenic Plants. National Research Council, National Academy of Sciences, 2002, p. 79. USDA APHIS (2007), op. cit., p. 20.

[75] USDA APHIS (2007), op. cit., p. 168. APHIS failed to finalize this Draft 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 Proposal. APHIS has never explained this sudden and unjustifiable about-face. However one logical explanation is that APHIS allowed itself to be influenced by industry stakeholders who wished (and wish) to throw off APHIS regulation altogether and instead regulate themselves.

of GE organisms.[76] The definition of genetic engineering in these reports is suitably inclusive,[77] and should be used instead of the definition proposed by APHIS, so that the Rule will capture all GE organisms for assessment and regulation:

> *Genetic engineering* means the introduction or change of DNA, RNA, or proteins by human manipulation to effect a change in an organism's genome or epigenome; where *genome* means the complete sequence of the DNA in an organism, and *epigenome* means the physical factors affecting the expression of genes without affecting the actual DNA sequence of the genome.[78]

Similarly, APHIS should define "genetically engineered organism"[79] to conform with this NASM definition of "genetic engineering." Using APHIS's proposed definition of "organism,"[80] this would include all organisms whose genomes or epigenomes have been intentionally altered using modern molecular technologies, which may include random or targeted nucleotide sequence changes such as nucleotide insertions, substitutions, or deletions. This definition applies to both the founder organism in which the initial alteration event occurred and the entire subsequent lineage of organisms that contains the genomic/epigenomic alteration(s).

Principles of Responsible Oversight

The rapid evolution of GE technology has created GE organisms that were not developed using any components from plant pests. This warrants an updated and more inclusive definition of genetic engineering and an application of the full scope of APHIS's authority—over both plant pest and noxious weed harms, as the statute broadly defines those types of harms.

The new GE regulations should be guided by the following principles:

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[76] NASEM, 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: National Academies Press, ISBN 978-0-309-43738-7 | DOI: 10.17226/23395, available at http://www.nap.edu/23395; NASEM, 2017. Preparing for Future Products of Biotechnology. Washington, DC: National Academies Press, ISBN 978-0-309-45205-2 | DOI: 10.17226/24605, available at http://www.nap.edu/24605

[77] NASEM 2016 at 36 explicitly lists some examples of what its definition includes and excludes: "The committee's definition of *genetic engineering* includes *Agrobacterium*-mediated and gene gun-mediated gene transfer to plants … as well as more recently developed technologies such as CRISPR, TALENs, and ZFNs [genome editing methods]. …Making sexual crosses of plants that have different genomes, selecting desirable plants to serve as parent lines, and changing (mutagenizing) the genome with chemical methods or irradiation are considered *conventional plant breeding*, which does not include *genetic engineering*..."

[78] NASEM 2016. Glossary at 384 – 388; NASEM, 2017. Glossary at 178 – 180.

[79] *Organism* is not specifically defined in the NASEM report glossaries.

[80] 84 Fed. Reg. 26538 (Proposed 7 C.F.R. § 340.3, defining "organism" as "any active, infective, or dormant stage of life form of an entity vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.")

1) Genetic engineering, properly defined, should be the trigger for regulation and GE organisms should not be commercialized or field tested without government assessment and approval.

2) APHIS must maintain oversight of field trials to prevent contamination and other harms. Field trials should only be allowed under permits that mandate stringent gene containment protocols with a management goal of full containment.

3) All GE organisms must undergo a pre-market review process that assesses and accounts for known adverse impacts discussed above. This process must be rigorous, transparent, and inclusive of APHIS's plant pest and noxious weed authority under the PPA. Field trial data is needed for making scientifically sound decisions.

4) Deregulation (and therefore commercialization) and/or environmental release must be denied if the GE organism is shown to cause harm. Where harmful effects can be completely prevented with limitations or geographic restrictions, such safeguards must be required for the organism during field trials and post-commercialization.

5) APHIS must maintain oversight and monitoring of GE organisms after commercialization through a commercial permitting system, and should conduct periodic reevaluations of regulatory status at set intervals.

APHIS must hold patent holders accountable and liable for direct and indirect harms caused by their GE products.

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COMMENTS ON DRAFT PEIS

The draft Programmatic Environmental Impact Statement (the Draft PEIS) is fundamentally flawed in numerous ways, in violation of NEPA, PPA, the Endangered Species Act (ESA), and the APA.

As detailed below, the agency's purpose and need for the Proposal is flawed and overly-narrow. The alternatives analysis fails to consider reasonable alternatives, and those it does consider are inadequately assessed. The agency fails to adequately analyze many direct, indirect, and cumulative impacts, and wholly fails to consider many others. Its treatment of direct, indirect, and cumulative impacts is contrary to the evidence and arbitrary and capricious. The Draft PEIS also fails NEPA's mandates of high quality, accurate scientific analysis and relevant data, including scientific and baseline data, and does not present accurate and complete information to allow informed decisions. It refuses to disclose and discuss opposing scientific views at relevant points. It also refuses to acknowledge and analyze scientific uncertainties where appropriate. It improperly relies on old data at places, and on incorrect data and assumptions at others. It improperly relies on different forms of direct and indirect mitigation. At times APHIS relies on factors Congress did not intend it to consider. It fails to analyze the reasonably foreseeable results of its programmatic decision here, namely the impacts of individual GE crops going unregulated in the future and cannot lawful defer consideration those impacts to later, particularly when the agency is proposing to abdicate its regulatory duties in some instances. The Draft PEIS also fails to consider risks to threatened and protected species and their habitats, instead unlawfully concluding that the proposed regulations would have no effect on these sensitive species. For all of these reasons, the Draft PEIS is not based on sound science, in violation of the PPA.

Because many of the Draft PEIS's discussions are substantially similar to the Draft PEIS APHIS previously prepared with the last round of rulemaking,[81] CFS incorporates by reference our prior comments on the 2017 DPEIS, which is concurrently filed with these comments.

Purpose and Need

APHIS improperly cabins the purpose and need, and the corresponding scope of its analysis of the proposed regulations, to only its plant pest authority under the PPA. APHIS acknowledges that its mission is "to protect health and value of America agriculture and nature resources," and recognizes that the PPA provides the agency with "authority to issue regulations that serve to

[81] See USDA, Revisions to USDA-APHIS 7 CFR Part 340 Regulations Governing the Importation, Interstate Movement, and Environmental Release of Genetically Engineered Organisms, Draft Programmatic Environmental Impact Statement (Jan. 2017), https://www.aphis.usda.gov/biotechnology/downloads/340/15-057-1_340_dpeis.pdf (hereafter the 2017 DPEIS).

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prevent or mitigate plant pest and noxious weed risks."[82] Yet, in providing the rationale for the proposed regulations, APHIS fails to mention the PPA, instead claiming that the proposed revisions is to address advances in biotechnology, the recommendations of the 2005 and 2015 OIG reports, the mandates in the 2008 Farm Bill, and to address the risks of GE technology as described in the National Research Council.

The PPA of 2000 was the major rationale for updating the regulations, a purpose and need on which APHIS has repeated relied up until this latest proposal. APHIS's silence on its broad authorities under the PPA is arbitrary and capricious. The agency had previously acknowledged the need for updating regulations in order to "make explicit [the] criteria for evaluation of GE organisms for noxious weed potential," and discussed its broader authority to regulate GE crops under the PPA in prior environmental impact statements in past rounds of rule proposals.[83] Now, rather than applying its full PPA authority to address the need for revised regulations, APHIS instead chose to apply that authority "in part" [84] only.

The stated purpose and need is also flawed, because, as APHIS previously recognized in the 2017 DPEIS, the OIG report recommended that APHIS "exercise broader and more stringent oversight of [GE field trials], and update its regulation to consolidate all requirements for conducting field tests, as well as incorporate the provisions of the [PPA]."[85] The PPA mandates that APHIS to regulate and prevent the dissemination of plant pests and noxious weeds, and to reduce the risk of dissemination of plant pests and noxious weeds.[86] In past rulemaking, APHIS has repeatedly admitted that GE plants may carry noxious weed risks and should be evaluated for such risks.[87] By declining to apply the noxious weed authority granted by the PPA, APHIS has plainly failed to consider the myriad of serious threats posed by GE organisms to American agriculture. And by failing to heed PPA's directive to regulate noxious weeds, USDA is effectively delaying the implementation of statutorily required regulations, in direct contravention of Congressional directive in enacting the PPA. The PEIS's failure to consider the PPA as part of the purpose and need for the proposed action is unlawful.

The Proposal also does not meet the stated purpose and need of updating in order to meet the advances in biotechnology since 1987 and the original rules, nor meet the mandates of the 2008

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[82] Draft PEIS at 1-1.
[83] 84 Fed. Reg. 26515 (referencing 73 Fed. Reg. 60007 (Oct 9, 2008)); See 73 Fed. Reg. at 60011 (stating that APHIS considers it "appropriate to align the regulations with both the plant pest and noxious weed authorities of the PPA."); see https://www.aphis.usda.gov/brs/pdf/complete_eis.pdf (July 2007 Draft PEIS); https://www.aphis.usda.gov/biotechnology/downloads/340/15-057-1_340_dpeis.pdf (January 2017 Draft PEIS).
[84] Draft PEIS at 1-1.
[85] 2017 DPEIS at ES-2.
[86] *See* 7 U.S.C. §7701(3).
[87] *See, e.g.,* 82 Fed. Reg. at 7010.

Farm Bill and OIG recommendations. Just the opposite, both the 2008 Farm Bill and OIG recommendations acknowledged the need for APHIS to enact more rigorous regulations and monitoring over field trials, and to assess GE plants for their noxious weed harms. The Proposed Rules significantly loosen regulations, despite the foreseeable (and current) arrival of new and novel types of GE organisms that present different risks and impacts, such as GE grasses and trees.[88] To the extent the purpose and need is not to address the current and future adverse impacts of GE organisms, the purpose and need are unlawfully narrow and improper. Nor does the Proposal fulfill the stated purpose and need of making regulations commensurate with the risk assessment methodologies of the National Research Council in 2002.

APHIS also improperly relies on extra-statutory factors and improper bases in setting the purpose and need. APHIS claims that the proposed regulations will increase efficiency, reduce regulatory burdens, and avoid actions that "inhibit innovation, stigmatize new technologies, or create trade barriers."[89] The PPA mandates that APHIS prevent and regulate noxious weed risks and plant pests risks to protect U.S. agriculture and economy; it says nothing about promoting technology or reducing regulatory burdens. Moreover, contrary to APHIS's misrepresentation, past contamination events have shown that the inadequate regulatory review of GE crops' contamination risks have created trade barriers.

Alternatives Analysis

NEPA requires that an EIS "rigorously explore and objectively evaluate all reasonable alternatives" and to "[d]evote substantial treatment to each alternative considered in detail so that reviewers may evaluate their comparative merits."[90] An agency's alternatives analysis is, in turn, a function of the "purpose and need" of the action under review.[91] If your purpose and need are flawed and overly narrow, it also causes a violation of NEPA's alternatives requirements, the heart of an EIS.

Here, APHIS abused its discretion when it improperly defined the purpose and need for the Proposed Rules relying on extra-statutory factors and improper bases, and misrepresenting the prior findings of Congress and the OIG reports.[92] APHIS also claims that the Proposed Rules would codify the Secretary of Agriculture's March 28, 2018 press statement.[93] APHIS's authority and the scope of its regulations of GE crops stems from the PPA. APHIS's failure to define a legitimate a

[88] Lambertini C. (2019). Why are tall-statured energy grasses of polyploid species complexes potentially invasive? A review of their genetic variation patterns and evolutionary plasticity. Biological Invasions. doi:10.1007/s10530-019-02053-2.
[89] Draft PEIS at ES-1.
[90] 40 C.F.R. § 1502.14.
[91] 40 C.F.R. § 1502.13.
[92] *See supra.*
[93] Draft PEIS at 2-11.

legitimate purpose and need, and its consequent failure to consider an adequate range of alternatives led APHIS to include only two alternatives, No Action / status quo, or the Preferred Alternative, implementation of the Proposed Rules as envisioned by APHIS. This is too narrow to comply with NEPA.

While CFS agrees that revisions to the current regulations are necessary, APHIS's failure to consider other reasonable alternatives is fatal to the Draft PEIS's entire assessment, and renders APHIS's impacts analysis illusory. Throughout the Draft PEIS, APHIS again and again concludes that the Preferred Alternative would have similar impacts as compared to the No Action Alternative: that is expected, Congress, the OIG, and APHIS itself, have all repeatedly acknowledged the shortcomings of the status quo—the No Action Alternative, and revisions of the current regulations are being proposed to better address the loopholes in the current regulations. APHIS's decision to analyze only one alternative that proposes even bigger loopholes than that currently exist under the No Action Alternative, and related conclusion that therefore, the Preferred Alternative would not have significant impacts on the environment, is arbitrary and capricious, and contrary to sound science, as well as the history and evidence before the agency. APHIS's decision to ignore the problems itself previously acknowledged and that Congress mandated it to resolve is unlawful.

While CFS agrees that revisions to the current regulations are necessary, as explained above and in past CFS comments, new regulations are needed to fully and properly implement APHIS's PPA authority, as well as address the harms of GE crops. APHIS's Proposed Rules fail to do so, in direct contravention of the PPA and the 2008 Farm Bill mandates, as well as the OIG's recommendations, and APHIS's own rationale as articulated in prior rounds of rulemaking.

Significantly, APHIS listed, but refused to consider, an alternative that the agency had previously considered in the draft environmental impact statement for its prior proposed revisions in 2017, an alternative for "regulation to facilitate coexistence."[94] APHIS rejected the "coexistence" alternative despite having previously recognized it as a viable alternative that must be examined in detail in the Draft PEIS. This was arbitrary and capricious.

APHIS rejected this alternative from being analyzed in the Draft PEIS, without conducting an actual cost-benefit analysis, on two chief grounds: that it is improperly based on the need to reduce economic harm to non-GE producers from GE contamination events; and would impose costs on GE crop developers. The benefits of this alternative stem from rigorous measures to facilitate "coexistence" – that is, measures that would mitigate GE contamination of organic and non-GE crop supplies, but that would also protect producers of GE crops approved in major export markets from contamination with GE crops that are NOT approved in those markets. Coexistence thus benefits ***all*** farmers, contrary to APHIS.

[94] Draft PEIS at 2-20 to 2-24.

APHIS's suggestion that economic harm from GE contamination is not cognizable under the PPA is mistaken. Elsewhere in the Draft PEIS, APHIS acknowledges that the mission of the USDA is to protect health and value of American agriculture and natural resources, and that the PPA mandates, inter alia, that the USDA "facilitate exports, imports, and interstate commerce in agricultural products and other commodities …"[95] As detailed in these comments and prior comments, APHIS's lack of effective coexistence regulations has cost U.S. agriculture many billions of dollars in lost sales as well as loss of important export markets to competitor nations.[96] The coexistence alternative would thus "facilitate trade," while benefiting all farmers economically, by significantly reducing these costs.

APHIS also claims that this alternative would delay the launch of GE plants and harm the returns of GE developers.[97] Not only does APHIS fail to quantify such costs, more importantly, consideration of the private economic costs that GE crop developers might assume for mitigating the negative impacts of their products on U.S. agriculture, or the benefits they might enjoy for being allowed to continue current harms, is not a proper purpose and need for action.

APHIS also claims, in broad strokes, that the coexistence alternative would have fewer environmental benefits, and inhibit development of GE technologies that could reduce the environmental load of agrichemical use. It is arbitrary and capricious agency decision-making to conclude that the Preferred Alternative would somehow decrease potential adverse environmental impacts. And APHIS's claim that promotion of GE technology is environmentally beneficial is entirely without basis, and contrary to the facts before the agency. Contrary to APHIS's unsubstantiated statements, as discussed in CFS's past comments and in the supporting documentations submitted herein, GE technologies have resulted in plants that have dramatically increased the use of agrichemicals, with significant environmental, agricultural, and human health harms.[98]

Nor is there any legal basis for APHIS's decision to reject this alternative from further consideration because, according to APHIS, "regulat[ing] based on economic impacts alone … would [be] inconsistent with the Agency's mission."[99] Elsewhere in the Draft PEIS, APHIS acknowledges that the mission of the USDA is to protect health and value of America agriculture and nature resources, and that the PPA mandates that the USDA "to facilitate exports, imports, and interstate commerce in agricultural products and other commodities …, "and to regulate GE crops for both plant pest and

[95] Draft PEIS 1-1; 7 U.S.C. § 7701(3).
[96] *See* Attachment A, CFS 2017 Comments, pp. 11-14, and references therein. *See also* Bunge J (2014). China's shut-out of American corn won't end anytime soon. The Wall Street Journal, 4/11/14. Shuping and Stanway (2014). China allows Brazilian corn imports, setback for U.S. Reuters, 4/8/14.
[97] Draft PEIS at 2-23.
[98] *See* Attachment A, CFS 2017 Comments.
[99] Draft PEIS 2-23.

noxious weed risks. [100] This is also contrary to the language of the PPA and the harms it regulates. As detailed in these comments and prior comments, consideration of economic impacts of GE crops fall squarely within APHIS's statutory duty. APHIS's failure to consider this alternative for lack of legal basis is arbitrary and capricious, and contrary to law.

APHIS also rejected from further consideration, an alternative to withdraw the current Part 340 regulations and instead regulating GE crops under Parts 330 and 360 regulations.[101] APHIS claims that such a regulatory scheme would result in lack of international acceptance for GE products that only undergo "voluntary consultation" with APHIS, as well as "creating a regulatory vacuum" that would have to be filled by other federal or state agencies.[102] Yet, those are the very same outcomes under the Proposed Rules, since APHIS is authorizing GE developers to self-determine whether their GE plants would need further regulation, exempting the vast majority of GE plants from any regulatory oversight, and relying on other federal and state agencies to cover loopholes of such a voluntary, "deregulatory" scheme.

APHIS generally decided to just have a "no action" and the "preferred alternative," without *any other alternatives*. NEPA does not permit such "go/no go" decision-making; avoiding that is the very purpose of the alternatives analysis.

APHIS also failed to consider other reasonable alternatives entirely, such as alternatives that would address not just the economic harms of contamination, but also the environmental harms of GE crops directly, including but not limited to the harms of resistant weed proliferation associated with GE HR crops, or the harms to farmers and the environment caused by GE HR crop systems, such as pesticide drift and runoff, and other human health and environmental harms detailed in our prior comments.[103] The agency should consider an alternative that restricts GE crops by permit in order to directly address these harms. APHIS fails to offer any alternative that protects against environmental harm from escapes from GE organisms into the wild, such as genetically engineered bentgrass. NEPA requires that APHIS examine policy alternatives that take into account environmental values. APHIS's failure to include and fully analyze alternatives to protect against the environmental harms of GE organisms violates NEPA's alternatives mandates, the heart of any EIS.

APHIS cannot have adequately considered alternatives if its analysis misrepresents the adverse impacts of its proposed alternative and fails to consider more environmentally beneficial alternatives, such as restricting GE crops using its PPA authority in order to prevent environmental harms, as well as socioeconomic harms. These include resistant weed harms and pesticide drift

[100] Draft PEIS 1-1; 7 U.S.C. § 7701(3).
[101] Draft PEIS 2-24.
[102] Draft PEIS 2-24.
[103] *See* Attachment A (CFS 2017 Comments, and Appendices therein).

harms, in addition to preventing transgenic contamination through permitting and restrictions on use. APHIS did not rigorously and objectively explore all reasonable alternatives.

APHIS also failed to consider an alternative that included measures specific to other, newer GE organisms under its purview that are not traditional crops, such as GE grasses, GE trees, and GE insects. These types of GE organisms are more than reasonably foreseeable, they are currently being proposed for commercial approval or field trials (GE bentgrass, Ge Eucalyptus, GE moths). These types of GE organisms are creating different types of risks than previous GE crops[104] that should necessitate new analyses and oversight mechanisms that APHIS has not considered.

Impacts' Analysis Errors

The Draft PEIS is fundamentally flawed, and its conclusion arbitrary and capricious, because it fails to analyze the direct, indirect, and cumulative impacts of the Preferred Alternative.

First, the Draft PEIS is deficient because it fails to analyze the direct, indirect, and cumulative impacts associated with the categories of GE plants that would be exempt from all USDA oversight under the Preferred Alternative. APHIS recognizes that impacts that must be analyzed in an environmental impact statement includes "effect on the environment which results from the added, incremental impact of past, present and reasonably foreseeable future actions"[105] APHIS also recognizes that, the practical effect of the Preferred Alternative is that most GE plants would be field-tested, planted, and sold without any regulatory oversight, as developers are likely to conclude that their GE plants fall within one of the broad exemptions. Yet, the Draft PEIS is entirely silent on the direct, indirect, and cumulative impacts of exempting broad categories of GE plants from all regulations. It is also silent on APHIS's decision to allow developers to self-determine whether or not to even go through any APHIS process. APHIS claims that "future regulatory decisions and actions" would be evaluated on a case-by-case basis, but its decision to relinquish its authority to monitor and regulate the vast majority of GE plants is a regulatory decision the agency is now proposing, and NEPA demands that the impacts of that decision be analyzed now in the DPEIS.

APHIS's Draft PEIS also makes many fundamental flaws and errors of analysis. These serious errors and omissions undermine its assessment in many important respects and belie its conclusions. These include direct, indirect, and cumulative impacts that are reasonably foreseeable.

Impacts on Agricultural Land Use: APHIS's consideration of the impacts of the Preferred Alternatives on agricultural land use is arbitrary and capricious. APHIS claims that there are no difference in impacts between the no action alternative and the Preferred Alternative. According to the agency, "APHIS's determinations of the regulatory status of GE crops are not considered the

[104] NASEM (2017), 105-106.
[105] Draft PEIS at 4-1.

driving factor in grower adoption of GE crop plants."[106] This is patently false. Under the current regulatory scheme, growers cannot commercially adopt a GE crop plant unless and until after APHIS affirmatively determined that the GE crop plant is unlikely to pose a plant pest risk. The Preferred Alternative would exempt the majority of GE crop plants from any APHIS regulatory determination, with significant impacts on the availability of varieties of GE crop plants for commercialization. And without any regulatory trigger, such crop plants will also never be analyzed for their noxious weed harms, which APHIS is required to consider under the PPA. APHIS's failure to analyze the impacts of the Preferred Alternative on the adoption and commercialization of GE crop plants under the Preferred Alternatives is arbitrary and capricious, and contrary to sound science.

APHIS's also failed to analyze the impact of the Preferred Alternative on the number, location, and total acreage of field trials of GE plants in the United States. APHIS admits that the impacts to land and land uses depend on "the species of GE organisms tested, the GE trait, and the environment in which the field trial is conducted,"[107] and claims that such impacts "would be considered on a case-by-case basis." Yet under the Preferred Alternative, APHIS will no longer require regulated field trials for the vast majority of GE organisms.[108] NEPA requires that these impacts be considered now, not indefinitely into the future, to be tiered to future agency actions that are being eliminated by APHIS's very Proposal.

APHIS also admits that the Preferred Alternative would leave outdoor field trials of GE Plant-Incorporated protectants (PIPs) of less than 10 acres without any regulatory oversight, but does not analyze the potential impacts of such deregulation.[109] This is arbitrary and capricious, and contrary to sound science.

Impacts from Altered Weather Patterns (aka climate change): APHIS's analysis of the impacts of potential altered weather patterns[110] as a result of climate change is also woefully inadequate. APHIS's discussion focuses on how altered weather patterns may impact growers' farming decisions, without any analysis of how the Preferred Alternative may *contribute* to climate change.

Moreover, APHIS simply assumes that the types of GE crops will be able address the problems associated with altered weather patterns/climate change, despite the lack of such traits on the market and no evidence that they will be successfully developed in the future, as opposed to more of the same pesticide-resistant varieties. APHIS selectively highlights GE drought tolerant crops as a potential benefit to growers under altered and extreme weather conditions, but as discussed in

[106] Draft PEIS at 4-3.
[107] Draft PEIS at 4-9.
[108] *See* Draft PEIS at 4-20.
[109] Draft PEIS at ES-18.
[110] Draft PEIS at 4-5.

CFS's comments, the vast majority of the GE crop technologies focus on conferring pesticide resistance, yet APHIS entirely fails to analyze how the impacts of herbicide-resistant GE crop systems, from increase in pesticide use, increased weed resistance and the corresponding increase use of tillage practices and even more pesticides, may exacerbate altered weather events and worsen the impacts of global warning. APHIS's analysis falls woefully short of NEPA's "hard look" requirement, and is entirely contrary to sound science.

APHIS also completely failed to analyze the foreseeable impacts of the Preferred Alternative, which APHIS claims would promote development of the GE industry, to global concentrations in seed market and seed supply.[111] This has led to increased privatization of the global seed supply as GE developers patent their products, and have in fact reduced research and development in the seed sector.[112] APHIS thus also fails to analyze the direct and indirect impacts of seed market concentration on farmers' ability to choose and grow different types of crops in response to changing weather patterns. Seed companies have aggressively undermined independent researchers' ability to fully investigate their patented crops' performance.[113] Finally, as detailed in CFS's prior comments and summarized below, APHIS entirely fails to analyze the impacts of the Proposed Regulations on farming practices, especially as they impact soil, water quality, and the environment, and the direct and indirect of such practices on the ability of U.S. agriculture to adapt and respond to altered weather patterns.

Pesticide Use: APHIS's analysis of pesticide usage and its related impacts on the environment is arbitrary and capricious, and contrary to sound science. APHIS's treatment of how GE crops have impacted pesticide use[114] shares many of the same flaws and biases that CFS found in its 2017 DPEIS.[115] Those CFS comments are incorporated here by reference. Here, we provide a partial summary of those comments, and introduce new material.

In the 2019 DPEIS, APHIS continues to rely on false and misleading modeling studies conducted by pesticide industry contractors Brookes and Barfoot (2013, 2016, 2017) and others (e.g. Klumper and Qaim 2014). APHIS's treatment is sloppy and internally inconsistent, presenting contradictory figures on herbicide use trends for the major crops in which GE HR varieties dominate, soybeans,

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[111] See, e.g., Kristina Hubbard, The Sobering Details Behind the Latest Seed Monopoly Chart, https://civileats.com/2019/01/11/the-sobering-details-behind-the-latest-seed-monopoly-chart/ (Jan. 11, 2019); Yamuna Ghale and Bishnu Raj Upreti, Concentration and Monopolisation of Seed Market: Impact on Food Security and Farmer's Rights in Mountains; CFS, Seed Giants vs. U.S. Farmers (2013), http://www.centerforfoodsafety.org/files/seed-giants_final_04424.pdf.
[112] USDA, Economic Research Serv., Have Seed Industry Changes Affected Research Efforts (2004), https://www.ers.usda.gov/amber-waves/2004/february/have-seed-industry-changes-affected-research-effort/.
[113] Emily Waltz, *Under Wraps*, 27 Nature Biotechnology 880, 882 (2009).
[114] Draft PEIS at 3-49 to 3-76.
[115] *See* Attachment A (CFS 2017 Comments, Appendix A).

cotton and corn, on different pages. For instance, total herbicide use on corn in 2016 is reported as 2.61 lbs./acre (correct) at Draft PEIS 3-58, and incorrectly as 2.40 lbs./acre at Draft PEIS 3-68. Similarly, cotton herbicide use is reported to have "remained fairly constant since 1991, around 1.2 lb. a.i./acre" (Draft PEIS 3-68), when in fact it has increased dramatically over the period of GE HR crop adoption, reaching 3.06 lbs./acre in 2015, as APHIS notes just a few pages earlier (Draft PEIS 3-65).

APHIS chooses false frames of reference to misrepresent the herbicide use impacts of herbicide-resistant crops. For instance, APHIS notes that herbicide use on corn has declined from 2.67 lbs./acre in 1996 to 2.61 lbs./acre in 2016 (Draft PEIS 3-58), yet fails to note that GE HR corn's influence on herbicide use patterns was negligible through 2002, the first year it was grown on more than 10% of total corn acres (11%). HR corn's rapid adoption since 2002 has driven a substantial increase in herbicide use, from less than 1.87 to 2.61 lbs./acre from 2002 to 2016. GE HR soybeans have driven an even greater increase in herbicide use, as even APHIS admits. The HR crop-driven increase in herbicide is also reflected in EPA figures, which show that overall herbicide use in U.S. agriculture rose by an astonishing 34% over just the seven years from 2005 to 2012, from 420 to 564 million lbs.

APHIS's cursory treatment provides no assessment of dicamba use on Monsanto's dicamba-resistant soybeans and cotton,[116] plantings of which have risen dramatically from just a few million acres in 2016, to 25 million acres in 2017, 50 million acres in 2018 and an estimated 60 million acres in 2019.[117] EPA reports a greater than 12-fold increase in dicamba use on soybeans and cotton in 2017 (10 million lbs.) relative to the average for those crops over 2012 to 2016, with "significantly more dicamba" expected in 2018.[118] CFS discusses the impacts of this surge in dicamba use infra.

More seriously, APHIS fails to link its discussion of herbicide use increases driven by GE HR crops to the epidemic of glyphosate-resistant weeds that have resulted, discussed infra, or other serious impacts.

APHIS's discussion of herbicide toxicity is also deeply flawed. With respect to glyphosate, APHIS extensively discusses a paper by a plant scientist with no expertise in human toxicology (e.g. Kniss 2017) for the proposition that glyphosate is less toxic than other herbicides, while practically ignoring the growing consensus that glyphosate is "probably carcinogenic to humans," as determined by the world authority on carcinogens, the World Health Organization's International

[116] Draft PEIS at 3-74 to 3-76.
[117] Unglesbee (2019). More dicamba to come? Dicamba-stacked corn on the horizon. DTN Progressive Farmer, 3/21/19.
[118] EPA (2018). Over the top dicamba products for genetically modified cotton and soybeans: benefits and impacts. EPA Office of Pesticide Programs, 10/31/19.

Agency for Research on Cancer, and supported by 94 leading medical scientists. Several recent studies have strengthened the evidence of glyphosate's genotoxicity (one element in carcinogenicity analyses),[119] and the link between exposure to glyphosate formulations like Roundup and the often deadly immune system cancer, non-Hodgkin lymphoma.[120] This is hardly the profile of a "less toxic" herbicide.

EPA's treatment of insecticide use trends over the GE crop era (Draft PEIS 3-52 to 3-53) fails to account for the dramatic rise in use of neonicotinoid seed treatments over roughly the same period that GE insect-resistant (Bt) corn and cotton came to dominate U.S. corn and cotton production[121] (nearly always in varieties that also have herbicide-resistant traits). Thus, APHIS's Figure 3-16 grossly misrepresents overall insecticide use on corn and cotton. Entomologists generally find that neonicotinoid seed treatments offer little if any benefit to growers, who are for the most part not even given the option of purchasing untreated seeds; and that these seed treatments are widely applied by seed-chemical companies as a price point to help justify the steeply rising price of transgenic seed.[122]

In sum, EPA underestimates the herbicide use increases triggered by GE HR crop systems, as well as the associated human toxicity of this herbicide use. in assessing herbicide use with GE HR crops, APHIS considers only glyphosate associated with first-generation HR crops; and fails to assess the astoundingly rapid rise in the use of dicamba associated with Monsanto's dicamba-resistant crops, much less project the herbicidal impacts of other new next-generation GE HR crops resistant to 2,4-D and a host of other herbicides that are only now being introduced, and which are expected to be very widely adopted and have enormous adverse impacts.[123] The Preferred Alternative will allow more herbicide-resistant GE crops to be commercialized without any further regulatory oversight, which in turn may massively increase GE HR crop acreage and pesticide use. Moreover, APHIS's cursory treatment of insecticide use over the period of GE Bt corn and cotton adoption is a gross misrepresentation due to exclusion of neonicotinoid seed treatments. APHIS's failure to competently analyze the impacts of GE crops on pesticide use is contrary to the evidence and arbitrary and capricious.

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[119] Benbrook C (2019). How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides? Environ Sci Eur 31:2.
[120] Zhang L et al (2019). Glyphosate and non-Hodgkin lymphoma: an independent evaluation. Mutation Research/Reviews in Mutation Research 781: 186-206. Leon ME et al (2019). Pesticide use and risk of non-Hodgkin lymphoid malignancies in agricultural cohorts from France, Norway and the USDA: a pooled analysis from the AGRICOH consortium. International Journal of Epidemiology 1-17.
[121] Douglas and Tooker (2015). Large-scale deployment of seed treatments has driven rapid increase in use of neonicotinoid insecticides and preemptive pest management in U.S. field crops. Environ. Sci. Technol. 49(8): 5088-5097.
[122] *Id.*
[123] *See also* Attachment A (CFS 2017 Comments, Appendix A).

Herbicide Drift: In comments on the 2017 Proposed Rules and DPEIS, CFS discussed the profound risks to non-target crops and wild plants presented by second-generation GE HR crop systems.[124] We noted initial reports of widespread damage caused by spray and vapor drift of dicamba applied to Monsanto's dicamba-resistant soybeans and cotton, and predicted that it would continue even with introduction of supposedly "low-volatility" formulations of dicamba. The crop injury from dicamba vapor and spray drift has continued at unprecedented scale throughout the 2017,[125] 2018[126] and now the present 2019 crop seasons,[127] with over 4,000 official reports of dicamba drift crop damage on roughly 5 million acres. Weed scientists are entirely clear that the newer dicamba formulations are to blame for the majority of crop damage episodes, and that the scale of damage they are observing is entirely unprecedented in the history of agriculture.

"We are in unprecedented, uncharted territory. We've never observed anything on this scale in this country since we've been using pesticides in the modern era."[128]

APHIS bears a large part of the blame for this betrayal of American farmers, because it abdicated its responsibilities to protect American agriculture by granting nonregulated status to dicamba-resistant soybeans and cotton, without any meaningful analysis of the likely impacts. In fact, APHIS actually predicted that deregulating these GE crops would result in ***less*** dicamba drift damage than not deregulating them,[129] an epic blunder based on blind trust in dicamba manufacturers' assurances, and an entirely broken GE regulatory system in which APHIS fobs off all responsibility for the actual uses to which the GE HR crops it regulates will be put, and their entirely foreseeable impacts. APHIS has thus failed American farmers in a major way. The Preferred Alternative can only make things worse going forward, since APHIS will relinquish any regulatory responsibility for many new GE HR crops on the horizon, crops varieties with ever more resistance traits, facilitating increasing amounts of multiple weed-killers applied in an attempt to kill every more herbicide-resistant weeds.

Herbicide-resistant weeds: APHIS's treatment of herbicide-resistant weed evolution in the context of GE HR crops (DPEIS, 3-78 to 3-86) is entirely inadequate, and shares the flaws of its very similar

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[124] *See* Attachment A (CFS 2017 Comments, pp. 49-51).
[125] Bradley K (2017). A final report on dicamba-injured soybean acres. University of Missouri, 10/30/17.
[126] Bradley K (2018). July 15 dicamba injury update. Different year, same questions. Univerisity of Missouri, 7/19/18.
[127] Hager A (2019). 2019 observations from the field: dicamba. University of Illinois, 8/2/19.
[128] Andrew Thostenson, pesticide specialist with the North Dakota State Extension Service, as quoted in: Unglesbee E (2017). States grapple with dicamba: state pesticide regulators face hundreds of dicamba investigations and 2018 decisions. DTN Progressive Farmer, 9/20/17.
[129] USDA APHIS (2014). Record of decision: Monsanto petitions (10-188-01p and 12-185-01p) for determination of non-regulated status for dicamba-resistant soybean and cotton varieties. Final Environmental Impact Statement. USDA APHIS, December 2014, p. 22.

treatment of this issue in the 2017 DPEIS. CFS incorporates the discussion of this topic in our comments on the 2017 Proposed Rule and DPEIS by reference.[130]

APHIS fails to appreciate the widely-understood fact that because GE HR crops foster exclusive or near-exclusive reliance on the associated herbicide(s), and are grown so widely, they thereby promote much more rapid and widespread evolution of weeds resistant to these herbicides than would have possibly occurred in the absence of those crops. Indeed, much of its discussion is entirely off-point, as it relates to HR weed development prior to introduction of GE HR crops, with the clear intent of downplaying the rapid acceleration and spread of weed resistance those GE crops have fostered.

A case in point is dicamba-resistant crops, introduced on a widespread basis just two year ago, in 2017. Researchers in Arkansas conducted greenhouse trials and found that Palmer amaranth, farmers' most feared weed, evolved dicamba resistance after just three generations of exposure.[131] In Tennessee, dicamba and glyphosate together are progressively less effective on the same weed in farmers' fields, a likely sign of evolving dicamba resistance in Palmer amaranth already immune to glyphosate, after just two short year of widespread dicamba use. Weed scientist Larry Steckel links this development to overuse of dicamba-resistant crops, which reminds him of the rapid evolution of glyphosate-resistance with Roundup Ready crops.[132]

APHIS claims that the weed-resistance risks from introduction of GE organisms would be same under the No Action Alternative and the Preferred Alternative. As stated supra, this binary impacts analysis is arbitrary and capricious, and contrary to sound science. APHIS thus fails to provide any meaningful analysis of the massive and growing herbicide-resistant (HR) weed threats caused by past and present GE HR crop systems. We note also that while APHIS could regulate GE HR crops for the resistant weeds they foster as plant pest risks (under the head of "weediness"), incorporation of its noxious weed authority into Part 340 is urgently needed to give APHIS even more regulatory tools to address this threat to U.S. agriculture that it has thus far entirely neglected.

Transgenic contamination: APHIS dramatically underestimates the frequency and economic impacts of GE contamination.[133] APHIS improperly limits its assessment of contamination harms to the organic sector, when GE-sensitive export and domestic markets are also severely impacted by it. APHIS fails to assess the full costs of GE contamination even to the organic sector, which include numerous costly measures to mitigate GE contamination, and lost market opportunities. APHIS also fails to assess the past and current, or project the future, impacts and costs of GE organisms that

[130] CFS 2017 Comments, Appendix B.
[131] Hightower M (2016). Dicamba resistance in pigweed selected in research greenhouse, not in the field. University of Arkansas, Division of Agriculture, 1/26/16.
[132] Spiegel (2018). Cracks may be showing in dicamba control of pigweed," Successful Farming, 12/2018.
[133] Draft PEIS at 4-99 to 4-106.

escape into wild or semi-natural habitats via seed dispersal, cross-pollination with sexually compatible relatives, or by other means.

APHIS claims that the Preferred Alternative would reduce the impacts of transgenic contamination by "reduc[ing] the number of unauthorized releases"[134] of GE plants is patently false, and arbitrary and capricious. As APHIS recognizes, the economic impacts of GE contamination is a function of market (both domestic and international) responses to the presence of GE materials, not whether such materials constitute "regulated articles" under APHIS's regulatory scheme. The economic costs of transgenic contamination are detailed in our prior comments, and resubmitted and incorporated herein. Telling, APHIS recognizes that the presence of GE materials in international trade "can be very costly," and admits that the regulatory status of GE products in the United States would have no impact on their status, and potential rejection, in international markets.[135]

In sum, the baseline analysis for all of these impacts is fundamentally flawed and inaccurate, contrary to the evidence. The impacts analysis is cabined to effects of the binary choices of the current deficient regulations (No Action alternative) and APHIS's proposed further deregulatory scheme exempting the majority of GE crops from any oversight (Preferred Alternative), rendering it an illusory exercise.

Types of GE Crops: The PEIS fails to provide an empirical assessment of the future types of GE crops to be introduced under the various alternatives. Instead, APHIS repeatedly assumes that future GE crops would incorporate traits for disease and stress resistance as well as product quality.[136] GE crops with these trait types have been promised and field-tested for three decades, yet extremely few have been commercially introduced. APHIS provides no analysis explaining this fact, the reasons for it, or why it anticipates that the future course of GE crop development should be so radically different than past history. For instance, APHIS discusses GE drought-tolerant crops as likely developments,[137] yet studies have found that conventional breeding is far more successful than genetic engineering in the development of this crop type.[138] GE disease-resistant crops occupy such miniscule acreage that they are not even covered by USDA statistics on commercial GE crop cultivation.

In contrast, as CFS previously commented (and incorporates herein), there is no dispute that GE HR crops have been by far the dominant type of GE crop grown in the U.S. and the world, comprising roughly 85% of U.S. GE crop acreage; and that next-generation GE HR crops dominate the current and future GE crop landscape. APHIS itself acknowledges this at times in the Draft PEIS, and also

[134] Draft PEIS at ES-11.
[135] Draft PEIS at ES-12.
[136] *See, e.g.,* Draft PEIS at 1-6, 3-35.
[137] Draft PEIS at 3-36.
[138] Gilbert N (2014). Cross-bred crops get fit faster. Nature 513: 292.

backed by APHIS's own data.[139] APHIS also ignores the obvious motivation for the industry's predilection for development of crops with HR versus other traits – the potential for vastly increased sales of herbicides the company sells together with the HR seed.[140]

APHIS's failure to discuss these clear and obvious trends, which are widely known and accepted in the agricultural community, is arbitrary and capricious. This assessment failure undermines the analysis in the PEIS numerous ways – most basically, it undermines APHIS's repeated baseless assumptions that GE crop development will respond to pressing agricultural needs, such as agricultural adaptation to climate change, more frequent and severe droughts, world hunger, malnutrition and numerous other worthy objectives. In contrast, a proper and objective analysis showing the predominance of GE HR crops in the present and future GE crop landscape would have laid the foundation for an entirely different PEIS in which empirical assessment of their many impacts (mostly adverse) predominated.[141]

Increase in GE organisms overall: APHIS fails to analyze the impacts of an overall increase in unregulated GE organisms and their impacts under the Preferred Alternative. As discussed prior in the Agricultural Land Use section, APHIS's conclusion that the Proposed Rules, which would exempt the majority of GE plants from regulatory oversight and can be planted and commercialized immediately, is belied by the evidence as well as contrary to common sense. It also conflicts with APHIS' economic analysis that there will be a lesser "regulatory burden" and thus more GE crops would be developed, more quickly. Similarly, the analysis that the rules revisions will not increase harms from field trials, and that there will be no change in experimental acreage, is illogical and contrary to the evidence that field trials will now go on without oversight.

Soil erosion and conservation tillage: As explained more fully in CFS's prior comments, first-generation GE HR crop systems have generated extremely rapid and widespread emergence of HR weeds, which has in turn led to increases in the use of tillage as a means of control, and corresponding reductions in soil-saving conservation tillage, over the past decade. This analysis is supported by USDA soil erosion data, which show unequivocally that substantial reductions in soil erosion rates in the pre-GE HR crop era, fostered by federal farm policy, came to a virtual halt in the GE HR crop era, especially in the Corn Belt, where cultivation of these varieties is most intensive. APHIS's numerous claims concerning the purported benefits of GE HR crops in reducing soil erosion via promotion of conservation tillage are thus arbitrary and capricious, and in direct contradiction to unimpeachable, mostly USDA, data that demonstrate the opposite.

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[139] Draft PEIS at 3-35.
[140] Kilman S (2010). Superweeed outbreak triggers arms race. Wall Street Journal, 6/4/10.
[141] *See* Attachment A (CFS 2017 Comments and Appendices).

Water resources: It is arbitrary and capricious and contrary to sound science for APHIS to conclude that the Preferred Alternative would improve water quality by reducing runoff of soil sediments, pesticides and fertilizers into streams and other surface waters.[142] The facts show precisely the reverse outcome. Because the Preferred Alternative increases introduction of GE HR crops, water quality will decline due to increased use and runoff of herbicides, and to increased runoff of soil sediments attributable to increased use of tillage to control HR weeds generated by GE HR crop systems. The increase in GE crops, and associated increase in pesticide use, will further contaminate our waterways.

APHIS's suggestion that the Preferred Alternative may increase the agency's consideration of risks to water quality is also baseless.[143] As detailed throughout these comments, the Preferred Alternative would leave the vast majority of GE crops without any regulatory oversight, including stacked GE HR crops that would significantly increase herbicide use and related herbicide resistance in U.S. agriculture. APHIS fails to meaningfully consider these impacts, and its summary conclusions are contrary to the evidence.

Air resources: As explained in our prior and current comments, GE HR crops have led to reductions in conservation tillage over the past decade, by promoting greater use of tillage to control HR weeds generated by these crop systems. The Draft PEIS recognizes this: "Where HR weeds have become a problem…, conventional tillage has increased to help control HR populations, and conservation tillage has diminished."[144] Greater use of tillage equates to increased tractor use and thus increases in fossil fuel emissions. As pointed out in CFS's prior comments, APHIS also completely fails to assess the air quality degradation that will be caused by the projected rapid adoption of the next-generation GE HR crop systems. Enlist crops resistant to 2,4-D, and Roundup Xtend crops resistant to dicamba. Use of both herbicides is projected to expand dramatically, both are known to be highly volatile. This means there will be large increases in volatilization of these herbicides, especially since they will be sprayed weeks to a month or more later in the season, when climatic conditions favor vapor drift. Dicamba volatilization has resulted in enormous crop injury in the very first year of (limited) planting of dicamba-resistant crops. Dicamba vapor drift degrades air quality, with associated adverse impacts to humans and non-target species.

Soil biota: As CFS pointed out in prior comments, first-generation GE HR crops resistant to glyphosate have led to substantial adverse changes in the rhizosphere (root-associated) microbial community, supported by reports of increased fungal disease in glyphosate-resistant soybeans. APHIS's conclusion that there would be no significant impact between the No Action alternative and

[142] Draft PEIS at 5-4.
[143] Draft PEIS at 4-27.
[144] Draft PEIS at 5-2.

its Preferred Alternative is tainted by its deficient alternative analysis, and is therefore arbitrary and capricious, and contrary to sound science.

Invertebrate organisms: APHIS's analysis of the impacts to invertebrate organisms is arbitrary and capricious, and contrary to sound science. As discussed in our prior comments, and is incorporated herein by reference,[145] APHIS downplays the consensus view of leading monarch scientists that dramatically increased glyphosate use driven by GE glyphosate-resistant crops has been a leading factor in the two-decade decline in monarch butterfly populations.[146] This consensus view is based on multiple lines of evidence: 1) Common milkweed is the primary host plant for monarch butterflies in their summer breeding range, which is centered in the Midwest corn belt where corn and soybeans dominate the landscape; 2) As recently as 1999, before widespread adoption of glyphosate-resistant crops, common milkweed was fairly common in Midwest corn and soybean fields, comprising a considerable portion of total milkweed available for monarch breeding;[147] 3) Glyphosate is unique among row-crop herbicides in its ability to kill common milkweed;[148] 4) The massive increase in glyphosate use accompanying near-universal adoption of glyphosate-resistant corn and soybeans in the Midwest led to near-eradication of common milkweed from those fields;[149] 5) The same period of time saw a dramatic decline in the migrating eastern monarch population.

APHIS's discussion deals with none of this evidence. Instead, it is cursory and highly biased, giving considerably more prominence to the views of a few researchers who dissent from the consensus view of these leading scientists, who have studied monarchs and their decline for decades, and published numerous articles on the subject in highly-regarded journals. APHIS's view is also directly at odds with those of all other federal government scientists who have studied monarch decline. For instance, APHIS fails to mention that the U.S. Fish and Wildlife Service (USFWS), in response to a petition from public interest groups and renowned monarch scientist Lincoln Brower, has made a preliminary finding that monarchs may merit listing as a threatened species under the Endangered Species Act. That petition is pending at this writing. APHIS ignores the fact that USFWS

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[145] *See* Attachment A (CFS 2017 Comments, p. 38).
[146] Draft PEIS at 3-119, 4-41.
[147] Hartzler and Buhler (2000). Occurrence of common milkweed (Asclepias syriaca) in cropland and adjacent areas. Crop Protection 19: 363-366. See also Pleasants and Oberhauser (2012) reference in CFS 2017 comments.
[148] CFS (2015). Comments to EPA on Risk Management Approach to Identifying Options for Protecting the Monarch Butterfly. Center for Food Safety and Center for Biological Diversity. Docket EPA-HQ-2015-0389. August 24, 2015.
[149] Pleasants JM (2015). Monarch butterflies and agriculture, in: Monarchs in a Changing World: Biology and Conservation of an Iconic Butterfly, eds. Oberhauser KS, Nail KR, Altizer S, Cornell University Press, Ithaca, NY. 2015.

finds glyphosate use with glyphosate-resistant crops to be a major contributing factor to monarch decline, as petitioners argued.[150]

APHIS fails to cite the finding of a team with two U.S. Geological Survey scientists that there was an 11% to 57% risk of quasi-extinction of eastern monarchs (meaning loss of a viable migratory population) over the next 20 years.[151] While APHIS acknowledges a government-wide effort to "benefit the monarch butterfly" that involves its USDA sister agency, the Natural Resources and Conservation Service, it carefully avoids mentioning the fact that this effort is chiefly directed to restoring monarch habitat – common milkweed – to the landscape.[152]

As noted in the section on Pesticide Use infra, neonicotinoid use as seed treatments on mainly GE corn, soybean and cotton seeds has risen dramatically over roughly the same period as GE crops; and one explanation for this trend is that the seed treatments, despite offering little or no benefits, serve as a price point to help justify the steeply rising costs of GE seeds, creating a linkage between GE seeds and use of these seed treatments. Neonicotinoids are highly toxic to a broad range of insects, and have been implicated as important factors in declining bee and pollinator populations,[153] and been shown to suppress important natural enemies of crop pests, with negative effects on crop production.[154]

APHIS's treatment of GE crops' effects on invertebrate populations is arbitrary and capricious, and contrary to evidence before the agency and sound science.

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[150] USFWS (2019). We've done this before. U.S. Fish and Wildlife Service, last updated 4/12/19. https://www.fws.gov/savethemonarch/done-this-before.html. Stating: "The wide-scale adoption of herbicide-resistant corn and soy crops, has drastically changed the agricultural landscape, once a vibrant source of breeding and migrating habitat for monarchs. This resistance enables broad and non-targeted application of herbicides that indiscriminately kills vegetation growing around farm fields and in nearby habitat, including milkweed."

[151] Semmens et al (2016), reference in CFS 2017 comments.

[152] NRCS (2015). USDA launches new conservation effort to aid monarch butterflies. USDA News Release, 11/12/15. NRCS (undated). Monarch Butterfly Habitat Development Project. Natural Resources Conservation Service, USDA. See also: Thogmartin et al (2017). Restoring monarch butterfly habitat in the Midwestern US: 'all hands on deck.' Environmental Research Letters 12: 074005.

[153] For two of many studies, see: Wood and Goulson (2017). The environmental risks of neonicotinoid pesticides: a review of the evidence post 2013. Environ. Sci. Pollut. Res. 24: 17285-17325. Tsvetkov et al (2017). Chronic exposure to neonicotinoids reduces honey bee health near corn crops. Science 356: 1395-97.

[154] Douglas et al (2015). Neonicotinoid insecticide travels through a soil food chain, disrupting biological control of non-target pests and decreasing soya bean yield. Journal of Applied Ecology 52(1): 250-260. Douglas and Tooker (2016). Meta-analysis reveals that seed-applied neonicotinoids and pyrethroids have similar negative effects on abundance of arthropod natural enemies. PeerJ 4: e2776. Doi: 10.7717/peerj.2776.

Vertebrates: APHIS admits risks to wildlife from unregulated PIPs plants under the new Proposed Rules, but fails to assess that risk.[155] The agency's conclusion that the risk to vertebrates are the same for both Preferred Alternative and no action alternative[156] is arbitrary and capricious because the Preferred Alternative will cause many more GE organisms and their pesticides to go completely unregulated and unrestricted. In addition, some Roundup formulations are highly toxic to amphibians, particularly frog species, and the massive use of these glyphosate formulations is thought to be one factor driving the worldwide decline in amphibian species (see Appendix A). To the extent that the Preferred Alternative is likely to result in greater cultivation of glyphosate-resistant crops without any regulatory oversight, it would likely result in greater harms to amphibians.

Insect and disease resistance: APHIS states that "the purpose of many of the GE organisms field tested is protection against plant pests and disease."[157] This is contrary to fact. The vast majority of GE crops are engineered for herbicide- and/or insect-resistance (IR), with HR trait-crops exceeding IR-trait crops by roughly two to one. USDA tracks commercial adoption of GE crops, but limits coverage to crops containing these two traits because others (e.g. GE virus-resistant papaya and squash) are too insignificant to track. Thus, APHIS's undocumented claim that the Preferred Alternative would likely spur cultivation of more GE crops designed to protect against plant pests and disease is unfounded, and is thus arbitrary and capricious. *See also* "Types of GE Crops" above.

Biodiversity: APHIS arbitrarily and capricious claims that that the Preferred Alternative, including no field trial regulation and front-end commercial approval for many GE organisms, will have the same impacts on biodiversity as No Action Alternative.[158] APHIS's proposal will lead to many more completely unregulated experimental GE crops and commercial GE crops, and consequentially much more harm to biodiversity. And as discussed above and in our prior comments, the epidemic of glyphosate-resistant weeds generated by GE HR crops has led to increased tillage over the past decade, and thus these crop systems cannot be associated with conservation tillage benefits. APHIS also fails to project the considerable impacts on biodiversity of next-generation GE HR crops that were first introduced in 2016, with massive adoption projected over the next few years, accompanied by large increases in the use of environmentally toxic herbicides like 2,4-D and dicamba. APHIS's conclusions are arbitrary and capricious, and contrary to sound science.

Public health: APHIS fails to analyze impacts of the regulatory gap created by its abdication of regulatory authority over PMPI plants, and associated risks to the food supply, in the Preferred

[155] Draft PEIS at 4-47.
[156] Draft PEIS at 4-46 to 4-47.
[157] Draft PEIS at 4-54.
[158] Draft PEIS at 4-78.

Alternative.[159] It is improper reliance for APHIS to defer entirely to FDA in its public (and animal) health assessment. The PPA's mandates and definitions of harm expressly include protecting the public health. Furthermore, FDA's process for GE food safety is entirely voluntary, and the agency undertakes no independent assessment of their safety. APHIS cannot rely on FDA to fulfil its own NEPA duties. The public health risks of the Proposed Rules are significant and require analysis. This includes the risks to the food supply from PMPI crops, which APHIS at the same time is proposing to discontinue regulating. Given what the Proposed Rules will do, the conclusion that the preferred alternative would increase protection of public health is arbitrary and capricious and country to the evidence.

Socioeconomic impacts: It is arbitrary and capricious for APHIS to claim that transgenic contamination and its socioeconomic impacts will decrease under the preferred alternative. As discuss above, APHIS reaches this conclusion based on the fact that, under the Preferred Alternative, the majority of GE crops would no longer be considered "regulated article." However, contrary to APHIS's assertion, as discussed elsewhere in these comments, the complete deregulation of the majority of GE crops and elimination of field trials under APHIS's oversight is likely to significant increase, not decrease, the frequency and risks of transgenic contamination. APHIS's analysis is also flawed because the agency excluded forms of contamination except field trial contamination from what it considers to be damaging, and, since it proposes to no longer regulate field trials, contamination from them will go down. But as we have explained, whether international markets will reject contaminated food supplies does not rest on whether the U.S. treats the GE contamination as from a field trial or a U.S.-approved crop, but instead with the regulatory status of the GE organism in the foreign or GE-sensitive domestic or foreign market.[160] APHIS's treatment is misleading in finding that the Preferred Alternative will lower instances of transgenic contamination. Instead, contamination overall is likely to increase, with increased acreage and with companies in charge of their own gene flow mitigation. Less oversight will mean increased contamination and harm, not less.

It is also arbitrary and capricious for APHIS to conclude that GE crops exempted from APHIS regulation, either through exemptions or streamlined regulatory status review, will not contaminate the food supply (based on the false assumption that GE crop developers would employ rigorous gene containment standards), or trigger costly market rejection episodes. GE contamination will increase consistent with increased overall GE acreage, and will increase since

[159] Draft PEIS at ES-17.

[160] Sharratt L, Chopra T. 2019. GM Contamination in Canada - The failure to contain living modified organisms: Incidents and impacts. Canadian Biotechnology Action Network (CBAN), www.cban.ca/ContaminationReport2019. See also: EU NGOs Position Paper 'New Techniques'. 2017. Why EU GMO law must be fully applied to the so-called 'New Plant Breeding Techniques', https://corporateeurope.org/sites/default/files/attachments/joint_position_new_techniques_of_genetic_engineering_february_2017.pdf.

APHIS will not monitor or apply any controls on it. It is also arbitrary and capricious for APHIS to fail to recognize and analyze that preferred will increase international contamination episodes and their costs.

In its cost-benefit analyzes, APHIS fails to account for or analyze the substantially increased harm to the U.S. agricultural economy from increased transgenic contamination episodes and lost foreign markets. The failure to consider this important part of the problem means APHIS's baseline economic calculations of alleged benefits to U.S. agriculture from less APHIS regulation are all incorrect and fail to account for this considerable cost and downside to the agricultural industry and farmers. APHIS also failed to consider or analyze harm from its proposal to traditional, non-GE farmers and farms. APHIS fails to separate these farmers' interests from those of the GE industry, or distinguish them in the agency's scope of review and baseline.

Protected Species: It is arbitrary and capricious, and a violation of NEPA/APA and the Endangered Species Act, for APHIS to conclude that the wholesale change of its regulations would have no effect on protected species or their habitat. It is arbitrary and capricious and contrary to the evidence and sound science, that APHIS' proposed change to its regulations will not cause any material change from the current regulations as to potential impacts on protected species and their habitat.

APHIS itself in the DPEIS acknowledges that the Proposed Rules may affect listed species and critical habitat. The agency states that "individual decisions made during implementation could impact T&E species."[161] "Could impact" is synonymous with "may affect," thus triggering the consultation requirement. Nor can APHIS avoid its ESA duties for the programmatic decision it is now making by deferring it to some future agency actions, as APHIS claims, especially since one of the key features of the Preferred Alternative is the elimination of the majority of GE plants from any further regulatory review or agency action that would trigger ESA protections. The ESA requires compliances at the programmatic level regardless of what may come at the later individual implementation decision level. The failure to enter consultation here is *even worse*, since APHIS is proposing to effectively deregulate GE organisms, negating any future possible regulatory engagement point for GE organisms. APHIS recognizes that its ESA obligation at the programmatic stage is broad: "This dPEIS section is an evaluation for an entire regulatory program to ensure that APHIS addresses – as required by the ESA – anticipated, project level actions,"[162] APHIS is obligated to engage in consultation on how its rule "could impact" species based on anticipated GE plant types that may be tested and commercialized in the near future. APHIS has failed to analyze these impacts and ignored an important part of the problem.

[161] Draft PEIS at 6-9.
[162] Draft PEIS at 6-1.

The ESA also defines agency action and effects very broadly, and APHIS's review of its proposal does not assess the full range of likely direct and indirect risks from it to ESA-protected species and designated critical habitat.

Improper baseline: APHIS fails to include in its scope of analysis, not just U.S. agricultural farmland but also all surrounding ecosystems and natural habitats, as well as reasonably foreseeable expansions of farmland acreage, due to other agronomic changes, climate change, and potentially due to APHIS' proposed rule change. APHIS fails to consider in its scope also forests and grasslands that can be affected by current and reasonably foreseeable future GE grasses and forest trees.

Mitigation

Repeatedly and throughout, APHIS improperly relies on the agricultural biotechnology industry's "best interests" and their "stewardship" efforts to self-regulate GE experimental and commercial organisms without meaningfully assessing how they would do that. That reliance is contrary to APHIS's PPA and NEPA duties as well as common sense, and creates an improper baseline for APHIS's analysis of the proposed new rule changes and their impacts on farmers and the environment.

Similarly, as highlighted above, throughout the Draft PEIS, APHIS improperly relies on the potential actions of other agencies, namely the FDA or the EPA, as well as the possibility of Congressional actions that have yet to occur, as solutions to the impacts of its Preferred Alternatives, without any meaningful assessment of whether and now these other agency actions and/or acts of Congress may occur.

Like all other elements of an EIS, mitigation must be discussed in sufficient detail to ensure a fair evaluation of the environmental consequences. Without such a discussion neither the agency nor the interested parties can properly evaluate the severity of the adverse effects. It is not enough to have a conclusory or perfunctory description. Nor can the agency pretend it is not relying on mitigation, or failure to discuss mitigation that it is actually relying on. The effectiveness of any mitigation must be carefully analyzed. Nor can APHIS rely on mitigation where it has insufficient authority, or in some cases, no authority, over the agricultural biotechnology industry, other federal agencies, and Congress.

Cumulative Impacts

APHIS's discussion of the potential cumulative impacts of the Proposed Rules is wholly inadequate. Rather than analyze the cumulative impacts of the Proposed Rules on various resources (water, air, soils, agricultural economy, wildlife, humans) when combined with other past, present, and reasonably foreseeable impacts to those resources, APHIS merely reiterated its conclusions as to

direct/indirect impacts. Not only are many of those conclusions speculative, unsupported, or defying logic, merely restating these potential impacts does not equal a cumulative effects analysis.

As discussed above, the fundamental conclusion that the Preferred Alternative would somehow increase environmental protections is arbitrary and capricious, and contrary to the agency's own prior conclusions, legislative, history, and evidence. It is not supported by sound science.

A cumulative impact is the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time. A proper cumulative impacts discussion includes both an appropriate scope of impacts to the affected resource(s) and an adequately detailed/quantified discussion of those impacts. A discussion of only the direct impacts of a proposed action on the affected resource, without taking into account the combined effects that can be expected as a result of other present impacts, and other foreseeable projects, in addition to the proposed action itself, does not satisfy the requirements of NEPA. Moreover, agencies cannot provide general conclusions without the supporting objective data upon which such conclusions are based.

APHIS identified various resources that might be impacted by the proposed action, however these categories are identical to the categories of direct/indirect impacts evaluated in Chapter 4 of the DPEIS: acreage used in agriculture; soil resources; water resources and quality; air quality; soil biota; invertebrates; wildlife; pests and disease management; weeds; gene flow; biodiversity; human health; animal food and welfare; climate change; domestic markets; and international trade.[163] APHIS proceeds to list conclusions as to whether each alternative (No Action or Preferred Alternatives) would increase or decrease effects to, or harm or benefit, that resource. Many of these categories are impacts, not resources (i.e. pests, gene flow, weeds). More importantly, APHIS fails to even list in most cases, or provide any detail for, the past, present, and reasonably foreseeable impacts from other projects/actions on these resources, including by other agencies and private parties.

For example, soils are a vital resource but APHIS fails to provide any detail or quantifiable data on the past/present/foreseeable impacts to soils. But such detail/data is required to take into account the combined effects of all those impacts with the impact proposed (the Preferred Alternative). And as with all resources examined, APHIS assumes only positive impacts from increased deregulation GE crops (and therefore increased benefit from the Preferred Alternative). Nowhere does APHIS analyze the cumulative impacts of progressively increasing resistance and rising toxic herbicide use that are the reasonably foreseeable future impacts of GE HR crop systems. APHIS cannot brush off

[163] *See generally* Draft PEIS, section 5.

the potential for cumulative impacts to resources like soil by ignoring impacts that it admits in later sections. APHIS must consider all impacts to each resource, and then assess the incremental impact of the proposed action along with those past/present/foreseeable impacts. For example, APHIS has a small section devoted to altered weather conditions, or climate change, but entirely fails to integrate the impacts of altered weather patterns into its cumulative analysis for other affected resources, like water availability, biodiversity, etc.

And as we pointed out in past comments, APHIS also failed to even provide quantifiable or detailed information about the ongoing impacts of all its past GE organism approvals under the existing rules. Given the decades-long history of approving every petition for a new GE organism received, APHIS should have access to some objective data about the cumulative impacts of these actions.

The cumulative effect analysis suffers from many unsupported conclusions and assumptions, many of which defy logic. APHIS focuses only on major commodity crops, and is entirely silent on new and novel GE plants, like grasses and trees. These novel GE plants are not just foreseeable, they are already being approved. For example, GE versions of newly- or un-domesticated grasses and trees grown for biofuels or used in ecological restoration will have new or greater impacts on resources such as forests and natural areas,[164] and this is completely unaddressed (particularly regarding cumulative impacts on resources like wildlife and biodiversity). Further, APHIS speculates that new GE traits will be successfully developed and widely adopted, like drought resistance and better nutrient utilization, with positive benefits to resources like water and the agricultural economy, but provides no support for this contention.[165] APHIS bases many of its conclusions in this section on its assumption that GE crops reduce pesticide use.

CONCLUSION

For the foregoing reasons, APHIS' Draft PEIS is inadequate, failing to comply with the mandates of NEPA and the APA. APHIS fails to rely on sound science, has conclusions that run counter to the evidence, and fails to consider important aspects of the issues at hand. APHIS must go back and fully analyze the impacts of current and reasonably foreseeable direct, indirect, and cumulative impacts of its proposed new rules in a supplemental EIS. The purpose and need of the EIS is improper and overly narrow, and the agency has failed to analyze reasonable alternatives.

Similarly, the Proposed Rules must be rejected. It would take U.S. oversight of GE organisms from bad to worse, and in the process have USDA abdicate its duties of protecting farmers, the public, and the environment. New rules are needed to implement the PPA authority in responsible way for GE organisms, but the Proposal is contrary to the PPA's statutory mandates, the APA, OIG recommendations, the 2008 Farm Bill, and basic principles of good governance. USDA must rescind

[164] NASEM (2017), 105-106.
[165] Draft PEIS at 5-2 to 5-8.

the Proposed Rules and issue a new proposed rule supported by sound science that fulfills the agency's regulatory mandates and addresses the adverse impacts of GE organisms.

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ATTACHMENT A

June 19, 2017

U.S. Department of Agriculture
Regulatory Analysis and Development, PPD, APHIS
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Riverdale, MD 20737–1238

Re: Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms Proposed Rule (Docket No. APHIS-2015-0057)

Center for Food Safety (CFS) submits the following comments on APHIS's proposed rule for regulating genetically engineered (GE) organisms and its accompanying documentation.

INTRODUCTION

CFS is a nonprofit, public interest organization with a mission to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture, while also promoting and protecting regenerative, sustainable agriculture. CFS represents over 850,000 farmer and consumer members who reside in every state across the country. For over two decades, CFS has been the leading U.S. public interest organization working on the issue of GE organisms and their oversight. CFS has a major program area specific to GE organism oversight and numerous staff members—scientific, policy, campaign, and legal—whose work encompasses the topic. CFS staff are recognized experts in the field and intimately familiar with the issue of GE organisms, the inadequacy of their oversight, their risks, and their adverse impacts.

CFS has a long history of participation in APHIS's GE regulatory process, including its ongoing and longstanding process of revising its GE organism regulations under the Plant Protection Act (PPA). CFS has submitted several rounds of comments on the prior stages of APHIS's rulemaking,[1] and during the scoping process for this newest rule proposal,[2] all of which are incorporated here by reference.

[1] *See* Docket Nos. 03-031-02 (Apr. 13, 2004); APHIS–2006–0112 (Sept. 11, 2007); APHIS-2008-0023 (Nov. 24, 2008); 2008-0023 (Mar. 20, 2009); 2008-0023 (June 29, 2009).
[2] APHIS-2014-0054 (Apr. 26, 2016).

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New Rules Are Necessary

APHIS first contemplated a regulatory change in 2004, drafted a programmatic Environmental Impact Statement in 2007, and issued a proposed rule in 2008, in which it recognized that new regulations were necessary to effectively regulate GE organisms[3] under its statutory authority, the Plant Protection Act (PPA) of 2000. Given this and the protracted history of these regulations, APHIS's continued delay or indefinite postponement of a final rule in this new rulemaking would constitute arbitrary and capricious agency action in violation of the Administrative Procedure Act (APA). CFS therefore urges APHIS to conduct and conclude this rulemaking in a timely manner.

New, effective regulations are long overdue and sorely needed due to the reality of GE crops in the United States and their adverse environmental and agronomic impacts. To summarize: APHIS oversight to this point has been an abysmal failure. Transgenic contamination episodes cost U.S. farmers, including organic and conventional farmers, billions of dollars as the result of a variety of economic consequences that flow from contaminated crops, including 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. Herbicide-resistant crops have had a host of negative impacts, including increased use of herbicides; effects on threatened, endangered, and other non-target species and their habitats; an herbicide-resistant weed epidemic and its associated economic and environmental harms, including soil erosion; negative impacts on sustainable weed control; herbicidal drift injury to sensitive plants and other non-target organisms; and public-health and socioeconomic impacts of air and water contamination. The GE crops system – the tight nexus between GE crops and their herbicide(s) -- also has many implications, including a substantial shift in farmer weed control practices that give rise to many of the problems mentioned herein. Further, beyond GE crops, newer GE organism types, including GE grasses and GE trees, pose their own novel risks that APHIS must regulate and analyze.

APHIS has specifically acknowledged that it must incorporate its noxious weed harm authority in order to carry out its duties under the Plant Protection Act (PPA) with respect to GE organisms. This is true now more than ever, as the rapid evolution of GE technology has created GE organisms that were not developed using any components from plant pests. This warrants an updated and more inclusive definition of genetic engineering and an application of the full scope of APHIS's authority—over both plant pest and noxious weed harms, as the statute broadly defines those types of harms.

APHIS's constrained application of its plant pest authority to date has allowed GE crops to proliferate, to sometimes devastating effect, as summarized above. The current state and

[3] Throughout, "GE organisms" refers to all GE life forms, as defined *infra* and "GE crops" refers to GE organisms, mainly plants, that are domesticated and/or cultivated, including GE seeds, crops and crop systems, perennial grasses and trees.

continued development of GE technology in the United States has brought APHIS to the point where new regulations are essential for the agency to carry out its statutory duties. Anything less than new regulations that provide meaningful oversight of GE organisms would amount to an abdication of APHIS's statutory duties and an arbitrary and capricious agency action.

Principles of Responsible Oversight

The new GE regulations should be guided by the following principles:

1) Genetic engineering, properly defined, should be the trigger for regulation and GE organisms should not be commercialized or field tested without government assessment and approval.

2) APHIS must maintain oversight of field trials to prevent contamination and other harms. Field trials should only be allowed under permits that mandate stringent gene containment protocols with a management goal of full containment.

3) All GE organisms must undergo a pre-market review process that assesses and accounts for known adverse impacts discussed above. This process must be rigorous, transparent, and inclusive of APHIS's plant pest and noxious weed authority under the PPA. Field trial data is needed for making scientifically sound decisions.

4) Deregulation (and therefore commercialization) and/or environmental release must be denied if the GE organism is shown to cause harm. Where harmful effects can be completely prevented with limitations or geographic restrictions, such safeguards must be required for the organism during field trials and post-commercialization.

5) APHIS must maintain oversight and monitoring of GE organisms after commercialization through a commercial permitting system, and should conduct periodic reevaluations of regulatory status at set intervals.

6) APHIS must hold patent holders accountable and liable for direct and indirect harms caused by their GE products.

SPECIFIC COMMENTS ON PROPOSAL

Noxious Weed Authority

CFS supports APHIS's recognition that its statutory noxious weed authority must be incorporated into its current Part 340 regulations. Such application and specific inclusion in the GE organism context is needed and long overdue.

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, and

which encompasses harms caused by non-viable 'plant products' as well as plants.[4] APHIS is statutorily obligated to integrate and apply this authority to GE crops. In doing so, APHIS must apply the 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 must define and apply its statutory noxious weed authority in a manner that is consistent with the statute's language, and which encompasses the broad types of noxious weed harms as defined by the PPA.

APHIS must also recognize that the types of harms posed by GE organisms are dynamic and evolving as the technology evolves; APHIS must apply its noxious weed authority in a manner that reflects this changing nature. APHIS's weed risk assessments cannot be blind to the specific context of GE crops and should take those differences into account. This includes accounting for both direct and indirect harms, including socioeconomic harms.

APHIS has previously recognized the broad noxious weed definition and authority mandated by the PPA. Currently, GE organisms pose many risks that are encompassed by the PPA's definition of noxious weed harms. APHIS currently refuses to consider or regulate these harms, which falls short of its statutory duty. A continued failure to do so or to otherwise apply the statutory scope of its authority would be contrary to sound science and constitute arbitrary and capricious agency action.[5]

Plants that Produce Pharmaceutical and Industrial Compounds (PMPI Plants)

CFS strongly opposes APHIS's proposal to effectively end its long-standing regulation of PMPI plants. It has long been recognized, by the scientific community and by APHIS itself, that PMPI plants produce potentially hazardous compounds that merit stringent regulation.[6] APHIS has recognized the problem, yet essentially thrown up its hands and disavowed its duties. The risks posed by PMPI plants to the food system, public health, and agriculture fall well within APHIS's broad PPA authority. APHIS states that these crops are not regulated by either FDA or EPA, and then goes on to disavow what regulatory authority USDA currently does have over these harmful crops. In light of their recognized risks and harms, it would be irresponsible and unlawful to halt PMPI regulation by APHIS, violative of APHIS's statutory duties to protect agriculture and the public health, contrary to sound science, and arbitrary and capricious. APHIS must continue to regulate these crops pursuant to its noxious weed authority under proposed Alternative 3 (EIS 2-40). Together, all of APHIS's PPA authority, over both plant pest and noxious weed harms,

[4] 7 U.S.C. § 7702(10).
[5] *See also* Appendix B.
[6] USDA APHIS (2007). Introduction of Genetically Engineered Organisms: Draft Programmatic Environmental Impact Statement. USDA Animal and Plant Health Inspection Service, July 2007, p. 35: ("…some of these substances [pharmaceutical or industrial compounds produced by GE plants] may be allergenic, toxic or otherwise biologically active in humans and APHIS requires extraordinary safeguards to ensure that they are not found in commodity food or feed channels.")

encompass these PMPI plants, and APHIS can and should regulate them to prevent dangerous contamination of the food supply.[7]

Definitions and the Scope of Regulation

CFS strongly opposes APHIS's proposal to limit the scope of its authority and its regulation to only a subset of GE organisms. APHIS should regulate all GE organisms using its broad PPA authority to prevent their harms.

Using GE, broadly defined, as the trigger for regulation is supported by the recommendation of a National Academy of Sciences committee, which conducted an exhaustive review of APHIS GE plant regulation and 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.[8] 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."[9]

Further, in order to be scientifically sound, the definition of genetic engineering must be robust and include all methods that use *in vitro* manipulation of nucleic acids and proteins to alter genetic material or its expression, including methods on the horizon, so that the proposed rule will be inclusive and durable. Based on this proper definition, all GE organisms should begin and stay regulated and not be eligible for commercialization absent APHIS analysis, affirmative approval, and continued monitoring and conditions.

Recently, the National Academies of Sciences, Engineering, and Medicine (NASEM) produced reports that dealt in part with the future landscape of genetically engineered plants and other kinds of GE organisms.[10] The definition of genetic engineering in these reports is suitably inclusive,[11] and

[7] *See also* Appendix B.
[8] NRC (2002). Environmental Effects of Transgenic Plants. National Research Council, National Academy of Sciences, 2002, p. 79. USDA APHIS (2007), op. cit., p. 20.
[9] USDA APHIS (2007), op. cit., p. 168. APHIS 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 2 (the Preferred Alternative). APHIS has never explained this sudden and unjustifiable about-face. However one logical explanation is that APHIS allowed itself to be influenced by industry stakeholders who wished (and wish) to throw off APHIS regulation altogether and instead regulate themselves.
[10] NASEM, 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: National Academies Press, ISBN 978-0-309-43738-7 | DOI: 10.17226/23395, available at http://www nap.edu/23395; NASEM, 2017. Preparing for Future Products of Biotechnology. Washington, DC: National Academies Press, ISBN 978-0-309-45205-2 | DOI: 10.17226/24605, available at http://www.nap.edu/24605
[11] NASEM 2016 at 36 explicitly lists some examples of what its definition includes and excludes: "The committee's definition of *genetic engineering* includes *Agrobacterium*-mediated and gene gun-mediated gene transfer to plants … as well as more recently developed technologies such as CRISPR, TALENs, and ZFNs [genome editing methods]. …Making sexual crosses of plants that have different genomes, selecting desirable plants to serve as parent lines, and changing (mutagenizing) the genome with chemical methods or irradiation are considered *conventional plant breeding*, which does not include *genetic engineering*..."

should be used instead of the definition proposed by APHIS, so that the Rule will capture all GE organisms for assessment and regulation:

> *Genetic engineering* means the introduction or change of DNA, RNA, or proteins by human manipulation to effect a change in an organism's genome or epigenome; where *genome* means the complete sequence of the DNA in an organism, and *epigenome* means the physical factors affecting the expression of genes without affecting the actual DNA sequence of the genome.[12]

Similarly, the definition of genetically engineered organism[13] should follow from the definition of genetic engineering, where organism has the same meaning as it does in APHIS' proposed Rule:[14]

> *Genetically engineered organism* means an organism developed using genetic engineering; where *organism* is any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.
>
> This includes all organisms whose genomes or epigenomes have been intentionally altered using modern molecular technologies, which may include random or targeted nucleotide sequence changes such as nucleotide insertions, substitutions, or deletions. This definition applies to both the founder organism in which the initial alteration event occurred and the entire subsequent lineage of organisms that contains the genomic/epigenomic alteration(s).

Proposed Definitional Exclusions

APHIS proposed three classes of exclusions to its basic definition of *genetically engineered organism* that unacceptably narrow the regulatory scope of the Rule.[15] APHIS claims that the excluded GE organisms do not pose risks because they could have been made using mutagens, sexual crosses with related organisms, or other traditional breeding methods. However, the proposed exclusions would allow GE organisms that could cause PPA risks to entirely escape review and regulation by APHIS. Such a decision would be contrary to sound science and arbitrary and capricious.

1) GE organisms that are produced using genome editing techniques that cause a deletion in a gene, or substitute one nucleotide base pair for another, would be improperly excluded from the definition.

A priori exemption of GE organisms that have loss-of-gene-function or small changes in nucleic acid sequences is contrary to sound science. Any type of change in a gene sequence can potentially

[12] NASEM 2016. Glossary at 384 – 388; NASEM, 2017. Glossary at 178 – 180.
[13] *Organism* is not specifically defined in the NASEM report glossaries.
[14] Proposed 7 CFR part 340.1 Definitions.
[15] Proposed Rule at 29-30, 35 – 36.

cause phenotypic changes[16] that have significant consequences, whether the change could occur naturally or not.[17] Moreover, genome editing methods are still in early development, and risks of their use are not known well enough to predict impacts *a priori*.

For example, genome editing can result in alterations at unintended sites in the genome with potentially harmful results, and the use of such technologies, in plants[18] and also in animals[19], are too new and diverse to accurately predict or reliably prevent such off-target effects. Unlike largely random, genome-wide mutations that result from chemical mutagenesis and irradiation, current research on the off-target mutations caused by genome editing indicates they are more likely to be non-random, presenting unique, uncharacterized risks.

Further, genome editing can be done sequentially, to intentionally alter one gene after another. Presumably, each intermediate organism with just one new intentional change could be exempt from the proposed definition, cumulatively resulting in a final GE organism with many intended changes, that would also be exempt. Additionally, plants produced by almost every GE method are regenerated from single cells in tissue culture at some point in their development, a process well known to introduce genetic and epigenetic changes that result in somaclonal variation with unpredictable consequences.[20]

2) GE organisms made by "introducing only naturally occurring nucleic acid sequences from a sexually compatible relative" are improperly excluded.

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[16] NASEM 2016 at 387: "Phenotype/Phenotypic - The visible and/or measurable characteristics of an organism (i.e., how it appears outwardly and physiologically) as opposed to its genotype, or genetic characteristics".

[17] NASEM 2016 at 331: "A few changes in an endogenous plant gene can confer an agronomic trait, such as herbicide resistance. Thus, small changes in gene sequence in an endogenous gene can result in large phenotype and fitness changes"; e.g., Xiong L, Lee H, Huang R, Zhu J-K (2004) A single amino acid substitution in the Arabidopsis FIERY1/HOS2 protein confers cold signaling specificity and lithium tolerance. The Plant Journal 40: 536–545; Doyle MR, Amasino RM (2009) A single amino acid change in the enhancer of zeste ortholog CURLY LEAF results in vernalization-independent, rapid flowering in Arabidopsis. Plant Physiology 151: 1688–1697

[18] Wolt JD (2017) Safety, Security, and Policy Considerations for Plant Genome Editing. Progress in Molecular Biology and Translational Science. http://dx.doi.org/10.1016/bs.pmbts.2017.03.005

[19] Schaefer KA, Wu WH, Colgan DF, Tsang SH, Bassuk AG, Mahajan VB (2017) Unexpected mutations after CRISPR-Cas9 editing in vivo. Nature Methods 14(6): 547-548; Shin HY, Wang C, Lee HK, Yoo KH, Zeng X, Kuhns T, Yang CM, Mohr T, Liu C, Hennighausen L.(2017) CRISPR/Cas9 targeting events cause complex deletions and insertions at 17 sites in the mouse genome. Nature Communications 8:15464.

[20] NASEM 2016 at 44: "Plants regenerated in tissue culture sometimes vary widely in phenotype (appearance) from the source plant and from each other, and the term *somaclonal variation* was established to refer collectively to such phenotypic variation…"; at 260: "…the construction of GE plants commonly relies on in vitro plant tissue culture, transformation, and plant regeneration. Among the complications often associated with the regenerated plants is that they can be variable in phenotype and fertility because of somaclonal variation rather than the genetic-engineering event itself…. Many factors—including crop, culture media, length of time in tissue culture, and genotype—can affect the frequency and severity of somaclonal variation. Altered gene expression can result from changes in chromosome number or structure, in DNA sequence, in epigenetic status—for example, DNA methylation…or in all the above…."; NASEM 2016 at 241; Neelakandan AK, Wang K (2012) Recent progress in the understanding of tissue culture-induced genome level changes in plants and potential applications. Plant Cell Reports 31: 597 – 620; Miguel C, Marum L (2011) An epigenetic view of plant cells cultured in vitro: somaclonal variation and beyond. Journal of Experimental Botany 62: 3713–3725.

Nucleic acids with sequences found naturally in closely related, sexually compatible organisms do not necessarily have acceptable risks when introduced into other species. For example, the introduced nucleic acids can direct the synthesis of toxins, change metabolism in harmful ways, turn on or off genes and metabolic pathways in the genetically engineered host, make the genetically engineered organism more susceptible to pests and pathogens, or more fit in the wild and more weedy.[21] Adding nucleic acid sequences derived from related organisms using genetic engineering results in the same unintended genome alterations from transformation-induced[22] and tissue-culture associated mutagenesis and epigenetic changes (see above footnote) as does adding nucleic acid sequences from unrelated sources, with risks that must be assessed.[23]

3) The progeny of GE organisms are improperly excluded when the nucleic acid sequences introduced into or changed in the parents have been removed by subsequent breeding to make "null segregants."

Bringing null segregants into the APHIS regulatory system to verify that any inserted or altered genes have indeed been fully removed, and are not present as partial, multiple, or scrambled versions somewhere in the genome, is necessary for assessment of risks. Also, having gone through the process of genetic engineering, the null segregants may still harbor somaclonal variation or off-target mutations with risks that must be assessed.

<u>The Scope of USDA oversight: Genetic engineering must be the trigger</u>

APHIS currently regulates only those GE organisms that were engineered using genetic sequences or vectors that were derived from plant pests such as pathogenic viruses and bacteria, even though it knew at least by the early 1990s that these plant pest components themselves were highly unlikely to turn crops into actual plant pests.[24] As CFS has long contended, using plant pest components in order to bring GE organisms into the USDA regulatory net is not related to risks, and is therefore arbitrary and contrary to sound science. Almost any plant can be genetically engineered using old or new methods that do not involve plant pest components, thus evading USDA regulation despite potential risks. Examples of GE crops that have gone unregulated because of not being engineered using plant pest components include herbicide-resistant turf grasses, fast-growing grasses and trees

[21] NRC (2002), op. cit., 43.
[22] Wilson AK, Latham JR, Steinbrecher RA (2006) Transformation-induced mutations in transgenic plants: Analysis and biosafety implications. Biotechnology and Genetic Engineering Reviews 23: 209 – 234; Latham JR, Wilson AK, Steinbrecher RA (2006) The mutational consequences of plant transformation. BioMed Research International 2006: 1 – 7; Van Leeuwen W, Ruttink T, Borst-Vrenssen AWM, Van der Plas LHW, Van der Krol AR (2001) Characterization of position-induced spatial and temporal regulation of transgene promoter activity in plants. Journal of Experimental Botany 52: 949 – 959; Liu Z, Li Y, Zhao J, Chen X, Jian G, Peng Y, Qi F (2012) Differentially Expressed Genes Distributed Over Chromosomes and Implicated in Certain Biological Processes for Site Insertion Genetically Modified Rice Kemingdao. International Journal of Biological Sciences 8: 953 - 963.
[23] Zsögön A, Cermak T, Voytas D, Peres LE (2016) Review: Genome editing as a tool to achieve the crop ideotype and *de novo* domestication of wild relatives: case study in tomato. Plant Science, http://dx.doi.org/doi:10.1016/j.plantsci.2016.12.01 .
[24] USDA APHIS 1992, FLAVR SAVR tomato deregulation decision, Petition Number 92-196-01p, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

for biofuels, and disease-resistant rice and grapes.[25] APHIS has colluded with the developers of dozens of GE organisms to allow them to make an end-run around its current regulatory process. Thus, many GE organisms are presumably in some stage of commercial development, without any monitoring or oversight. From field trials through commercialization, companies and researchers are free to plant most of these never-regulated GE crops anywhere.[26] This irresponsible practice must be halted, one of many reasons why new regulations are needed. Even GE crops designed to produce pharmaceuticals or industrial chemicals could go unregulated by USDA, and be grown in open field trials, based on the criteria of this regulatory "loophole."

This chaotic situation regarding oversight and assessment of GE organisms is untenable, irresponsible, and contrary to sound governance. The current problem of the "loophole" created by the "Am I Regulated?" process for GE organisms developed using non-plant pest nucleotide sequences and vectors must be fixed, and these GE organisms must be included in the regulatory system from the start. To this end, APHIS must use its broad authority under the PPA to regulate all GE organisms to prevent the myriad risks they pose, and to protect our health, environment, and agricultural economy in a scientifically sound way. Genetic engineering, broadly defined, should be the unambiguous trigger for bringing GE organisms into the regulatory system, as the National Academy of Science has long recommended.[27] On this basis, all GE organisms should begin and stay regulated, with no commercialization absent USDA analysis, affirmative approval and continued monitoring/restrictions.

Under the proposed rule, APHIS would no longer use plant pest components as the trigger for GE crops to enter its regulatory system, as it admits that this does not predict plant pest risks.[28] However, rather than close the loophole by bringing all GE organisms into the regulatory system, APHIS would create gaping new loopholes via an extensive set of exemptions and exclusions. As such, the proposed system would be still more unscientific and arbitrary, and likely less protective, that the current one.

First, APHIS proposes to exempt GE organisms from regulation if they were engineered to make certain types of changes, regardless of potential for risks. CFS opposes those improper and unscientific definitional exclusions. *See supra*.

Second, APHIS proposes to introduce additional loopholes that would narrow its scope of regulation still further. A GE organism (one that is not already excluded by definition) would be exempted from review and possible regulation by APHIS unless it met one of the following four criteria: 1) Prior to genetic engineering, the organism itself was a plant pest, as listed in 340.2; 2)

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[25]USDA APHIS "Regulated Article Letters of Inquiry," https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/Regulated_Article_Letters_of_Inquiry; accessed June 11, 2017.

[26] Depending on their particular traits, a few of the crops that are not being regulated by USDA will be regulated later by EPA or FDA, when releases are over 10 acres, and when the GE crops are grown commercially for food.

[27]NRC (2002), op. cit.

[28] Proposed Rule at 38 – 41.

The organism was engineered to contain plant pest DNA that enables the GE organism to produce infectious entities or toxins that cause plant disease; 3) The organism has a plant-and-trait combination that APHIS has not previously evaluated for plant pest or noxious weed risks; or 4) The organism has previously been found by APHIS to pose plant pest or noxious weed risks.[29] The first two criteria would only rarely if ever apply to GE plants, since: 1) The only plants listed as plant pests under Part 340.2 are agriculturally damaging "parasitic plants;" and 2) Genetic engineering is seldom if ever used to render plants disease-ridden. The fourth criterion is also unlikely to be triggered. This leaves criterion 3 as the only effective trigger for APHIS regulation.

The proposed rule would end APHIS' current event-based regulation[30] in favor of a narrower system based on novel trait-and-organism combinations.[31] This is contrary to sound science. In 2007, APHIS proposed event-based regulation as part of its Preferred Alternative, conceding that it was more protective than a trait-and-organism approach, and would "eliminate potential gaps that may occur as genetic engineering technologies continue to advance."[32] As noted previously, the National Academy of Sciences has also advocated use of genetic engineering [i.e. transformation] as "both a useful and scientifically justifiable regulatory trigger" because "there is no scientific basis" on which to exclude GE organisms from regulatory review prior to evaluation of data on the interactions between "trait, organism and environment."[33] This is because every event is unique and potentially has a novel phenotype[34] that must be assessed to determine appropriate regulation. CFS strongly opposes APHIS's proposal to exclude GE organisms from regulations based on the loopholes discussed above.

APHIS anticipates that GE organism developers would frequently choose to consult with it as to the regulatory status of their products (e.g. the "Am I Regulated?" process). However, this is unlikely to be the case, because the proposed regulatory criteria are explicit enough that in most cases they will be enabled to make their own regulatory determinations. For those many GE organisms that clearly meet the exclusions and exemptions discussed above, developers would have little or no reason to consult with APHIS. These GE plants could be grown and commercialized not only in the absence of regulation, but without APHIS's knowledge. This is undesirable for many reasons, not least because it would likely complicate remediation of GE contamination episodes with market impacts too big for APHIS to ignore.

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[29] Proposed Rule, 37-38.

[30] "Currently, APHIS regulates GE organisms as "transformation events." An event is a single successful insertion of a gene or gene fragment into a cell's genetic material or a successful deletion of a gene or gene fragment from a cell. Each event can be genetically unique, even if the event results from a single transformation experiment in which many individual cells were treated under identical conditions. Biotechnology techniques allow scientists to regenerate entire organisms, such as whole plants, from a single cell. A plant produced from one transformed cell may also be called an event." (USDA APHIS 2007 draft PEIS GE Organisms at 22)

[31] Proposed Rule at 42, footnote 6.

[32] USDA APHIS (2007), op. cit., pp. 133-134; 168.

[33] NRC (2002), op. cit., p. 79.

[34] *Phenotype* means "[t]he visible and/or measurable characteristics of an organism (i.e., how it appears outwardly and physiologically) as opposed to its genotype, or genetic characteristics." NASEM 2017 at 129.

These exemptions also make the proposed rule exceedingly non-transparent. Transparency is a universally accepted principle of regulatory practice, building public trust in the objectivity and legitimacy of governance. The public, the scientific community and America's trading partners, among others, would be given the false impression that "GE organisms" are under APHIS regulation (absent explicit determination of "nonregulated status"), when in fact a large number will be exempted from review altogether. The "Am I Regulated?" process is also non-transparent. In those few cases where the regulatory status of a GE organism is in doubt, regulatory decisions would be made behind the scenes, on an *ad hoc* basis, in communications between APHIS and individual GE plant developers. In contrast, a clean regulatory trigger based on the use of genetic engineering would make APHIS's regulatory regime just what the public perceives it to be – building trust in the honesty and legitimacy of APHIS's regulatory program.

In sum, instead of fixing the growing problem of GE organisms escaping regulation by APHIS based on arbitrary criteria, the proposed rule would create still more arbitrary and unjustifiable loopholes. The number of GE organisms evading APHIS's PPA authority would increase considerably, particularly GE plants, by far the dominant category.[35] Of the smaller pool subject to initial regulation, most would likely be rapidly exempted based on perfunctory "upfront" assessments for plant pest and noxious weed risks. APHIS should reject these proposed changes, which would dramatically expand the universe of unregulated GE organisms and associated risks they pose. All GE organisms should begin and stay regulated, with no commercialization allowed absent USDA analysis, affirmative approval and continued monitoring/restrictions. Action otherwise is an abdication of statutory responsibilities.

Permits and Notifications

CFS theoretically supports the proposal to eliminate notifications in favor of permits, because permits are stricter and provide APHIS with greater means of enforcing safeguards and control over GE crops. CFS also supports establishing and strengthening the general reporting requirements for all permits.

However, the practical effect of APHIS's proposal is to not require permits or notifications for experimental field trials. Instead, it would allow the majority of GE plant field trials to occur without permits or notifications, and for commercialized GE crops to be completely unregulated. Because permits will only apply to those GE crops that APHIS determines at the outset require regulation, the proposal would result in permits for only a small minority of currently-regulated GE plant field trials. Instead, genetically engineered organisms exempted at the outset by APHIS from regulation would be field-tested by developers as part of their private research and development,

[35] Plants have been the most commonly engineered type of organism released into the environment, and will likely be so in the future; NASEM 2017 at 44: "On the basis of its information-gathering efforts, the committee found that plant hosts will continue to be a dominant area for biotechnology product development."

without reporting to or oversight by APHIS. Such a decision is arbitrary and capricious, contrary to sound science, and an improper delegation of APHIS's duties to industry.

And it would have dramatically negative effects. Ending regulation of many experimental GE crops, as proposed, would sharply increase harms to farmers, markets, and the environment from GE escapes and contamination. APHIS's contrary conclusions are belied by evidence and past history of GE crops. APHIS assumes that GE crops exempted from its regulatory regime under the proposed rule would not cause contamination-related harms for two main reasons: GE crop developers would, of their own accord, employ rigorous gene containment measures;[36] and economic losses would not occur if the contaminating GE crop were exempted from APHIS oversight.[37] Neither assumption is valid.

First, developers would relax or abandon the gene containment measures they now are required to apply (which are often inadequate in any case) in order to realize significant cost savings – in line with APHIS's projection that the Preferred Alternative would reduce companies' regulatory costs. APHIS presents no analysis to support its contrary assumption that industry would maintain current gene containment standards, absent accountability to government, and to assume so is arbitrary and capricious and contrary to the evidence that is before the agency from this and prior rule-making comments. Relying on GE crop developers to voluntarily practice gene containment is an improper delegation of APHIS's responsibilities to industry.

Second, APHIS-exempted GE crops would continue to be regulated in most of our export markets, which have stricter regulatory regimes, and thus export shipments contaminated by them would likely be rejected. There have already been numerous costly episodes in which export markets rejected shipments contaminated with GE crops that had been officially granted nonregulated status by APHIS, but were not approved in the receiving country. Known losses reach the many billions of dollars.[38] APHIS devotes a few sentences to one such episode,[39] which caused billions in losses and "prompted law suits in 22 states between U.S. producers and Syngenta [the GE crop developer]."[40] Yet despite the serious economic losses that constrained so many American farmers to seek redress in the courts, the episode is discussed only in terms of its impact on Syngenta. This provides a striking illustration of how entirely APHIS's proposed rule is geared to serve the interests of the biotechnology industry, whatever the costs might be to American farmers. Such episodes and their costs would likely increase dramatically under the proposed rule, with most GE crops either never-regulated, or subject only to perfunctory "upfront" assessments. APHIS provides no projection of the costs associated with such episodes, despite

[36] Proposed Rule, 96-97; PEIS, ES-28 to ES-29.
[37] PEIS, 4-185.
[38] For instance, see: Durison and Wilson (2014). U.S. grain losses seen up to $6.3 billion on China ban. Bloomberg, 4/16/14. Newman J (2014). China's hard line on biotech burns U.S. hay. Wall Street Journal, 12/15/14.
[39] Durison and Wilson (2014), op. cit.
[40] PEIS, 4-189 to 4-190.

recognizing that they would cause "disruption in the market,"[41] the costs of which, as usual, would be borne chiefly by American farmers.

Domestically, organic and non-GE farmers already incur substantial costs from GE contamination. APHIS only assesses costs to organic farmers,[42] and limits it assessment to organic crop value lost from presence of genetically modified organisms in reported cases. APHIS leaves unaccounted the numerous other costs borne entirely by organic farmers to avoid or manage GE contamination: loss of production and revenue from the planting of non-organic buffer strips, yield losses from delayed planting (for temporal isolation), costs of testing for GE content, and loss of sales due to the increased risk of contamination, among others.[43] The threat and experience of GE contamination, and the many costs it imposes, are one important factor dissuading many U.S. farmers from transitioning to organic to meet skyrocketing demand. The result is substantial imports of organic corn and soybeans from overseas.[44] Clearly, the world's leading producer of corn and soybeans (the U.S.) is capable of meeting, and vastly exceeding, domestic demand for organic supplies of these crops. That market-savvy U.S. farmers are not meeting this demand (despite often huge organic price premia) speaks volumes to the impediments posed by GE contamination. Similarly, Whole Foods Market, a major purveyor of organic products, reported in a recent submission to APHIS that organic sales, though rising, could be growing at a still faster clip if it were not for supply constraints, particularly in grains and dairy products.[45] APHIS makes no attempt to account for revenue foregone by the U.S. organic farming sector due to the threat and experience of GE contamination, but it is surely substantial, and likely dwarves losses from reported contamination episodes. For all of these reasons, the already considerable economic harms to the organic sector caused by GE contamination would increase dramatically under the proposed rule.

APHIS also fails to account for the costs of contamination to the non-organic, non-GMO sector, beyond anecdotal descriptions of a few high-profile contamination episodes involving unauthorized releases.[46] Yet, Whole Foods Market reports even faster growth in non-GMO sales than in sales of organic products, and has set a deadline of 2018 for GMO transparency for its food products.[47] For the same reasons as discussed above for the organic sector, the increase in GE contamination episodes that would occur under the proposed rule also poses dire threats to the vibrant non-GMO food chain, from farmers to food companies to grain traders. Overseas producers will likely reap the rewards of APHIS mis-regulation, as they have in the organic sector.

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[41] Proposed Rule, 16.
[42] PEIS, 4-174 to 4-177. Although the title of this section is "Producers of non-GE crops," APHIS focuses entirely on the organic sector and ignores the impacts on other non-GE producers.
[43] FWW-OFARM (2014). Organic farmers pay the price for GMO contamination. Food and Water Watch and Organic Farmers' Agency for Relationship Marketing. Issue Brief, March 2014.
[44] Bjerga A (2015). U.S. forced to import corn as shoppers demand organic food. Bloomberg, 4/15/15.
[45] Schweizer E (2015). Organic and non GMO market growth 2015. Executive Global Grocery Coordinator, Whole Foods Market, 2015, slide 18.
[46] PEIS, 4-177 to 4-178.
[47] Schweizer (2015), op. cit.

Finally, the Preferred Alternative is not responsive, as APHIS claims, to the 2008 Farm Bill, or to the 2005 and 2015 reports of the USDA's Office of Inspector General (OIG). The 2008 Farm Bill contained provisions that explicitly directed APHIS to strengthen its regulation of GE crop field trials to forestall GE contamination events. These provisions were enacted by Congress in response to thousands of rice farming constituents who were victimized by an extremely costly GE contamination episode involving an unapproved, experimental GE rice variety known as LLRICE601.[48] LLRICE601 contaminated 30% of U.S. long-grain rice in 2006 and 2007, resulting in massive export market rejection of contaminated shipments, and huge losses estimated at up to $1.3 billion to 11,000 American rice farmers and others in the rice food chain.[49] APHIS's regulatory failure forced farmers to sue the GE crop's developer, Bayer CropScience, which denied all responsibility. Only after five years of litigation did farmers obtain at least partial compensation. APHIS's claim that the Preferred Alternative, which will vastly increase the potential for similar episodes in the future, is responsive to the 2008 Farm Bill is entirely without merit. Neither does the proposed rule respond to the USDA OIG's 2005 and 2015 reports, which detailed the numerous regulatory deficits that enabled GE contamination to occur, particularly but not solely with respect to PMPI plants.

APHIS's proposed rule is contrary to the evidence before the agency in this rulemaking and in prior dockets that have led to the current proposal, where the records are replete with evidence of harms that stem from APHIS's repeated failures to prevent escapes and contamination from field trials. This course of proposed action is also contrary to sound science, arbitrary and capricious, and a direct violation of the 2008 Farm Bill.

CFS also opposes APHIS's proposal to list requirements for permit applications on the internet or through guidance, rather than in federal regulations with the force of law. Permit information should be made public and easily accessible; however, it must be codified with the force of law and implemented or changed through notice-and-comment rulemaking procedures. If APHIS intends to treat these requirements as legally binding, it cannot issue them through a process that does not guarantee public participation and accountability.

The proposal also makes it impossible for APHIS to carry out its statutory duties with respect to risk assessments. Conducting an assessment before the developer is required to apply for a permit puts the cart before the horse, because APHIS will lack information that is necessary to a meaningful risk assessment unless the developer is required to submit the same level of information that would be required in a permit. This issue is discussed further *infra*, under "Upfront Risk Assessment Process."

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[48] Blue EN (2007). Risky Business: economic and regulatory impacts from the unintended release of genetically engineered rice varieties into the rice merchandizing system of the US. Neal Blue Consulting and Greenpeace, 2007.

[49] Harris and Beasley (2011). Bayer agrees to pay $750 million to end lawsuit over gene-modified rice. Bloomberg, 7/2/11. CFS (2011). Legal settlements and awards for Bayer contamination of U.S. rice with experimental, genetically engineered LibertyLink rice. Center for Food Safety, April 2011.

Petitions for Deregulation

CFS strongly opposes the proposal to end petitions for deregulation. CFS strongly opposes any proposal to end regulated status for GE organisms. GE organisms must go through a deregulation/review decision, based on sound science, before they can be commercialized. A contrary decision violates sound science principles and is arbitrary and capricious. An agency needs data to assess risks. This cannot just be accomplished "on the front end" without proper data, as APHIS proposes. *See infra* below. APHIS should require more data, not less, and the data it requires should encompass GE crops' actual impacts under real-world production conditions and constraints. APHIS must make clear that all GE organisms begin at minimum as regulated organisms. APHIS must regulate and assess each GE organism on individual basis, and must include an assessment of their actual direct and indirect harms.

As mentioned above, the proposal will leave APHIS without the data and information necessary to make a meaningful risk assessment. It is simply illogical for APHIS to claim that it can conduct risk assessments prior to receiving data based on properly conducted experiments at the field trial stage. Moreover, it would be unlawful and contrary to the PPA for APHIS to make such assessments without necessary data.

APHIS further suggests that the process for complying with the National Environmental Policy Act (NEPA) will vary depending on the order in which APHIS makes its decisions. NEPA applies to every major federal action that may significantly affect the human environment, and APHIS must comply with NEPA's obligations whenever it takes such actions, regardless of where in the process the action may fall for a particular GE organism.

To the extent APHIS proposes instead to essentially codify its current "Am I Regulated?" process, creating a regulatory loophole for many GE organisms, CFS strongly opposes any such decision. Regulations that exempt GE organisms would be contrary to sound science and arbitrary and capricious, as well as an improper delegation of APHIS's duties to private industry.

For these reasons, the proposal with respect to deregulation petitions is contrary to sound science, arbitrary and capricious agency action, contrary to the evidence before the agency, and an improper delegation of APHIS's statutory authority to private parties.

"Upfront" Risk Assessment Process

Under the proposed rule, APHIS would evaluate the potential plant pest and noxious weed risks of some novel GE crops in an "upfront risk assessment process" (PEIS at ES-6). Such assessments would be based on information submitted by the GE plant developer, primarily genotypic data and a description of the "intended phenotype(s) of the GE organism," including "known and potential

differences from the non-GE organism that would substantiate that the GE organism is unlikely to pose a greater noxious weed risk or plant pest risk than the non-GE organism from which it was derived" (Proposed Rule at 70-72). The GE plant developer is left to decide if experimental data from any field trials it may have conducted is relevant to APHIS's evaluation, but is not required to submit them (Proposed Rule at 72). APHIS anticipates that its upfront assessments will be made in the complete absence of such "data from outdoor plantings" (Proposed Rule at 18, 22).

Elimination of the field trial data requirement constitutes a "significant departure" from the current rules, which specify that a petition for nonregulated status must contain "field reports for all trials conducted under permit or notification procedures ... including .... methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment" (Proposed Rule at 74).

This proposed change must be rejected, as contrary to sound science. APHIS cannot perform scientifically sound assessments without field trial data, and its proposal to do so will likely result in widespread cultivation of GE crops that pose unexamined plant pest and/or noxious weed risks. This is particularly true with respect to unintended or unexpected effects of the genetic engineering process, which are unlikely to be detected from genotypic data or a description of the "intended phenotype of the GE organism."

APHIS justifies its elimination of this requirement on several specious grounds. First, APHIS cites a 1989 NRC report to support its assertion that field trial data are unnecessary (Proposed Rule at 74). At the time of this report, extremely few data sets were available to the authors of this report, since field tests of GE organisms began in very small numbers only in the late 1980s. Second, APHIS states that past field trial reports have not revealed plant pest or noxious weed issues (Proposed Rule at 74). However, this is due to the unscientific nature of the field trial reports, which involve only "observations" rather than controlled tests, and APHIS's lax assessment process.

For instance, in the examples discussed under the Plant Pest Risk section, scientific literature clearly demonstrates the potential for plant pest risks in each case – namely, increased disease susceptibility of Arctic apple and of glyphosate-resistant soybeans treated with glyphosate. In these cases, APHIS should have demanded controlled tests involving intentional exposure of the GE organisms to plant pest organisms known to infest them. Observational field trials may not detect increased disease susceptibility simply because the plant pest organisms were not present, or not at sufficiently high levels, where and when the field trials were conducted. In the case of glyphosate-resistant crops, field trial experiments must obviously include application of glyphosate. In APHIS's deregulation of MON 89788 glyphosate-resistant soybeans, however, APHIS inexplicably relied on Monsanto observations of field trials that did not involve application of glyphosate.

In general, APHIS should take a more proactive role in plant pest risk and noxious weed risk assessments. APHIS should not rely entirely on developer-submitted information, since conflict of

interest considerations and APHIS's own directions suggest that submitted data would tend to both "substantiate that the GE organism is unlikely to pose a greater noxious weed risk or plant pest risk than the non-GE organism from which it was derived" (Proposed Rule at 72) and to omit or downplay contrary information. APHIS cannot farm out its statutory duties to the regulated entities. APHIS should conduct comprehensive literature searches to uncover any potential unintended effects of the genetic modification, or of changes in agricultural practices associated with the genetic modification, that are potentially relevant to the plant pest or noxious weed risk assessment. Targeted testing should be undertaken to confirm or rule out such effects, whether or not they are intended or reported by the GE crop developer.

PIP field trials of less than 10 acres

CFS opposes APHIS's attempt to delegate its statutory duties to other agencies, without meaningful assurance or certainty that those agencies will effectively regulate these organisms. Shifting responsibility over these organisms to another agency amounts to an unlawful abdication of APHIS's statutory duties, which constitutes arbitrary and capricious agency action. Currently, APHIS is the primary agency regulating GE organisms. EPA shares responsibility with APHIS for field trials of GE plants that are engineered with pesticidal substances (Plant Incorporated Protectants - PIPs), with EPA joining the process when field trials exceed 10 acres. Unlike APHIS, EPA indefinitely maintains regulation of GE crops engineered to express PIPS via registration reviews of the PIPs after deregulation by APHIS and during commercial production. APHIS proposes relinquishing its regulatory authority to EPA over GE crops that are engineered with PIPs and predicts that many PIP-producing plants will be exempt or excluded from regulation, and thus will be grown in field trials without oversight, until and unless the trials exceed 10 acres and EPA assumes oversight.[50] Such a decision would be contrary to sound science and arbitrary and capricious. Risks from field trials of less than 10 acres would be left arbitrarily unregulated. Sharing regulation of field trials between APHIS and EPA is necessary and should continue. In addition to EPA's FIFRA responsibilities, all GE crops with PIPs have the potential for Plant Pest and/or Noxious Weed risks under APHIS' PPA authority because each event is a novel organism, and field trials of any size are capable of causing harm to the environment or human health. APHIS is already positioned to oversee field trials, whereas EPA is not and would have to develop that capacity.

Synchronous Decisions with the EPA re: Herbicide Resistant GE Plants and Herbicides

As discussed more fully in Appendix B, GE herbicide-resistant (HR) crop systems pose high risks of herbicide drift causing damage to other farmers' crops, often at great distances. Over just the past year, crops on hundreds of thousands of acres have reportedly experienced sometimes severe injury due to the use of dicamba on very limited plantings of GE dicamba-resistant crops. Glyphosate has been a leading cause of drift injury since the advent of glyphosate-resistant crops. Because the higher risk of drift injury is attributable to features of both the GE crop (which

[50] Proposed Rule at 21 – 23.

facilitates high-rate herbicide use far later in the growing season than would otherwise be possible) and the herbicide (e.g. its volatility), APHIS and EPA must work together to jointly regulate GE HR crop systems so as to protect farmers from drift injury. At a minimum, APHIS and EPA must coordinate their analyses of the GE crop (APHIS) and herbicide (EPA) components of these crop systems, and bring their respective areas of expertise to bear in formulating policies and restrictions that reduce the frequency and severity of herbicide drift injury episodes to an absolute minimum. Synchronizing approvals of the GE crop and associated herbicide would be a start, but far from sufficient. Past experience shows the current bifurcated regulatory regime is not working. Even when decisions are synchronized, far too many farmers have had their crops damaged. APHIS and EPA must carefully assess real-world data on the herbicide use practices, the frequency and severity of crop injury episodes, and the efficacy or lack of efficacy of individual policy measures (e.g. label prescriptions, fines), for each and every HR crop system. Based on the results of such analyses, the agencies should impose protective restrictions on, and if necessary deny or rescind approval of, such HR crop systems. APHIS cannot abdicate its statutory responsibility to EPA, not when the HR crop itself is partially responsible for drift-related harms. APHIS and EPA's current practice is failing American farmers, is contrary to sound science, and arbitrary and capricious—especially in light of APHIS's acknowledgment of the problem. APHIS's plea of powerlessness in this matter[51] is belied by its affirmation that under Alternative 3, it could work in coordination with EPA to at least ensure synchronous timing of GE HR crop and herbicide approvals.[52]

Plant pest harms

In the new regulations APHIS must resolve a long-standing and fundamental contradiction with respect to its application of the PPA's plant pest authority to GE crops. The contradiction – which centers on the difference between "plant pest" and "plant pest risk" – must be resolved in the interests of a rational, consistent, and scientifically coherent regulatory system.

Under the current rules, APHIS sometimes describes the regulatory trigger criterion, correctly, as whether or not a GE plant developed with the use of one or more plant pest organisms poses a "plant pest risk" or "more of a plant pest risk than its non-GE counterpart."[53] "Plant pest risk" is defined as a GE organism's potential to have greater "disease and pest susceptibilities," "create pest or disease problems," have "non-target effects that might affect organisms beneficial to agriculture," promote changes "in agricultural practices that might exacerbate pest or disease problems," to be itself weedy or to increase the weediness of any other sexually compatible plant, "transmit the introduced trait to organisms with which it does not interbreed," or to have "indirect plant pest effects on other agricultural products."[54]

[51] Proposed Rule, 23-26.
[52] PEIS, 2-41.
[53] Proposed Rule, 66.
[54] Proposed Rule, 66-67; current Part 340.6.

In contrast, APHIS sometimes describes the trigger criterion as whether or not the GE plant is itself a "plant pest."[55] Genetic engineering does not and arguably cannot transform any non-parasitic plant into any of the plant pest taxa enumerated in Part 340.2.[56] Thus, under this narrow definition, APHIS would have had absolutely no scientifically defensible authority to regulate any GE plant that it in fact has regulated during its 30-year history in this arena, even provisionally as a "presumptive plant pest."[57] Therefore, a GE organism's potential to pose a "plant pest *risk*" has been, is and must continue to be the relevant regulatory criterion. This term aligns with the definition of plant pest as "any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[58]

In order to clear up the long-standing confusion, APHIS should adopt the following definition of "plant pest risk" in the proposed rule:

Plant pest risk: A GE organism poses a plant pest risk when, relative to the unmodified organism from which it was derived, it has greater susceptibility to disease or non-vertebrate pests, adverse non-target effects on organisms beneficial to agriculture, weediness, capacity to impart weediness to sexually compatible relatives or transmit the introduced GE trait to organisms with which it does not interbreed, or indirect plant pest effects on other agricultural products; promotes changes in agricultural practices that exacerbate pest or disease problems; or there is reason to believe a GE organism might pose such plant pest risks.

This definition is needed because the plant pest criteria proposed in the Preferred Alternative are far too narrow to capture potential plant pest risks of GE organisms, and as such, are not supported by sound science. Under these criteria, APHIS would only regulate a GE organism for plant pest risk: 1) That has received DNA from a plant pest organism listed under Part 340.2; 2) Such DNA "is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to case plant disease symptoms;" and 3) The organism has not been previously evaluated for plant pest risk (Proposed Rule 340.0(b)(2)).

These plant pest criteria alone are far too narrow particularly in the case of GE plants and would be contrary to the statute's broad definition of types and kinds harms, as applied in the context of GE organisms. First, the criteria would be virtually meaningless for GE plants since it is difficult to imagine a scenario in which a developer would *intentionally* engineer a plant to be disease- or pest-ridden. It would make the authority a virtual nullity, contrary to sound science and the plain broad definitional language of the statute.

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[55] Proposed Rule, 11-12; PEIS, 2-12.
[56] Proposed Rule, 85.
[57] APHIS falsely claims that "current criteria reflects the concern in the 1980s that if an organism was modified using genetic material from a plant pest, or a plant pest was used as a vector or vector agent to modify an organism's genome, the resulting GE organism could also be a plant pest." (Proposed Rule, 38). On the contrary, scientific concerns re: GE ***plants*** encompassed the full range of plant pest ***risk*** concerns enumerated above (not whether a GE plant was parasitic), as codified in 340.6.
[58] Proposed Rule, 85.

Second, the criteria would entirely exclude cases in which genetic engineering *unintentionally* generates plant pest risks, again contrary to sound science and the statute's broad definition of what constitutes plant pest harms. For instance, the genetic engineering of Arctic apple to resist browning (the intended purpose) involved the silencing of a family of genes that generate enzymes – polyphenol oxidases – that are critical to defense against disease and insect pests in some plants. Thus, their silencing may well have the unintended effect of rendering Arctic apple trees more susceptible to disease or insect pests, creating plant pest risks.[59] This is true even though the engineering of Arctic apples did not involve introduction of plant pest DNA that can produce an infectious entity or encode a pathogenesis-related compound.

The proposed new rule must be structured so as to regulate and assess such potential plant pest risks, whether intentional or unintended, direct or indirect, from the GE crops that APHIS is charged with regulating. APHIS does not have the requisite experience to dismiss such risks, *a priori*, particularly with respect to advanced techniques, such as the RNA interference technique that was used in the development of the Arctic apple. One major purpose of the proposed rule is to respond to challenges presented by "advances in genetic engineering."[60] Failure to so make this change would be contrary to that need and purpose of the proposed new rules.

GE plants may also be specifically intended to alter agricultural practices in ways that increase pest or disease susceptibility. The proposed criteria must be broadened to assess and regulate potential plant pest risks generated by such changes in agricultural practice. For instance, GE herbicide-resistant crops are designed for direct application of an herbicide that would kill or severely damage, and thus cannot be applied to, its non-GE counterpart. The herbicide use is part and parcel of the GE crop system. Herbicide application to a GE crop can increase the crop's susceptibility to plant disease pathogens. For instance, glyphosate application to GE glyphosate-resistant crops results in exudation of glyphosate from the crop's roots, which in turn fosters colonization of the roots by *Fusarium* fungi as well as other changes in rhizosphere-associated microbial poulations.[61] Several studies have shown that glyphosate treatment increases the incidence and severity of sudden death syndrome, a disease caused by the plant pest organism *Fusarium virguliforme* (formerly *F. solani* f. sp. *glycines*), in glyphosate-resistant soybeans.[62] Glyphosate is also harmful to organisms beneficial to agriculture. For instance, glyphosate is toxic to *Bradyrhizobium japonicum*, an important nitrogen-fixing symbiont that colonizes soybean roots,

[59] CFS (2013). Comments to USDA/APHIS on plant pest risk assessment and environmental assessment for determination of nonregulated status of apples genetically engineered to resist browning. Docket No. APHIS-2012-0025, Center for Food Safety, Dec. 16, 2013.
[60] Proposed Rule, 1.
[61] Kremer RJ and Means NE (2009). Glyphosate and glyphosate-resistant crop interactions with rhizosphere microorganisms. European Journal of Agronomy 31(3): 153-161.
[62] Sanogo S, Yang XB, Scherm H (2000). Effects of herbicides on *Fusarium solani* f. sp. *glycines* and development of sudden death syndrome. Phytopathology 90(1): 57-66. Sanogo S, Yang XB, Lundeen P (2001). Field response of glyphosate-tolerant soybean to herbicides and sudden death syndrome. Plant Disease 85(7): 773-779. Navi SS, Jing L, Yang XB (2013). Effects of glyphosate application rates and frequency of soybean sudden death syndrome. Plant Pathology Presentations and Posters. 4. http://lib.dr.iastate.edu/plantpath_conf/4.

due to the sensitivity of its EPSPS enzyme to inhibition by glyphosate.[63] Suppression of this important symbiont is likely related to the finding that glyphosate application to glyphosate-resistant soybeans reduces foliar nitrogen content, seed nitrogen content, biomass, and yields, especially under conditions of water stress, early application of glyphosate, and high application rates.[64]

In sum, the impacts and risks of GE crops can and do fall within the PPA's broad plant pest harm authority, and APHIS should not try and nullify that authority in any new proposed rule, but rather apply it in the GE crop context, taking account of their differences from traditional plant pests.

[63] Zablotowicz, R.M. and K.N. Reddy (2007). "Nitrogenase activity, nitrogen content, and yield responses to glyphosate in glyphosate-resistant soybean," *Crop Protection* 26: 370-376.
[64] Zablotowicz et al (2007), op. cit.; King, C.A., L.C. Purcell and E.D. Vories (2001). "Plant growth and nitrogenase activity of glyphosate-tolerant soybean in response to foliar glyphosate applications," Agron. J. 93: 179-186.

COMMENTS ON DRAFT PEIS

The draft Programmatic Environmental Impact Statement (PEIS) is fundamentally flawed in numerous ways. Among other errors: The alternatives analysis fails to consider reasonable alternatives, and those it does consider are inadequately assessed. The agency's purpose and need for the proposal is flawed and overly-narrow. The agency fails to adequately analyze many direct, indirect, and cumulative impacts, and wholly fails to consider many others. Its treatment of direct, indirect, and cumulative impacts is contrary to the evidence and arbitrary and capricious. APHIS fails NEPA's mandates of high quality, accurate scientific analysis and relevant data, including scientific and baseline data, and does not present accurate and complete information to allow informed decisions. It refuses to disclose and discuss opposing scientific views at relevant points. It refuses to acknowledge and analyze scientific uncertainties where appropriate. It improperly relies on old data at places. It improperly relies on incorrect data and assumptions at places. It improperly relies on different forms of direct and indirect mitigation. At times APHIS relies on factors Congress did not intend it to consider. It fails to analyze the reasonably foreseeable results of its programmatic decision here, namely the impacts of individual GE crops going unregulated in the future and cannot lawful defer consideration those impacts to later, particularly when the agency is proposing to abdicate its regulatory duties in some instances.

Alternatives Analysis

CFS agrees that Alternative 1 -- No Action, meaning no revisions to the existing 7 CFR Part 340 regulations -- is not the Preferred Alternative; as explained above, new regulations are needed to fully and properly implement APHIS's PPA authority, as well as address the harms of GE crops. CFS opposes APHIS's Preferred Alternative of implementing the proposed rule for the reasons explained above. Among the alternatives provided, CFS supports Alternative 3 as the best given alternative considered in furthering APHIS's statutory mandates of protecting agriculture and the environment.

It is arbitrary and capricious agency decision making to conclude, as APHIS does in the PEIS (ES-8, ES-26), that the Preferred Alternative would somehow decrease potential adverse environmental impacts. That conclusion runs contrary to the evidence of past harm, that will be increased by APHIS's proposal to exempt many GE crops entirely from any oversight, rather than increase their oversight as is needed. Repeatedly and in numerous contexts, APHIS errs in equating the preferred alternatives' impacts with that of alternative 3, in particular with regards to the two alternatives' likely environmental impacts, on biodiversity, species, climate change, and public health. While alternative 3 is flawed in its failure to include measures to protect against environmental harms directly, Alternative 3 offers more environmental benefits indirectly than the preferred alternative by requiring restrictions on GE crop planting to prevent transgenic contamination, and including monitoring and commercial permits. It is also arbitrary and capricious for APHIS to conclude that the preferred alternative will increase transparency, when it

will potentially result in many more GE crops being unregulated and field experiments done privately, without oversight.

APHIS has failed to analyze other reasonable alternatives. Namely, APHIS has failed to include analysis of any alternatives that would address not just the economic harms of contamination, but also the environmental harms of GE crops directly. Alternative 3 protects farmers against transgenic contamination, but it does not include measures to address the harms of resistant weed proliferation associated with GE HR crops, or the harms to farmers and the environment caused by GE HR crop systems, such as pesticide drift and runoff. The agency should consider an alternative that restricts GE crops by permit in order to directly address these harms. Additional human health and environmental harms are discussed in the Appendices. APHIS fails to offer any alternative that protects against environmental harm from escapes of GE organisms into the wild, such as genetically engineered bentgrass. NEPA requires that APHIS examine policy alternatives that take into account environmental values. APHIS's failure to include and fully analyze alternatives to protect against the environmental harms of GE organisms violates NEPA's alternatives mandates, the heart of any EIS.

APHIS cannot have adequately considered alternatives if its analysis misrepresents the adverse impacts of its proposed alternative and fails to consider more environmentally beneficial alternatives, such as restricting GE crops using its PPA authority in order to prevent environmental harms, as well as socioeconomic harms. These include resistant weed harms and pesticide drift harms, in addition to preventing transgenic contamination through permitting and restrictions on use. APHIS did not rigorously and objectively explore all reasonable alternatives.

APHIS also failed to consider an alternative that included measures specific to other, newer GE organisms under its purview that are not traditional crops, such as GE grasses, GE trees, and GE insects. These types of GE organisms are more than reasonably foreseeable, they are currently being proposed for commercial approval or field trials (GE bentgrass, GE Eucalyptus, GE moths). These types of GE organisms are creating different types of risks than previous GE crops[65] that should necessitate new analyses and oversight mechanisms that APHIS has not considered.

Purpose and Need

APHIS violates NEPA's mandates regarding the purpose and need of this proposal. If the purpose of the proposed rule is, as APHIS claims, to answer the critiques of USDA's OIG and the 2008 Farm Bill, then the Preferred Alternative does not comply, since it will increase instances of contamination and exacerbate impacts on farmers by offering them less protection and less transparency, not more. The Preferred Alternative also does not fulfill the purpose of protecting agriculture and the environment. If purpose and need is to apply the PPA's noxious weed authority in a meaningful way to GE crops and align the GE organism regulations with the PPA's authority, then the Preferred Alternative does not fulfill that purpose. Nor does the proposal meet

[65] NASEM (2017), 105-106.

the purpose and need stated of updating in order to meet the advances in biotechnology since 1987 and the original rules, as it loosens oversight considerably, despite the foreseeable (and current) arrival of new and novel types of GE organisms that present different risks and impacts, such as GE grasses and trees. Nor does the proposal fulfill the stated purpose and need of making regulations commensurate with the risk assessment methodologies of the National Research Council in 2002.

In contrast to the Preferred Alternative, in all ways, Alternative 3 better fulfills the agency's purpose and need. It addresses the HR seed/herbicide coordination problem, regulates PMPI plants, and better protects farmers, agriculture, and the environment. NEPA also requires that APHIS examine policy alternatives that take into account environmental values, which it does not. To the extent the purpose and need is not to address the current and future adverse impacts of GE organisms, the purpose and need are unlawfully narrow and improper. Finally, APHIS improperly relies on the regulated entities' purpose and need.

Impacts' Analysis Errors

APHIS's draft PEIS makes many fundamental flaws and errors of analysis. These serious errors and omissions undermine its assessment in many important respects and belie its conclusions. These include direct, indirect, and cumulative impacts that are reasonably foreseeable. Many of these are discussed at greater length in the Appendices to these comments. In brief:

Pesticide use: APHIS fails to report available data on herbicide since 2010; relies heavily on fraudulent modeling studies that vastly underestimate the herbicide use increases triggered by GE HR crop systems, as demonstrated by EPA data; and underestimates the increase in toxicity of the sharply rising herbicide use triggered by GE HR crop systems, and associated impacts to human health and the environment. Finally, in assessing herbicide use with GE HR crops, APHIS considers only glyphosate associated with first-generation HR crops; and fails to analyze the herbicidal impacts of next-generation GE HR crops resistant to a host of other herbicides that are now being introduced, and which are expected to be very widely adopted and have enormous adverse impacts.[66] This renders its analysis contrary to the evidence and arbitrary and capricious.

Herbicide-resistant weeds: APHIS fails to provide any meaningful analysis of the massive and growing herbicide-resistant (HR) weed threats caused by past and present GE HR crop systems. APHIS arbitrarily excludes HR crop volunteers from the definition of "weed" to avoid assessing their adverse impacts. APHIS fails to assess the resistance-promoting features of GE HR crop systems, or to assess the enormous costs they impose on U.S. farmers, despite readily available analysis by USDA personnel. APHIS arbitrarily relies on pesticide-seed firms to stem the epidemic of HR weeds created by their HR crop systems, in contradiction to abundant evidence demonstrating that the marketing and pricing policies of these firms has had and will continue to have the opposite effect of exacerbating HR weeds and their adverse impacts on farmers and U.S.

[66] *See also* Appendix A.

agriculture as a whole. Although APHIS's noxious weed authority gives it ample powers to address these harms, it has entirely failed to apply it to address them. In short, APHIS has entirely failed to use sound science and readily available data in its assessment, or to apply its authority to address the foreseeable impacts of GE HR crop systems.[67] Furthermore, it is arbitrary and capricious for APHIS to claim that Alternative 3, which it projects would lead to reduced use of GE HR crop systems, would lead to increased use of less environmentally benign herbicides (PEIS, 4-118 to 4-120), when in fact abundant evidence shows that precisely the opposite is true.[68] It is likewise arbitrary and capricious to conclude that the increased availability of GE HR crops under the Preferred Alternative would have no impact on HR weed development and associated weed control practices (PEIS, 4-166 to 4-177), since abundant evidence demonstrates that GE HR crop systems exacerbate HR weeds and thereby increase harmful herbicide use and soil-eroding tillage practices.

Transgenic contamination: APHIS dramatically underestimates the frequency and economic impacts of GE contamination. APHIS improperly limits its assessment of contamination harms to the organic sector (PEIS, ES-18 to ES-20), when GE-sensitive export and domestic markets are also severely impacted by it. APHIS fails to assess the full costs of GE contamination even to the organic sector, which include numerous costly measures to mitigate GE contamination, and lost market opportunities. APHIS also fails to assess the past and current, or project the future, impacts and costs of GE organisms that escape into wild or semi-natural habitats via seed dispersal, cross-pollination with sexually compatible relatives, or by other means.[69]

In sum, the baseline analysis for all of these impacts is fundamentally flawed and inaccurate, and contrary to the evidence.

Types of GE Crops: The PEIS fails to provide an empirical assessment of the future types of GE crops to be introduced under the various alternatives. Instead, APHIS repeatedly assumes that future GE crops would incorporate traits for disease and stress resistance as well as product quality (e.g. PEIS, ES-18, 4-2, 4-184, for three of many instances). GE crops with these trait types have been promised and field-tested for three decades, yet extremely few have been commercially introduced. APHIS provides no analysis explaining this fact, the reasons for it, or why it anticipates that the future course of GE crop development should be so radically different than past history. For instance, APHIS discusses GE drought-tolerant crops as likely developments (PEIS, 4-2, 4-5), yet studies have found that conventional breeding is far more successful than genetic engineering in the development of this crop type.[70] GE disease-resistant crops occupy such miniscule acreage that they are not even covered by USDA statistics on commercial GE crop cultivation.

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[67] *See also* Appendix B.
[68] *See* Appendix A re: sharply increased use of toxic herbicides like 2,4-D and dicamba with GE HR crop systems.
[69] *See also* Permits and Notifications section *supra*.
[70] Gilbert N (2014). Cross-bred crops get fit faster. Nature 513: 292.

In contrast, there is no dispute that GE HR crops have been by far the dominant type of GE crop grown in the U.S. and the world, comprising roughly 85% of U.S. GE crop acreage; and that next-generation GE HR crops dominate the current and future GE crop landscape. These conclusions are based on numerous reliable sources of information, including USDA data on percent adoption of major GE crop types (HR crops are over twice as prevalent as insect-resistant varieties, the only other significantly adopted GE trait in commercial GE crop production); GE crop field trials, the most numerous of which involve HR crops (PEIS, Figure 3-16); USDA-deregulated GE crops (40%, the largest category, are HR (PEIS, 2-10), with all six major pesticide-seed firms having obtained nonregulated status for several to many different HR crop types); and marketing projections and development pipelines of pesticide-seed firms (which show various new HR crops projected to be introduced on the majority of U.S. corn, soybean and cotton acreage in the near to medium-term future[71]). APHIS also ignores the obvious motivation for the industry's predilection for development of crops with HR versus other traits – the potential for vastly increased sales of herbicides the company sells together with the HR seed.[72]

APHIS's failure to discuss these clear and obvious trends, which are widely known and accepted in the agricultural community, is arbitrary and capricious. This assessment failure undermines the analysis in the PEIS numerous ways – most basically, it undermines APHIS's repeated baseless assumptions that GE crop development will respond to pressing agricultural needs, such as agricultural adaptation to climate change, more frequent and severe droughts, world hunger, malnutrition and numerous other worthy objectives. In contrast, a proper and objective analysis showing the predominance of GE HR crops in the present and future GE crop landscape would have laid the foundation for an entirely different PEIS in which empirical assessment of their many impacts (mostly adverse) predominated.[73]

Increase in GE organisms overall: APHIS fails to analyze the impacts of an overall increase in unregulated GE organisms and their impacts due to the proposed rule. Given the point is to lessen "regulatory burden" and speed approvals, the decision to front-end load APHIS's decision on regulatory status, and allow most environmental releases without regulation, is illogical and contrary to the evidence. The related analysis that (EIS 4-16) the new determination of regulatory status will not increase the commercial acreage of GE crops, when many now would not have to go through deregulation at all, is belied by the evidence as well as contrary to common sense. It also conflicts with APHIS' economic analysis that there will be a lesser "regulatory burden" and thus more GE crops would be developed, more quickly. Similarly, the analysis that the rules revisions will not increase harms from field trials, and that there will be no change in experimental acreage, is illogical and contrary to the evidence that field trials will now go on without oversight (EIS 4-14, 4-27).

[71] For instance, see Appendix A for projection of 2,4-D use with Dow's Enlist (2,4-D-resistant) corn and soybeans, which includes projections of Enlist crop adoption.
[72] Kilman S (2010). Superweeed outbreak triggers arms race. Wall Street Journal, 6/4/10.
[73] *See* Appendices A, B and C for some of the missing analysis.

Soil erosion and conservation tillage: As explained more fully in Appendix C, first-generation GE HR crop systems have generated extremely rapid and widespread emergence of HR weeds, which has in turn led to increases in the use of tillage as a means of control, and corresponding reductions in soil-saving conservation tillage, over the past decade. This analysis is supported by USDA soil erosion data, which show unequivocably that substantial reductions in soil erosion rates in the pre-GE HR crop era, fostered by federal farm policy, came to a virtual halt in the GE HR crop era, especially in the Corn Belt, where cultivation of these varieties is most intensive. APHIS's numerous claims concerning the purported benefits of GE HR crops in reducing soil erosion via promotion of conservation tillage are thus arbitrary and capricious, and in direct contradiction to unimpeachable, mostly USDA, data that demonstrate the opposite.

Water resources: It is arbitrary and capricious and contrary to sound science for APHIS to conclude that the Preferred Alternative would improve water quality by reducing runoff of soil sediments, pesticides and fertilizers into streams and other surface waters (PEIS, 4-37). The facts show precisely the reverse outcome. Because the Preferred Alternative increases introduction of GE HR crops, water quality will decline due to increased use and runoff of herbicides, and to increased runoff of soil sediments attributable to increased use of tillage to control HR weeds generated by GE HR crop systems. The increase in GE crops, and associated increase in pesticide use, will further contaminate our waterways. APHIS fails to meaningfully consider these impacts, and its summary conclusions are contrary to the evidence. Conversely, Alternative 3 would increase water quality rather than reduce it as APHIS claims (PEIS, 4-43) by inhibiting the introduction of GE HR crops.[74]

Air resources: APHIS notes correctly that conservation tillage can reduce fossil fuel emissions by reducing tractor use for tillage (PEIS, 3-80). However, APHIS's conclusion that the regulatory provisions of Alternative 3 would increase fossil fuel emissions by suppressing adoption of GE HR crops (versus the Preferred Alternative) (PEIS, 4-53) is not supported, and in fact is contradicted, by the available evidence. As explained more fully in Appendix C, GE HR crops have led to reductions in conservation tillage over the past decade, by promoting greater use of tillage to control HR weeds generated by these crop systems. Greater use of tillage equates to increased tractor use and thus increases in fossil fuel emissions. Surprisingly, APHIS completely fails to assess the air quality degradation that will be caused by the projected rapid adoption of the two major next-generation GE HR crop systems: Enlist crops resistant to 2,4-D, and Roundup Xtend crops resistant to dicamba. Use of both herbicides is projected to expand dramatically (see Appendix A for 2,4-D use projection), and both are known to be highly volatile. This means there will be large increases in volatilization of these herbicides, especially since they will be sprayed weeks to a month or more later in the season, when climatic conditions favor vapor drift. As discussed in Appendix B, dicamba volatilization has resulted in enormous crop injury in the very

[74] *See* Appendix C for additional analysis.

first year of (limited) planting of dicamba-resistant crops. Dicamba vapor drift degrades air quality, with associated adverse impacts to humans and non-target species. Alternative 3, by suppressing introduction of these hazardous crop systems, would thus indirectly improve air quality relative to the Preferred Alternative, an impact APHIS failed to assess (PEIS, 4-50 to 4-53).

Soil biota: As discussed above under the Plant Pest Harms section, first-generation GE HR crops resistant to glyphosate have led to substantial adverse changes in the rhizosphere (root-associated) microbial community, supported by reports of increased fungal disease in glyphosate-resistant soybeans. In addition, APHIS suggests that Alternative 3 could potentially lead to adverse impacts on soil biota by increasing the use of tillage consequent to suppressing the adoption of GE crops (relative to the Preferred Alternative) (PEIS, 4-63). These arguments, once again, appear to be based on the false linkage of GE HR crops and conservation tillage, which as discussed above is faulty. APHIS fails to assess the likely adverse impacts on soil biota from increased herbicide use with the greater use of GE HR crops under the Preferred Alternative (relative to lesser impacts with Alternative 3).

Invertebrate organisms: APHIS maintains that the regulatory provisions of Alternative 3 might lead some growers to abandon a GE glyphosate-resistant crop in favor of a conventionally bred cultivar, with a consequent increase in the use of other herbicides "which may not be as environmentally benign," potentially leading to agronomic practices that are "less beneficial to invertebrate communities" (PEIS, 4-75). APHIS cites no data to support these insipid speculations. More importantly, APHIS fails to analyze or consider the impacts of next generation GE crops, stacked and combined with multiple pesticides, on insects and nontarget invertebrates. APHIS entirely ignores the three- to seven-fold rise in use of 2,4-D that is projected to occur over the next three to five years with adoption of 2,4-D-resistant corn and soybeans on tens to over 100 million acres of U.S. cropland (see Appendix A). According to an analysis based on pesticide toxicity data submitted to the EPA, 2,4-D is "very highly toxic" to aquatic invertebrates; and based on spring wheat usage rates, poses a threat to endangered aquatic invertebrates. The authors also note that 2,4-D poses a 2,634-fold greater risk to these organisms than Roundup.[75] This is a striking example of bias, emblematic of how APHIS ignores next-generation GE HR crop systems and their impacts throughout the PEIS. In addition, APHIS violates NEPA with improper reliance on FDA and EPA alone (PEIS 4-37), instead of doing its job.[76]

Vertebrates: – APHIS admits risks to wildlife from unregulated PMPI plants under the new proposed rule (PEIS, 4-84), but recognizes they would be regulated under Alternative 3 (PEIS 4-87). The agency's conclusion (EIS 4-88) that the Preferred Alternative and Alternative 3 are the

[75] Peterson RKD and Hulting AG (2004). A comparative ecological risk assessment for herbicides used on spring wheat: the effect of glyphosate when used within a glyphosate-tolerant wheat system. Weed Science 52(5): 834-844, p. 838 and Table 7.

[76] Elsewhere APHIS also improperly relies on FDA and/or EPA to comply with APHIS's NEPA duties (*see, e.g.*, ES-29).

same for wildlife is arbitrary and capricious because the Preferred Alternative will cause many more GE organisms and their pesticides to go completely unregulated and unrestricted. In addition, some Roundup formulations are highly toxic to amphibians, particularly frog species, and the massive use of these glyphosate formulations is thought to be one factor driving the worldwide decline in amphibian species (see Appendix A). To the extent that the Preferred Alternative favors greater cultivation of glyphosate-resistant crops relative to Alternative 3, it would likely result in greater harms to amphibians.

Insect and disease resistance: APHIS states that "a primary goal in the development of GE organisms is protection against disease" (PEIS, 4-100). This is contrary to fact. The vast majority of GE crops are engineered for herbicide- and/or insect-resistance (IR), with HR traited-crops exceeding IR-trait crops by roughly two to one. USDA tracks commercial adoption of GE crops, but limits coverage to crops containing these two traits because others (e.g. GE virus-resistant papaya and squash) are too insignificant to track. Thus, APHIS's undocumented claim that the Preferred Alternative would likely spur cultivation of a greater number of "disease-resistant resistant varieties, and stacked-trait varieties resistant to both a particular insect pest, and disease," is entirely speculative and contradicted by the available evidence. *See also* "Types of GE Crops" above. In addition, APHIS downplays or ignores evidence that some GE crops are likely more susceptible to plant pest and disease infestations (*see* Plant Pest Harms above).

Biodiversity: For APHIS to conclude repeatedly (EIS, 3-96 4-146 & 148) that the Preferred Alternative, including no field trial regulation and front-end commercial approval for many GE organisms, will have the same impacts on biodiversity as No Action – no revisions to the existing regulations – is arbitrary and capricious and contrary to the intent of the rule and sound science. If APHIS goes ahead with the proposed rule, there will likely be many more completely unregulated experimental GE crops and commercial GE crops, and consequentially much more harm to biodiversity. Moreover APHIS cites a review authored by a pesticide industry-funded scientist (Carpenter 2011) to support the claim that GE crops reduce impacts on biodiversity by facilitating adoption of conservation tillage and use of more environmentally benign pesticides (PEIS, 3-96). However as discussed above and in Appendix C, the epidemic of glyphosate-resistant weeds generated by GE HR crops has led to increased tillage over the past decade, and thus these crop systems cannot be associated with conservation tillage benefits. In addition, APHIS fails to project the considerable impacts on biodiversity of next-generation GE HR crops that were first introduced in 2016, with massive adoption projected over the next few years, accompanied by large increases in the use of environmentally toxic herbicides like 2,4-D and dicamba. Thus, Alternative 3, which APHIS concludes would decrease adoption of GE HR crops, would promote biodiversity relative to the Preferred Alternative. APHIS's conclusions to the contrary (PEIS, 4-151) are arbitrary and capricious.

Public health: APHIS fails to analyze impacts of the regulatory gap created by its abdication of regulatory authority over PMPI plants, and associated risks to the food supply, in the Preferred Alternative (PEIS, 4-160). In contrast, Alternative 3 fulfills the statutory public health mandate

much better by providing for regulation of these plants. It is improper reliance for APHIS to defer entirely to FDA in its public (and animal) health assessment. The PPA's mandates and definitions of harm expressly include protecting the public health. Furthermore, FDA's process for GE food safety is entirely voluntary, and the agency undertakes no independent assessment of their safety. APHIS cannot rely on FDA to fulfil its own NEPA duties. The public health risks of the proposed rule are significant and require analysis. This includes the risks to the food supply from PMPI crops, which APHIS at the same time is proposing to discontinue regulating. Given what the proposed rule will do, the conclusion that the preferred alternative would increase protection of public health is arbitrary and capricious and country to the evidence.

Socioeconomic impacts: It is arbitrary and capricious for APHIS to claim that transgenic contamination and its socioeconomic impacts will decrease under the preferred alternative (*see, e.g.* 4-185). APHIS does this by excluding other forms of contamination except field trial contamination from what it considers to be damaging, and, since it proposes to no longer regulate field trials, contamination from them will go down. But whether international markets will reject contaminated food supplies does not rest on whether the U.S. treats the GE contamination as from a field trial or a U.S.-approved crop, but instead with the regulatory status of the GE organism in the foreign or GE-sensitive domestic or foreign market. APHIS's treatment is misleading in finding that the Preferred Alternative will lower instances of transgenic contamination. Instead, contamination overall is likely to increase, with increased acreage and with companies in charge of their own gene flow mitigation. Less oversight will mean increased contamination and harm, not less.[77]

It is also arbitrary and capricious for APHIS to conclude that GE crops exempted from APHIS regulation, either through definitional loopholes or after a perfunctory "upfront" assessment, will not contaminate the food supply (based on the false assumption that GE crop developers would employ rigorous gene containment standards), or trigger costly market rejection episodes. GE contamination will increase consistent with increased overall GE acreage, and will increase since APHIS will not monitor or apply any controls on it. It is also arbitrary and capricious for APHIS to fail to recognize and analyze that preferred will increase international contamination episodes and their costs.

In its cost-benefit analyzes, APHIS fails to account for or analyze the substantially increased harm to the U.S. agricultural economy from increased transgenic contamination episodes and lost foreign markets. The failure to consider this important part of the problem means APHIS's baseline economic calculations of alleged benefits to U.S. agriculture from less APHIS regulation are all incorrect and fail to account for this considerable cost and downside to the agricultural industry and farmers. APHIS also failed to consider or analyze harm from its proposal to traditional, non-GE farmers and farms. APHIS fails to separate these farmers' interests from those of the GE industry, or distinguish them in the agency's scope of review and baseline.

[77] *See also* Permits and Notifications section *supra*.

Protected Species: It is arbitrary and capricious, and a violation of NEPA/APA and the Endangered Species Act, for APHIS to conclude that the wholesale change of its regulations would have no effect on protected species or their habitat. It is arbitrary and capricious and contrary to the evidence and sound science, that APHIS' proposed change to its regulations will not cause any material change from the current regulations as to potential impacts on protected species and their habitat. APHIS has failed to analyze these impacts and ignored an important part of the problem.

Improper baseline: APHIS fails to include in its scope of analysis, not just U.S. agricultural farmland but also all surrounding ecosystems and natural habitats, as well as reasonably foreseeable expansions of farmland acreage, due to other agronomic changes, climate change, and potentially due to APHIS' proposed rule change. APHIS fails to consider in its scope also forests and grasslands that can be affected by current and reasonably foreseeable future GE grasses and forest trees.

Mitigation

Repeatedly and throughout, APHIS improperly relies on the agricultural biotechnology industry's "best interests" and their "stewardship" efforts to self-regulate GE experimental and commercial organisms without meaningfully assessing how they would do that. That reliance is contrary to APHIS's PPA and NEPA duties as well as common sense, and creates an improper baseline for APHIS's analysis of the proposed new rule changes and their impacts on farmers and the environment. Like all other elements of an EIS, mitigation must be discussed in sufficient detail to ensure a fair evaluation of the environmental consequences. Without such a discussion neither the agency nor the interested parties can properly evaluate the severity of the adverse effects. It is not enough to have a conclusory or perfunctory description. Nor can the agency pretend it is not relying on mitigation, or failure to discuss mitigation that it is actually relying on. The effectiveness of any mitigation must be carefully analyzed. Nor can APHIS rely on mitigation where it has insufficient authority, or in some cases, no authority, over the agricultural biotechnology industry.

Cumulative Impacts

As discussed above, the fundamental conclusion that the Preferred Alternative would somehow increase environmental protections is A&C (EIS 5-24) and contrary to all history and evidence.

APHIS's discussion of the potential cumulative impacts of its proposed Part 340 rule revision is wholly inadequate. Rather than analyze the cumulative impacts of the proposed rules on various resources (water, air, soils, agricultural economy, wildlife, humans) when combined with other past, present, and reasonably foreseeable impacts to those resources, APHIS merely reiterated its conclusions as to direct/indirect impacts. Not only are many of those conclusions

speculative, unsupported, or defying logic, merely restating these potential impacts does not equal a cumulative effects analysis.

A cumulative impact is the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time. A proper cumulative impacts discussion includes both an appropriate scope of impacts to the affected resource(s) and an adequately detailed/quantified discussion of those impacts. A discussion of only the direct impacts of a proposed action on the affected resource, without taking into account the combined effects that can be expected as a result of other present impacts, and other foreseeable projects, in addition to the proposed action itself, does not satisfy the requirements of NEPA. Moreover, agencies cannot provide general conclusions without the supporting objective data upon which such conclusions are based.

APHIS identified various resources that might be impacted by the proposed action, however these categories are identical to the categories of direct/indirect impacts evaluated in Chapter 4 of the DPEIS: acreage used in agriculture; soil resources; water resources and quality; air quality; soil biota; invertebrates; wildlife; pests and disease management; weeds; gene flow; biodiversity; human health; animal food and welfare; climate change; domestic markets; and international trade (PEIS at 5-1—5-24). APHIS proceeds to list conclusions as to whether each alternative (No Action, Preferred, or Alternative 3) would increase or decrease effects to, or harm or benefit, that resource. Many of these categories are impacts, not resources (i.e. pests, gene flow, weeds). More importantly, APHIS fails to even list in most cases, or provide any detail for, the past, present, and reasonably foreseeable impacts from other projects/actions on these resources, including by other agencies and private parties.

For example, soils are a vital resource but APHIS fails to provide any detail or quantifiable data on the past/present/foreseeable impacts to soils. (PEIS at 5-3—5-4). But such detail/data is required to take into account the combined effects of all those impacts with the impact proposed (the Preferred Alternative). And as with all resources examined, APHIS assumes only positive impacts from GE crops (and therefore increased benefit from the Preferred Alternative). APHIS assumes that GE crops increase the use of conservation tillage practices, despite contrary evidence it neglected to assess (see Appendix C), but fails to assess herbicide-resistant GE crops' contribution to herbicide-resistant weeds (which in turn reduce the use of conservation tillage). APHIS notes that weed resistance is a cumulative impact (PEIS at 5-12), yet completely fails to examine the accumulation of multiple resistances over time. Glyphosate-resistance with today's GE HR crops usually arises in weeds already immune to other modes of action used more heavily in the past; acquisition of additional resistance to herbicides used with new GE HR crops will make these weeds progressively more expensive and toxic to control. That weed resistance is "not exclusively related to GE HR crops" is a *non sequitur* that misses entirely the serious cumulative impacts of multiple HR weeds. In addition, most new GE HR crops are designed for combined

use of two herbicides that will exacerbate resistance (*see* Appendix B), not alternating use of each in "rotation" "to allay development of resistant weeds." APHIS's unsupported claim that new GE HR crops will "delay the selection of resistant weeds" is directly contradicted by its correct admission that they will boost herbicide use and "increase the selection pressure for greater herbicide resistance..." (PEIS, 5-12). Nowhere does APHIS analyze the cumulative impacts of progressively increasing resistance and rising toxic herbicide use that are the reasonably foreseeable future impacts of GE HR crop systems. APHIS cannot brush off the potential for cumulative impacts to resources like soil by ignoring impacts that it admits in later sections.

Moreover, later evaluation of impacts pursuant to NEPA on a case-by-case basis does not relieve APHIS's duty to examine the cumulative impacts of its proposed regulation revisions before they are implemented. Comparing the potential for cumulative impacts of each alternative with each other is not the same as considering these incremental impacts in the context of other past/present/foreseeable impacts to a particular resource.

APHIS must consider all impacts to each resource, and then assess the incremental impact of the proposed action along with those past/present/foreseeable impacts. For example, climate change is addressed in terms of the action's effects on climate, and the changing climate's effects on agriculture (PEIS at 5-17—5-20). But nowhere is climate change integrated into the analysis for other affected resources, like water availability, biodiversity, etc. Even in the section assessing the impacts of climate change on agriculture, which explains the challenges to be expected in the future for this resource, APHIS then just assumes that GE crops will be 1) required, and 2) able to address the problems, despite the lack of such traits on the market and no evidence that they will be successfully developed in the future, as opposed to more of the same pesticide-resistant varieties.

APHIS also failed to provide any quantifiable or detailed information about the ongoing impacts of all its past GE organism approvals under the existing rules. Given the decades-long history of approving every petition for a new GE organism received, APHIS should have access to some objective data about the cumulative impacts of these actions. APHIS's analysis of agricultural/noxious weed issues is an example: APHIS states that the potential for releases to contribute cumulatively to the development of herbicide resistant weeds is "negligible," (PEIS at 5-11), but APHIS fails to provide information on the ongoing GE creeping bentgrass escapes in Oregon and Idaho, which cannot be characterized as "negligible." While the acreage of test plots is a small fraction of commercial agriculture, once man-made noxious weeds like GE creeping bentgrass escape, many more acres can be affected, and herbicide-resistant traits spread to wild relatives, as is currently happening in eastern Oregon. Between weedy plants (like creeping bentgrass) with intentionally engineered herbicide resistance and weeds with evolved herbicide resistance through selection pressure from the overuse of a single herbicide on GE crops, the potential for APHIS's proposed action to cumulatively impact weed control (in combination with other impacts like climate change) is anything but "negligible."

The cumulative effect analysis suffers from many unsupported conclusions and assumptions, many of which defy logic. APHIS focuses only on major commodity crops, and fails to address new and novel GE plants, like grasses and trees. These novel GE plants are not just foreseeable, they are already being approved. For example, GE versions of newly- or un-domesticated grasses and trees grown for biofuels or used in ecological restoration will have new or greater impacts on resources such as forests and natural areas,[78] and this is completely unaddressed (particularly regarding cumulative impacts on resources like wildlife and biodiversity). Further, APHIS speculates that new GE traits will be successfully developed and widely adopted, like drought resistance and better nutrient utilization, with positive benefits to resources like water and the agricultural economy, but provides no support for this contention (PEIS at 5-6, 5-22). APHIS bases many of its conclusions in this section on its assumption that GE crops reduce pesticide use, but not only is this inaccurate based on objective data, APHIS itself contradicts its own false premise (DPEIS at 5-12). The cumulative impacts analysis also suffers from the false assumption that transgenic contamination only causes harm when it originates from "regulated" articles, as opposed to impacts from GE traits showing up in any sensitive markets (organic, non-GMO, export), whether originating from regulated or commercialized GE sources.

Finally, APHIS summarizes the cumulative impacts by stating that because it developed the concepts of this regulation revision with other agencies, it does not anticipate that the revisions will have any adverse cumulative impact. One does not lead to the other. The fact that a proposed action was developed in consultation with other agencies does not negate the possibility of cumulative impacts from that action on affected resources. APHIS's cumulative impacts analysis is merely a rehashing of its direct/indirect impacts section, it is based on unsupported, contradictory, and illogical conclusions, and it fails to actually identify what the cumulative impacts of its proposed revisions will be, when added to the past, present, and reasonably foreseeable impacts to various affected resources.

CONCLUSION

For the foregoing reasons, APHIS' draft EIS is inadequate, as it fails to comply with the mandates of NEPA and the APA. APHIS fails to rely on sound science, has conclusions that run counter to the evidence, and fails to consider important aspects of the issues at hand. APHIS must go back and fully analyze the impacts of current and reasonably foreseeable direct, indirect, and cumulative impacts of its proposed new rules in a supplemental EIS. The purpose and need of the EIS is improper and overly narrow, and the agency has failed to analyze reasonable alternatives.

Similarly, the proposed rule revision must be rejected. It would take U.S. oversight of GE organisms from bad to worse, and in the process have USDA abdicate its duties of protecting farmers, the public, and the environment. New rules are needed to implement the PPA authority in responsible way for GE organisms, but the proposal is contrary to the PPA's statutory mandates,

[78] NASEM (2017), 105-106.

the APA, and basic principles of good governance. The only block to responsible regulation of agricultural biotechnology is political, not legal or regulatory. USDA must rescind the proposed rule and issue a new proposed rule supported by sound science that fulfills the agency's regulatory mandates and addresses the adverse impacts of GE organisms.

Submitted by:
Center for Food Safety

Appendix A: Herbicide Use

Herbicide-resistant varieties dominate the production of five of six crops for which they are available, representing 89% of U.S. acres planted to corn and cotton, 94% of soybeans, 95% of canola, 99% of sugarbeets and 13% of alfalfa (USDA ERS 2017, 2016). At present, the great majority of these HR crops are engineered for resistance to glyphosate, with a much smaller presence of glufosinate-resistant crops. Newer crops resistant to other herbicides, such as 2,4-D and dicamba, are only beginning to be introduced, and are discussed further below.

The three major HR crops (soybeans, cotton and corn) are responsible for the use of 527 million more pounds of herbicide in U.S. agriculture over the sixteen years from 1996 to 2011 than would have been used in their absence (Benbrook 2012). The two major factors responsible for this large increase in herbicide intensity are the displacement of lower rate herbicides by higher-rate glyphosate; and the increasing number and rate of herbicide applications in response to the epidemic emergence of glyphosate-resistant weeds (Benbrook 2012, NRC 2010). Benbrook's assessment is based on gold standard pesticide use data from USDA's National Agricultural Statistics Service (NASS). Those same data show that herbicide use per acre has also increased dramatically over the HR crop era: 55% for cotton, 54% for soybeans, and 10% for corn (Figure 1). These HR crop-driven increases in herbicide use are also reflected in EPA figures, which show that overall farm use of herbicides rose by an astonishing 34% over just the seven years from 2005 to 2012, from 420 to 564 million lbs. (EPA 2017, Table 3-2).

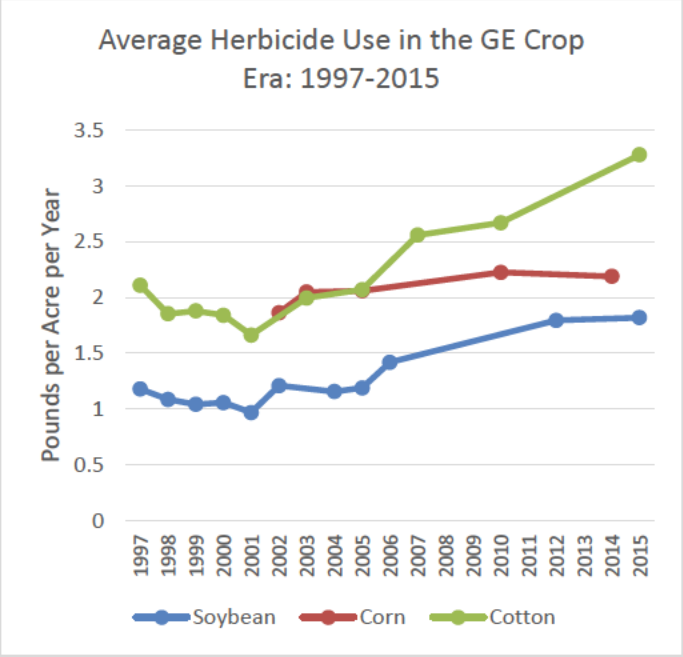

Figure 1: Average herbicide use in U.S. corn, soybeans and cotton, based on USDA National Agricultural Statistics Service (NASS) Agricultural Chemical Usage data (USDA NASS ACU). In order to better isolate the effects of herbicide-resistance traits from other factors, we have charted rates beginning in the year that adoption of the pertinent herbicide-resistant crop first exceeded 10% of total crop acres planted: soybeans (17% HR adoption in 1997); cotton (10.5% in 1997); corn (11% in 2002).

APHIS's treatment of herbicide use is deeply flawed in several respects. First, APHIS relies in part on false and misleading modelling studies conducted by pesticide industry contractors (Brookes and Barfoot 2010, 2013b) and others (Klumper and Qaim 2014). These studies are fraudulent because they employ false assumptions and frames of reference to vastly underestimate pesticide use with GE crops, particularly in the U.S. context (Heineman 2014), and their results are entirely inconsistent with the reliable U.S. government data reported above and shown in Figure 1. USDA should omit all references to these studies. Second, APHIS misrepresents the herbicide use impacts of HR crops by choosing false frames of reference and leaving out readily available data after 2010 (Figure 3-18, PEIS at 3-55). For instance, APHIS states that annual herbicide application rates to corn have declined since "the advent of GE crops." Yet the rate reductions from 1995 to 2001 (Figure 3-18, PEIS at 3-55) have essentially nothing to do with with GE HR corn, which comprised no more than 9% of U.S. corn acres over this period[79] and thus could not have had a meaningful impact on herbicide use. GE HR corn only became prevalent in subsequent years, when herbicide use rose modestly (Figure 1). In addition, APHIS's assertion that herbicide rates on cotton have remained "largely unchanged" is based on erroneous data for 2010 (as portrayed in Figure 3-18), and failure to present 2015 data, both of which show a trend of consistent and sharply rising herbicide use rates on cotton since the year 2001 (Figure 1).

APHIS objects to weight-based assessments of pesticide usage by "Benbrook and others" as "misleading" on the mistaken grounds that such assessments include the weight of formulation additives such as "carriers/solvent such as water or oils" (PEIS at 3-56). APHIS is in error. Benbrook, for instance, assesses trends in herbicide use based on the weight of the active ingredient(s), as reported by USDA NASS, which excludes the weight of these formulation additives (Benbrook 2012).

APHIS misrepresents the effect of HR crops not only on the amount, but also the toxicity, of herbicides applied to them in several ways. First, APHIS notes that pesticides are classified into one of four categories based on "toxicity" (PEIS at 3-52), but fails to appreciate that the metric used for this crude classification scheme is highly misleading. The metric, known as the lethal dose 50 (LD_{50}), represents the average amount of a pesticide that it takes to kill 50% of a group of test animals (e.g. rats) when administered in a single dose. Higher LD_{50} values indicate more is needed to kill, and hence "less toxic." However, LD_{50} values tell us next to nothing about the actual risks posed to humans or wildlife under realistic conditions, which involve exposure to

[79] During this period (1996-2001), most GE corn was insect-resistant, which has no influence on herbicide use. The pre-HR corn reduction in herbicide use is attributed to several factors, including EPA's belated phase-out of high-rate cyanazine because of its carcinogenicity (EPA 1/6/00) and increasing use of lower-rate herbicides such as nicosulfuron (Coupe and Capel 2015).

much lower levels over longer periods of time (Zbinden and Flury-Roversi 1981). For instance, a fact sheet on glyphosate by the National Pesticide Information Center states that: "... the LD_{50}/LC_{50} does not reflect any effects from long-term exposure (i.e. cancer, birth defects or reproductive toxicity) that may occur at levels below those that cause death" (NPIC 2010). The assignment of pesticides into one of four, LD_{50}-based toxicity categories is used only for pesticide labeling purposes, and plays essentially no role in EPA's actual risk assessments, even for assessment of acute toxicity.

APHIS claims that the toxicity of herbicides used in U.S. agriculture has declined with GE HR crops because they have led to "less toxic" glyphosate displacing some "more toxic herbicides," citing agricultural economists with no evident qualifications in toxicology (PEIS, 3-54). Glyphosate is only "less toxic" as measured by the misleading LD_{50} metric discussed above. The world's leading cancer authority, the World Health Organization's International Agency for Research on Cancer (IARC), has found glyphosate to be "probably carcinogenic to humans" (Guyton et al. 2015), a determination endorsed by 94 leading medical scientists (Portier et al. 2016). Environmentally, some glyphosate formulations are extremely toxic to amphibians, and their use is thought to be one factor driving the worldwide decline in amphibians (Relyea 2005). Glyphosate is also a major contributor to the dramatic decline in the monarch butterfly population over the past two decades (Pleasants and Oberhauser 2012). These are hardly the effects one would expect from a "less toxic" herbicide. APHIS's treatment of glyphosate is flawed and inadequate.

APHIS' doubt about the connection between glyphosate use and monarch decline (PEIS, 4-70) is contrary to the evidence. The consensus view of the world's leading monarch scientists is that massive glyphosate use with HR crops has nearly eradicated common milkweed, the monarch's primary host plant, from cropland in the monarch's major summer breeding range, and thereby been a leading contributor to monarch decline over the past two decades (Hartzler 2010, Pleasants and Oberhauser 2012, Pleasants 2015, Flockhart et al. 2015, Pleasants et al. 2016, Stenoien et al. 2016). As a result, there is an 11% to 57% risk that monarchs will be driven to quasi-extinction in the next 20 years (Semmens et al. 2016). The U.S. Fish and Wildlife Service is presently considering a petition from public interest groups and renowned monarch scientist Lincoln Brower to designate the monarch butterfly as a threatened species under the Endangered Species Act (CBD et al. 2014). FWS has made a preliminary finding that such listing may be warranted. Scientists have estimated the extent of milkweed loss and projected the number of milkweeds that must be restored to stabilize the monarch butterfly population (Thogmartin et al. 2017, Pleasants 2017). Multiple efforts are underway to plant milkweed to restore monarch habitat with the goal of saving the monarch butterfly from potential extinction (USDA NRCS 2015, USFWS 2017). APHIS failed to consider these impacts.

The growing evidence of glyphosate's toxicity to human beings and the environment contradicts APHIS's propositions about the herbicide. It also exemplifies the unreliability of schemes that purport to transform the amount of pesticide used into a "toxicity-adjusted" number. One such scheme – the Environmental Impact Quotient, which is used in several of the assessments cited by

APHIS – has been heavily criticized for not incorporating a meaningful exposure metric, and as inaccurate particularly for herbicide toxicity (Dushoff et al. 1994, Peterson and Schleier 2014, Kniss and Coburn 2015). While it is true that one must consider a number of factors beyond weight in assessing the harms of pesticide use, there is not and never will be a simple number that accurately reflects "toxicity." Toxicity varies depending on the organism (e.g. humans, amphibians, non-target plants); the level, route, timing and length of exposure; the disease outcome(s) under consideration; and many other factors.

APHIS also fails to analyze and consider the herbicide use impacts of "next-generation" HR crops, which are now being introduced to combat the resistant weed epidemic generated by massive glyphosate use with their first-generation predecessors. These new HR crops will drive dramatic increases in use of additional herbicides, like 2,4-D and dicamba, with no countervailing reduction in glyphosate use. For instance, Dow AgroSciences projects a three- to seven-fold increase in agricultural use of 2,4-D with introduction of "Enlist" corn and soybeans, which are resistant to both glyphosate and 2,4-D (Figure 2). Similarly, Monsanto predicts that widespread adoption of its GE soybeans and cotton engineered for dual resistance to dicamba and glyphosate will make dicamba one of the world's leading herbicides, along with glyphosate (Monsanto 2016), while in 2012 dicamba ranked just 18th among agricultural pesticides in terms of annual use in the U.S. (EPA 2017, Table 3.4). Like glyphosate, exposure to both herbicides has been linked to increased incidence of non-Hodgkin lymphoma in farmers (Loomis et al. 2015, Schinasi and Leon 2014, McDuffie et al. 2001), while both have greater toxicity than glyphosate to a number of different plant and animal groups (Peterson and Hulting 2004).

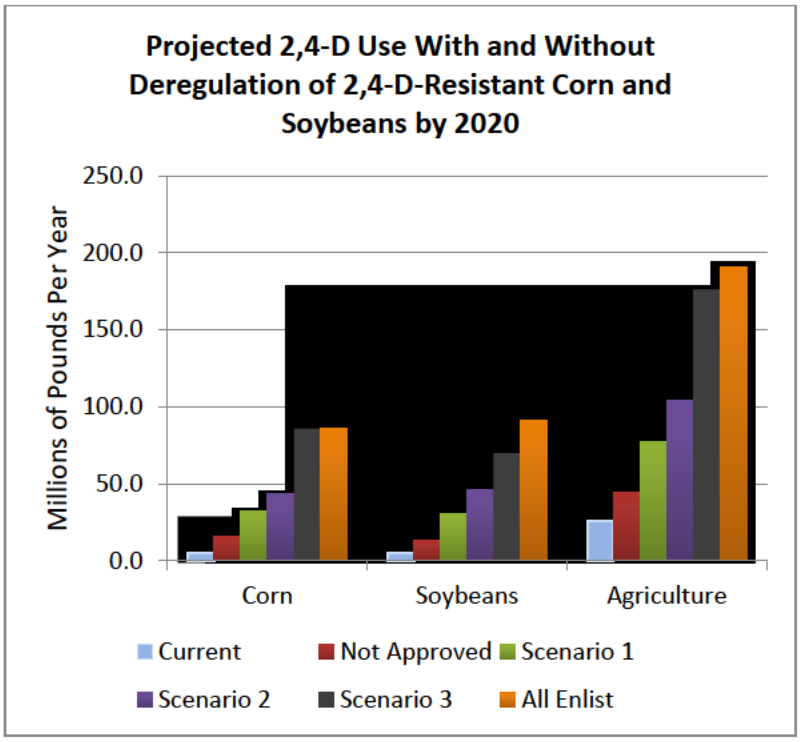

Figure 2: Dow's estimates of 2,4-D use by 2020 with varying adoption rates of 2,4-D-resistant (Enlist) corn and soybeans, compared to 2011 (current) usage rates. Scenario 1 represents low-end, 2 mid-range, and 3 high-end adoption rates, while "All Enlist" represents use assuming all glyphosate-resistant corn and soy is replaced with Enlist varieties. Based on projections made by Dow and adopted by USDA (USDA APHIS 2014).

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USDA APHIS (2014). Dow AgroSciences Petitions (09-233- 01p, 09-349-01p, and 11-234-01p) for Determinations of Nonregulated Status for 2,4-D-Resistant Corn and Soybean Varieties:

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Appendix B: Noxious Weed Authority

APHIS must utilize its robust noxious weed authority to address the known harms and foreseeable future impacts of GE crops. However, the implementation proposed in the Preferred Alternative falls far short of what is needed. APHIS should apply its noxious weed authority to assess and mitigate harms in at least three major areas: 1) Herbicide-resistant crops; 2) Crops engineered for production of pharmaceuticals and industrial compounds; and 3) Unwanted presence of GE crops in the non-GE and organic food chains (i.e. GE contamination). APHIS should adopt the use of genetic engineering as the trigger for regulation, as we recommend *supra*. Alternatively and in addition, the noxious weed authority can and should also be used to regulate all GE crops that are not covered by the plant pest provisions of the proposed rule.

APHIS has proposed to implement its noxious weed authority by conducting weed risk assessments (WRAs) of some novel GE crops[80] – those that meet its overly-restrictive definitions of "genetically engineered organism" and "regulated organism." Those highly restrictive definitions must be revised to properly cover the scope of the topic. *See supra*. The weed-related risks posed by the GE crop would be assessed relative to those of its conventional counterpart, regarded as the "baseline." However, the draft WRA guidelines are fundamentally misguided. They are geared to determine whether or not GE crops are traditional noxious weeds, which would be entirely duplicative of regulations under Part 360 and would fail to account for the differences of GE organisms. Although GE crops can have many of the same grave, adverse impacts of traditional noxious weeds, the factors responsible for these impacts are often quite different, and require a different assessment approach. It is improper for APHIS to focus solely on traditional noxious weed risks when applying its broad statutory authority in a totally different context.

The draft WRA guidelines focus heavily on assessment of "weedy" attributes of the GE plant that enable persistence and spread in the wild – properties such as competitive growth ability, reproductive potential, and tolerance to biotic and abiotic stresses. While these factors are relevant to some, mostly experimental, GE plants (e.g. switchgrass engineered for biofuels use), they are on the whole more relevant to traditional (i.e. Part 360) noxious weeds. The vast majority of GE plants are domesticated crops like corn and soybeans that require a fuller assessment.

To make weed risk assessments relevant to GE crops, APHIS must fully assess the changes in agricultural practice that they trigger. This approach is consistent with the Coordinated Framework, which stipulates that it is not only the "characteristics of the organism," but also "the environment and the application that determine the risk (or lack thereof) of the introduction" of a GE organism (PEIS, 1-9 to 1-10). Thus, in order to properly apply in this context, WRAs must fully assess the agricultural and environmental contexts of "the application," including most basically the agricultural practices involved, such as herbicide use employed in growing the GE crop.

[80] Draft Weed Risk Assessment Work Instructions, Version 4.1.2. USDA-APHIS-BRS, Nov. 1, 2016.

Herbicide-resistant crops

Two decades of experience demonstrate that herbicide-resistant (HR) crops pose several risks cognizable under APHIS's noxious weed authority. HR crops themselves may be serious weeds, in the form of volunteers. They also trigger substantial changes in herbicide use patterns that lead to more rapid evolution of agriculturally damaging herbicide-resistant weeds, as well as greater injury to nearby crops and non-target organisms through increased incidence of herbicide drift. HR traits may also interact with other GE traits to cause harms not caused by GE crops with either trait individually. APHIS's draft WRA guidelines improperly ignore these risks, which are also not addressed in the proposed rule or the PEIS. APHIS ignores these harms in part by neglecting HR crop-induced changes in agricultural practices, and also by establishing a false dichotomy between "agricultural weeds and noxious weeds" (PEIS, 3-90). In fact, many traditional noxious weeds are noxious by virtue of the substantial harms they cause to agriculture (e.g. reduced crop yield); and as discussed below, HR crop-associated weeds often cause equally substantial harms to the interests of agriculture.

HR crop volunteers

Crops like corn become weeds when unharvested seed sprouts and grows in the following season's crop grown on that same field. Undesired crop plants of this sort are known as "volunteers." According to agronomists: "Crop plants that volunteer in planted crops are considered weeds" that "present the farmer with many of the same problems associated with traditional weeds," including reduced yields, disease and pest transmission, interference with harvest operations, and reduced quality.[81] Agronomists have found that volunteers of GE HR crops are a much more serious weed threat than those of their non-HR counterpart, because they cannot be controlled by the herbicide(s) to which the HR crop is resistant. For instance, herbicide resistant volunteer cotton, corn or soybean plants "compete for essential nutrients, water, and light with the crop" and therefore "meet the definition of a weed (an unwanted plant);"[82] "Increased adoption of GR [glyphosate-resistant] corn has resulted in volunteer corn becoming a problem weed in GR soybean grown in rotation."[83] Similarly, a dramatic increase in weedy volunteer corn is closely correlated with increasing cultivation of GE HR corn varieties.[84] The weed harms caused by GE HR crop volunteers generally increase with the number of herbicides to which the GE HR crop is resistant. For instance, the cultivation of corn resistant to both glyphosate and glufosinate gives rise

[81] Ogg AG and Parker R (2000). Control of volunteer crop plants. Washington State University Cooperative Extension, EB1523.
[82] Morgan et al (2011). Managing volunteer cotton in grain crops. SCS-2011-04, AgriLife Extension, Texas A&M System.
[83] Chahal, P.S. and Jhala, A.J. (2015) Herbicide programs for control of glyphosate resistant volunteer corn in glufosinate-resistant soybean. Weed Technology 29:431-443.

[84] Davis, V. M., Marquardt, P. T., and Johnson, W. G. 2008. Volunteer corn in northern Indiana soybean correlates to glyphosate-resistant corn adoption. Online. Crop Management doi:10.1094/CM-2008-0721-01-BR.

to volunteer corn that reduces yield and is a "very aggressive competitor" of follow-on corn.[85] In this study, none of the herbicides tested to control the volunteer GE HR corn provided adequate control; some caused damage resulting in 5% to 11% lower yield; and soil-eroding tillage was judged to be the only effective control measure. Volunteers of cotton resistant to one or more herbicides are already problematic, and will become still more damaging with the introduction of new HR cotton varieties resistant to 2,4-D, dicamba, and other herbicides.[86] Volunteer GE HR plants can also cause plant pest harms.[87]

Despite this consensus of agricultural experts, APHIS refuses to even acknowledge that GE crop volunteers are weeds at all: "For the purposes of this Weed Risk Assessment, the term "weed" does not include volunteers," and explicitly excludes from the WRA the often substantial reductions in agricultural yield and quality that volunteers, such as HR crop volunteers, can cause.[88] In its draft WRA of EPSPS-mediated glyphosate-resistant (GR) corn, APHIS similarly states: "Volunteer corn is not considered in this WRA."[89] The discussion of volunteer plants in the PEIS (3-47 to 3-51) fails to address any of the issues discussed above in any meaningful way.

APHIS seeks to avoid a finding that GE crops pose noxious weed risks by arbitrarily excluding them, in their capacity as "volunteer crop plants," from the very definition of weed. APHIS's refusal is contrary to sound science and arbitrary and capricious. APHIS does this in direct contraction to the consensus view of the agricultural scientific community that crop volunteers are in fact weeds, and that the presence of GE traits (particularly herbicide resistance) can dramatically increase the weed harms caused by such volunteers. By excluding GE HR crop volunteers from the definition of weed, APHIS avoids assessment of a key attribute they share with traditional noxious weeds: "plants that ... are extremely difficult to manage or control ..."[90]

The WRA guidelines must be altered to assess and project the extent of HR crop volunteers, the management responses taken to control them, including estimates of additional herbicide use or tillage, costs of control; and also estimates of reduced yield or agricultural quality when HR crop volunteers are not (adequately) controlled.

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[85] Soltani, N., et al. (2014) Volunteer Glyphosate and Glufosinate Resistant Corn Competitiveness and Control in Glyphosate and Glufosinate Resistant Corn. Agricultural Sciences, 5, 402-409. http://dx.doi.org/10.4236/as.2014.55042. Contrary to APHIS, volunteer plants are weeds not only in follow-on crops of a different species; they are also weeds when they appear in crops of the same species (PEIS, 3-47).
[86] Morgan et al. (2011), op. cit.
[87] Morgan et al. (2011), op. cit.; Krupke et a. (2009). Volunteer corn presents new challenges for insect resistance management Agronomy Journal 101(3): 797-799.
[88] Draft Weed Risk Assessment Work Instructions, Version 4.1.2. USDA-APHIS-BRS, Nov. 1, 2016, pp. 36-37, 51.
[89] BRS Weed Risk Assessment of Roundup Ready corn, pp. 19, 44, 45. https://www.aphis.usda.gov/biotechnology/downloads/340/example_wra/draft_2015-163-001_4.0.pdf.
[90] Proposed Rule for 7 CFR Part 340. Federal Register, Vol. 73, No. 197, 10/9/08, p. 60013.

Evolved herbicide resistance

APHIS also entirely ignores the noxious weed risks posed by substantial changes in agricultural practices triggered by HR crops. In the PEIS, APHIS fails to assess either the resistance-promoting features of GE HR crop herbicide use patterns or the gravity of the weed resistance harms they cause (PEIS, 3-90 to 3-92; 4-25 to 4-26). The WRA guidelines include no assessment of evolved herbicide resistant weeds.

HR crops promote excessive reliance on the herbicide(s) to which they are resistant, which leads to rapid evolution of resistant weeds.[91] This is exemplified by the dramatic emergence of glyphosate-resistant (GR) weeds on over 60 million acres of U.S. cropland, in step with the enormous increase in area planted to GR crops and the associated sharp increase in glyphosate use.[92] By 2012, roughly half of U.S. farmers surveyed had one or more GR weeds in their fields.

Resistant weeds associated with GE HR crops are particularly costly. Agronomists report that GR weeds have led to six-fold increases in the cost of using herbicides in cotton and soybeans.[93] The additional herbicides employed to control resistant weeds are a big factor in the astronomical 34% increase in herbicide use in the U.S. over just the seven years from 2005 to 2012.[94] Costs increase still more when yield reductions are factored in. USDA economists found that the total returns of corn farmers with glyphosate-resistant (GR) weeds were $67.29/acre less than those without GR weeds in 2010. Similarly for soybean growers, declining glyphosate efficacy (a sign of weed resistance) was associated with a $22.53/acre reduction in total returns in 2012.[95] If one assumes conservatively that half of corn and soybean cropland is infested with GR weeds (which was already true in 2012, see Stratus 2013 reference), the losses attributable to GR weeds in corn and soybeans, in terms of decreased yield and increased fuel and herbicide expenditures, is an enormous $3.8 billion annually.[96] Costs increase still more if one factors in the technology fee for

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[91] Powles SB (2010). Gene amplification delivers glyphosate-resistant weed evolution. PNAS 107(3): 955-56. Neve P (2008). Simulation modelling to understand the evolution and management of glyphosate resistance in weeds. Pest Management Science 64: 392-401. Service (2013). What happens when weed killers stop killing? Science 341: 1329.

[92] Stratus (2013). Glyphosate resistant weeds – intensifying. Stratus Research, January 25, 2013. Benbrook, C (2012). Impacts of genetically engineered crops on pesticide use in the U.S. – the first sixteen years. Environmental Sciences Europe 24:24. http://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24.

[93] Service (2013), op. cit.

[94] EPA (2017). Pesticides Industry Sales and Usage: 2008 – 2012 Market Estimates. Environmental Protection Agency, 2017, Table 3-2.

[95] Livington M et al. (2015). The economics of glyphosate resistance management in corn and soybean production. USDA Economic Research Service, Report No. 184, April 2015.

[96] Based on 88.2 million planted acres of corn (2010) and 77.2 million planted acres of soybeans (2012). Half of each is multiplied by the respective decline in total returns/acre.

the herbicide-resistance trait, which can double the price of the seed vs. a conventional variety.[97] APHIS fails to address these important issues, and even misreports basic facts. For instance, APHIS maintains that "agricultural expenditures on herbicides are currently $400 billion annually" (PEIS, 3-90), when in fact they are just $5.1 billion (U.S.) and $24.7 billion (world).[98]

Because new HR crops are virtually certain to have similar resistance-promoting effects, the resistant weed problem will only become worse, with GR weeds evolving additional resistance to other herbicides associated with them.[99] In contrast, APHIS erroneously assumes that "stacked-trait" GE crops with resistance to multiple herbicides will solve the weed resistance problem rather than exacerbate it (PEIS, 4-111).[100] However, the major new HR crops have dual resistance to glyphosate and 2,4-D (Dow) or glyphosate and dicamba (Monsanto). GR weeds sprayed with the respective dual herbicide formulations will experience only one effective mode of action (2,4-D or dicamba), and hence readily evolve additional resistance to these herbicides, making them still more difficult and expensive to control.[101]

APHIS also incorrectly assumes that herbicide manufacturers and farmers will stem the emergence of weed resistance because it is in their "best interest" to do so (PEIS, 4-111). Herbicide producers will "ensure [that] weed resistance management practices are properly implemented, as the market share of their herbicide will be significantly reduced where weeds resistant to their product develops." The facts show otherwise. GR weeds are extremely prevalent, despite two decades of HR weed resistance recommendations. Glyphosate use is at an all-time high, and is projected to remain high, despite epidemic emergence of GR weeds. Finally, the emergence of weed resistance is not viewed as a problem by pesticide companies, but rather as a market opening for sale of expensive new HR seeds and increased sales of the additional herbicides used with them.[102]

The marketing practices and pricing policies of pesticide companies work against farmer adoption of resistance management recommendations. For instance, the seed-pesticide industry offers very few varieties of non-HR seed in major crops like corn, soybeans and cotton, the cultivation of which is most effective means of reducing selection pressure for resistance.[103] The high cost of HR seed constitutes a strong financial incentive for excessive reliance on the HR crop-associated

[97] Orloff SB et al (2009). Avoiding weed shifts and weed resistance in Roundup Ready alfalfa systems. University of CA Publication 8362, February 2009.
[98] EPA (2017), op. cit., Table 2.1.
[99] Mortensen DA et al (2012). Navigating a critical juncture in sustainable weed management. Bioscience 62(1): 75-84. Keim (2014). The next generation of GM crops has arrived – and so has the controversy. Wired 6/24/14. Keim (2015). Monsanto's newest GM crops may create more problems than they solve. Wired 2/2/15.
[100] APHIS mistakenly equates "stacked-trait" GE crops with those resistant to multiple herbicides (PEIS, 4-111). In fact, the great majority of stacked GE crops combine glyphosate resistance with insect resistance, not resistance to two or more herbicides. "These figures include adoption of "stacked" varieties of cotton and corn, which have both HT and Bt traits." See https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx.
[101] Mortensen et al (2012), op. cit.
[102] Kilman S (2010). Superweed outbreak triggers arms race. Wall Street Journal, June 4, 2010.
[103] Heap IM (1997). The occurrence of herbicide-resistant weeds worldwide. Pesticide Science 51: 235-243.

herbicide(s), which promotes resistance.[104] Companies market HR crops as HR crop "systems," encouraging farmers to rely excessively on the HR crop-associated herbicide(s).[105]

Rather than assess the enormous and growing costs of HR weeds associated with GE HR crops, APHIS attempts to divert attention from the issue with irrelevant discussion of HR weeds that have arisen in other contexts, and on a global basis rather than limited to the U.S., the subject of this PEIS (PEIS, 3-57 to 3-60, 4-111). However, weeds resistant to triazines, ALS inhibitors and other herbicide modes of action (PEIS, Figures 3-19 & 3-20) are not associated with GE HR crops, nor have they had adverse impacts on anywhere near the scale of GE HR weeds, particularly in the U.S. For instance, weeds resistant to atrazine, the major triazine herbicide, were estimated to infest 3 million hectares of cropland globally in 1997,[106] while GR weeds infest over eight times more cropland in the U.S. alone, and triazine-resistant weed species have increased very little since this estimate was made in the late 1990s (PEIS, Figure 3-19).

Weeds resistant to these other herbicides are relevant to the PEIS in one respect, but APHIS completely fails to address it. When resistance emerges in response to herbicide(s) used with GE HR crops, it often does so in weed populations with pre-existing resistance to these other modes of action (e.g. ALS inhibitors, triazines). Thus, many "glyphosate-resistant weeds" are actually resistant to other herbicides as well, reducing control options and making them still more environmentally damaging and costly to control.[107] New HR crop systems now being introduced will compound the adverse impacts of resistance by selecting for additional resistance to 2,4-D and dicamba (for example) in weed populations already resistant to glyphosate and other herbicides.[108] APHIS completely fails to analyze this foreseeable part of the problem.

The WRAs should be revised to incorporate projections of acreage of specific HR crops, frequency and amounts of herbicides to be applied, the extent of HR weed emergence, and the costs imposed by these HR weeds. APHIS should take special account of multiple HR weeds. APHIS must not assume ideal world "best management practices" will be applied. They most often are not, as discussed above. APHIS must reject or restrict approvals of GE HR crops as necessary based on properly conducted WRAs.

Plant and crop injury from herbicide drift

HR crops lead to greatly increased injury to neighboring crops by shifting herbicide use by weeks to over a month later in the growing season, at a time when crops have leafed out and thus are

[104] Orloff SB et al (2009), op. cit.
[105] Dow (2017). Enlist Weed Control System. Downloaded 6/15/17.
[106] Heap (1997), op. cit.
[107] Service (2013), op. cit. ISHRW (2017). Weeds resistant to EPSP synthase inhibitors (G/9). International Survey of Herbicide-Resistant Weeds, downloaded 6/15/17. Notes: Glyphosate is the only "EPSP synthase inhibitor," thus this is a list of glyphosate-resistant weeds. Entries highlighted in red are resistant to glyphosate and one or more additional groups of herbicide.
[108] Mortensen et al. (2012), op. cit.

more susceptible to injury.[109] This explains why glyphosate, which is not a drift-prone herbicide, has been a leading cause of crop injury in the GE crop era.[110] A second reason is that HR crop applications occur when temperatures are higher, increasing vapor drift injury from more volatile herbicides like 2,4-D and dicamba. In 2016, hundreds of thousands of acres of crops in ten states were reportedly injured by application of dicamba herbicide to Monsanto's dicamba-resistant (Roundup Ready Xtend) soybeans and cotton.[111] Dicamba drift also threatens the survival of Missouri's largest peach grower.[112] Farmers have launched two lawsuits against Monsanto to recoup their losses from this devastating crop injury, with damages estimated in the "many hundreds of millions" of dollars.[113] Texas winegrowers already experience injury to their grapes from 2,4-D and dicamba drift. They anticipate that significant planting of 2,4-D and dicamba-resistant cotton in their state will lead to much greater use of these herbicides, and hence greatly increased drift damage to their grapes that will likely put them out of business.[114]

APHIS completely fails to address crop injury from HR crop herbicide use practices, either in the PEIS or the WRA guidelines. APHIS only discusses a problem it refers to as "asynchronous timing:"

> "APHIS recognizes that the asynchronous timing of the deregulation of herbicide-resistant plants and the associated herbicide registration may lead to situations where a developer could sell the GE HR plant/seed without waiting for the associated herbicide registration. In such a situation, farmers may be tempted to use an herbicide that is not registered for use on the GE HR crop, which would comprise an illegal use of an herbicide." (PEIS, ES-33 to ES-34).

APHIS fails to mention, much less discuss, the underlying problem indirectly referred to here – devastating crop injury from herbicide drift. The assumption appears to be that drift-related crop injury only occurs when an HR crop is deregulated by USDA before the specific herbicide formulation intended for it is approved by EPA. This is certainly not the case. Glyphosate, 2,4-D and dicamba have been among the most frequently implicated herbicides in crop injury complaints for many years. While some seek to blame the massive damage from dicamba drift discussed above on older versions of dicamba not registered for dicamba-resistant crops, weed scientists express skepticism. Univesity of Missouri's Kevin Bradley does not believe that EPA approval of newer dicamba formulations for use on dicamba-resistant crops will solve the crop injury

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[109] Mortensen et al. (2012), op. cit.
[110] AAPCO (1999 & 2005). Pesticide drift enforcement surveys: 1999 & 2005. Association of American Pesticide Control Officials.
[111] Chow (2016). 10 states report crop damage from illegal dicamba use on Monsanto's GMO seeds. EcoWatch, 9/2/16.
[112] Gray B (2014). Illegal herbicide use may threaten survival of Missouri's largest peach farm. St. Louis Post-Dispatch, 8/14/16.
[113] Unglesbee (2017). Second dicamba lawsuit: class action lawsuit filed against Monsanto for 2016 dicamba damage. The Progressive Farmer, 2/16/17.
[114] Mejia Lutz (2017). Texas winegrowers fear new herbicides will wipe out industry. The Texas Tribune, January 2, 2017.

problem,[115] perhaps because Monsanto has not permitted university weed scientists to test the new formulations for their drift potential.[116] Recent reports of dicamba drift damage reportedly occurred with spraying of Engenia, BASF's dicamba formulation that is supposedly less drift-prone, and is registered for use on dicamba-resistant crops.[117]

The 2016 and 2017 dicamba episodes are just the latest in a long history of HR crop-related crop injury that EPA regulation has failed to mitigate. Because HR crops drive herbicide use patterns that lead to more frequent and severe harms, APHIS must apply its noxious weed authority to assess and mitigate these harms in the context of GE HR crops. The issue goes well beyond ensuring "synchronous timing" of USDA and EPA approvals of the HR crop and associated herbicide formulation(s). In some cases, the required solution may be to deny approval of the HR crop in whole or in part.

Crops engineered for production of pharmaceuticals and industrial compounds

Some GE plants are engineered as "biofactories" for production of plant-made pharmaceutical or industrial compounds (PMPI plants).[118] The PMPI is generally extracted from harvested plant material, though in some cases it may remain embedded (e.g. Enogen corn, discussed below). In most cases, PMPI plants are not intended for food use, because they contain bioactive compounds that are potentially hazardous to human and animal health. PMPI plants are particularly risky when they are food crops, because in this case contamination of the food supply with these compounds becomes possible through cross-pollination. Emergence of volunteer PMPI plants in food crops grown on the same field in subsequent years could also lead to PMPI contamination, whether or not the PMPI plant itself is a food crop. There have been several high-profile episodes in which pharmaceutical-producing corn illegally contaminated soybeans and corn.[119] APHIS's deficient regulation of PMPI plants figured prominently in two audits of the agency by USDA's Office of the Inspector General in 2005 and 2015.

Under current regulations, APHIS regulates most PMPI plants because plant pests were used in their development. However under the Proposed Alternative, APHIS would discontinue its regulation of most PMPI plants, since they would not meet the overly narrow criteria APHIS proposes for what constitutes plant pest and noxious weed risks. FDA does not regulate PMPI plants, and would only assess the plant-made pharmaceuticals derived from them if the PMPI is submitted to FDA for approval as a drug. EPA would only become involved in regulation if the PMPI was determined to fall under the Toxic Substances Control Act, which to our knowledge has

[115] Laws (2016). Farmers need to approach 2017 crop spraying season very carefully. Delta Farm Press, 9/6/16.
[116] Steever (2016). Weed scientist: dicamba needs more research. Brownfield Ag News, Sept. 1, 2016. Unglesbee (2017), op. cit.
[117] Steed (2017). Crops newly hurt by dicamba. Northwest Arkansas Democrat Gazette, 6/9/17.
[118] 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.
[119] GAO (2008). Genetically Engineered Crops: Agencies are proposing changes to improve oversight, but could take additional steps to enhance coordination and monitoring. US Government Accountability Office, November 2008, Appendix VII.

never occurred. Because the cultivation of PMPI plants is not regulated by FDA or EPA, the result would be "a gap in federal oversight" (PEIS, E-31). APHIS recognizes that federal oversight of PMPI plant field trials is necessary to prevent unlawful entry of PMPIs into the food supply (PEIS, E-31), and that its regulatory role is critical: "One of the reasons APHIS' oversight of such crops has been an important part of the Coordinated Framework for GE plants is that companies are not necessarily required to notify FDA or EPA when the company plants a GE P/I-producing plant" (PEIS, E-31). APHIS proposes several possible regulatory alternatives involving other federal agencies or a new statute, however none of them are feasible or desirable, nor are they necessary.

In fact, APHIS itself can regulate PMPI plants because they contain "plant products" that meet the PPA's definition of noxious weed as potentially hazardous products. As in other areas discussed, APHIS's broad noxious weed authority easily covers these GE crops and their harms. In fact, USDA proposed to regulate PMPI plants on these grounds in the 2007 PEIS, and in the revised Part 340 rules it proposed in 2008.

One example of a GE industrial crop is Enogen corn, which is meant exclusively for production of ethanol for biofuels use. Enogen produces high levels of a bacteria-derived alpha-amylase enzyme that initiates the process of converting corn starch to ethanol. Even low-level contamination of food-grade corn with Enogen degrades the agricultural quality of the corn by converting starches to sugars, potentially rendering it unfit for food use. APHIS deregulated Enogen corn over the strong objections of major corn commodity and public interest groups on the strength of assurances from Syngenta, its developer, that it would be managed in a "closed loop" production process that would prevent contamination of food-grade corn.[120] Despite these assurances, and as APHIS was warned would happen, Enogen has widely contaminated white corn in Nebraska, resulting in substantial losses to white corn growers. Corn flour contaminated with Enogen was detected in California, and the amylase contaminant rendered it unfit for food uses and reportedy made some people sick.[121]

APHIS conducted a draft WRA for Enogen corn that is illogical, speculative and entirely unacceptable.[122] The passage dealing with the potential for Enogen to contaminate food-grade corn follows:

> "As with any other specialty corn variety, the potential co-mingling of Maize Event 3272 grain with other specialty corn grains may preclude use of that grain source (though this grain source

[120] CRA (2011). Letter from the Corn Refiners Association to USDA's Deputy Undersecretary for Marketing and Regulatory Programs, January 31, 2011. NGFA et al. (2009). Letter from the National Grain and Feed Association, North American Export Grain Association, North American Miller's Association and Pet Food Institute to APHIS, Docket No. APHIS-2007-0016, July 6, 2009. CFS (2009). Comments from Center for Food Safety to APHIS, Docket No. APHIS-2007-0016, January 20, 2009.

[121] Roseboro K (2017). GMO-ethanol corn contamination raises concerns about another "StarLink" disaster. The Organic & Non-GMO Report, Feburary 22, 2017.

[122] BRS Weed Risk Assessment of Enogen (alpha-amylase) corn, maize event 3272. https://www.aphis.usda.gov/biotechnology/downloads/340/example_wra/draft_2016-015-001_4.0.pdf.

> may be used in other corn products, e.g., animal feed). However, any potential co-mingling of Maize Event 3272 is most likely to occur during transport and not as a result of Maize Event 3272 growing in the same field with other specialty corn varieties. Thus, any potential negative impact resulting from co-mingling of Maize Event 3272 with other specialty corn varieties is not likely to result from any inherent weediness, but from a breakdown in the production process."

APHIS states that Enogen corn is like "any other specialty corn variety," yet this is obviously untrue, since even extremely low-level presence of Enogen in food-grade corn degrades the quality of that corn substantially, and may pose food safety risks, unlike other specialty corn varieties. APHIS appears to assume it has no jurisdiction over Enogen because it lacks "inherent weediness," yet its noxious weed authority clearly encompasses the agricultural quality harms discussed above. APHIS implies that co-mingling of Enogen with food grade corn is beyond its jurisdiction if it occurs during transport rather than in the field, which is likewise an incorrect, excessively narrow interpretation of its expansive noxious weed authority. Regardless, APHIS's account of how Enogen contamination is "most likely" to occur (i.e. during transport) is pure speculation. In fact, Enogen-contaminated white corn was grown adjacent to Enogen fields, making cross-pollination the most likely mode of contamination.[123]

APHIS must revise its WRAs to thoroughly assess GE PMPI plants and plant products. The default position should be to prohibit outdoor cultivation of all GE plants that produce PMPIs if the host plant has food or feed uses. When the PMPI host plant is not a food or feed plant, APHIS must thoroughly assess the potential for the PMPI plant to contaminate the food/feed supply, and prohibit or restrict cultivation as needed to prevent it.

[123] Roseboro (2017), op. cit.

Appendix C: Tillage, Soil Erosion and Environmental Impacts

Soil erosion is among the greatest threat to the long-term productivity of U.S. agriculture.[124] The traditional practice of tilling the soil to eliminate weeds is a major cause of soil erosion in simplified, herbicide-dependent, industrial farming systems. From the 1980s to mid-1990s, there was a concerted effort in U.S. agriculture to reduce the intensity of tillage operations in order to better conserve this vital resource. These efforts included promotion of "conservation tillage" – a set of less intensive cultivation practices, including "no-till" – that leave substantial amounts of crop residue on the soil, thereby inhibiting soil erosion.

APHIS misleadingly attempts to forge a link between GE herbicide-resistant crops, conservation tillage, and reduced soil erosion based on the proposition that "effective weed control using herbicides greatly facilitates conservation and no-till farming, and this was simplified by the introduction of GE HR cropping systems" (PEIS, 3-51, 3-67, 4-24). APHIS avoids and/or misrepresents the facts that disprove this supposed linkage.

First, a National Academy of Sciences committee recently found that "the greatest expansion of no-till and conservation tillage and the concomitant reductions in soil erosion actually predate the release of the first HR varieties of maize and soybeans in 1996."[125] This assessment is fully supported by USDA data. Cropland soil erosion rates declined by an impressive 40% in the pre-GE HR crop era, from 1982 to 1997. This declining soil loss is attributable primarily to strong federal farm policy that incentivized farmers to adopt soil-conserving practices, and to retire erosion-prone farmland and plant it to soil-conserving grasses instead.[126] In contrast, national soil erosion rates declined very little over the period when GE HR crops were massively adopted, from 1997 to 2012. In the Corn Belt region, which has the greatest intensity of HR corn and soybeans, erosion rates actually increased a bit over this period (see figure below). Thus, contrary to APHIS, GE HR crops are clearly not associated with reduced soil erosion.

APHIS also misrepresents the facts on use of conservation tillage, falsely claiming that "the majority of U.S. farmers are moving away from conventional to conservation tillage practices" (PEIS, 3-67), and that "trends in adoption of conservation tillage practices ... have accelerated after introduction of GE crops" (PEIS, 3-51). First, as noted by NRC (2016) in the passage quoted above, the greatest expansion of no-till and conservation tillage occurred before GE HR crops were introduced, not afterwards as APHIS claims. Second, stagnating soil erosion rates during the GE HR crop era simply cannot be reconciled with "accelerated" adoption of soil-saving practices on the 150+ million acres of HR crops grown in the U.S. Third, there is abundant evidence that GE HR crop systems lead to increased use of tillage – to control the HR weeds they generate.

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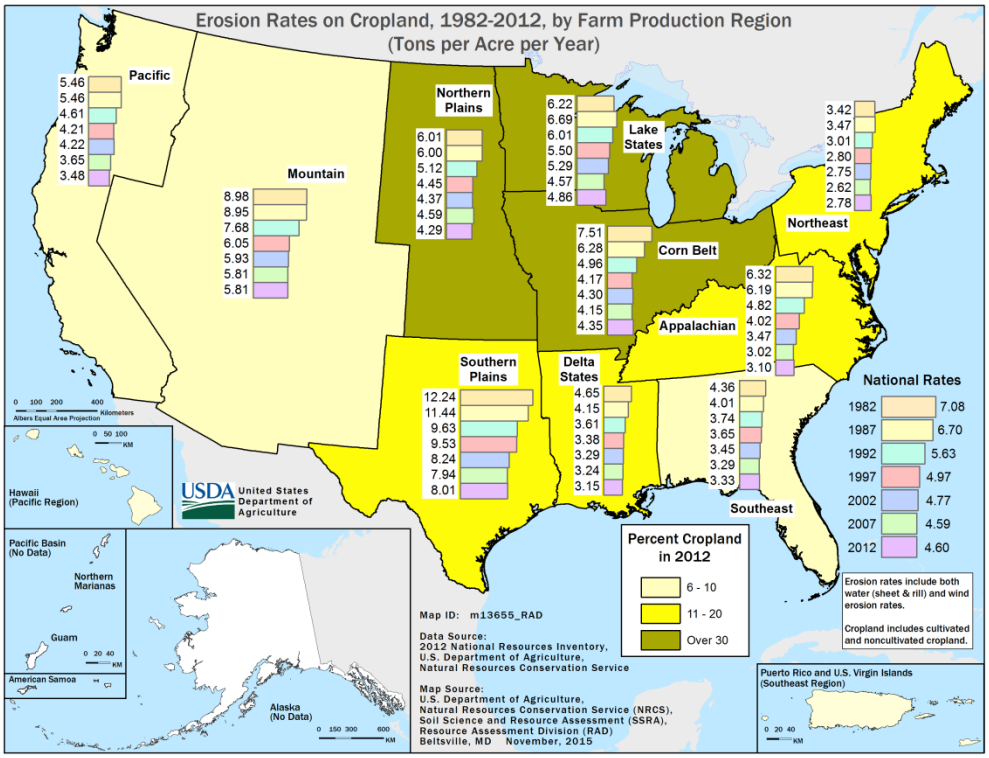
[124] Montgomery DR (2007). Soil erosion and agricultural sustainability. PNAS 104(33): 13268-72.
[125] NRC (2016). Genetically engineered crops: experiences and prospect. National Research Council, National Academy of Sciences, 2016, pre-publication copy, p. 98, emphasis added.
[126] Claassen et al (2004). Environmental compliance in U.S. agricultural policy: past performance and future potential. USDA Economic Research Service, Report No. 832, June 2004.



Source: USDA National Resources Conservation Service.
https://www.nrcs.usda.gov/Internet/NRCS_RCA/maps/m13655.png

Glyphosate-resistant (GR) weeds generated by GR crop systems have led to increased use of soil-eroding tillage in all three major GR crops over the past decade: cotton[127] as well as corn and soybeans.[128] With the continuing dramatic rise in weeds resistant to multiple herbicides, tillage becomes ever more likely, because herbicidal control options diminish and become more expensive.[129]

APHIS notes that effective weed control with herbicides facilitated conservation tillage in the era prior to GE crops, "and this was simplified by the introduction of GE HR cropping systems" (PEIS, 3-51, emphasis added). However, weed control is "simplified" only by excessive reliance on the HR crop-associated herbicide, which is precisely the factor that leads to rapid evolution of

[127] PEIS, 3-52. See also: Neuman and Pollack (2010). U.S. famers cope with Roundup-resistant weeds. New York Times. 5/4/10. Steckel L et al (2006). The impact of glyphosate-resistant horseweed and pigweed on cotton weed management and costs. University of Tennessee Plant Sciences, 2006. Nichols R et al. (2010). Meeting the challenge of glyphosate-resistant Palmer amaranth in conservation tillage. Cotton Incorporated, 2010. Sosnoskie LM and Culpepper AS (2014). Glyphosate-resistant Palmer amaranth (*Amaranthus palmeri*) increases herbicide use, tillage, and hand-weeding in Georgia cotton. Weed Science 62(2): 393-402.

[128] Owen MKD (2011). The importance of atrazine in the integrated management of herbicide-resistant weeds. Iowa State University, 11/9/11. NRC (2010). Impact of Genetically Engineered Crops on Farm Sustainability in the United States. National Research Council, National Academy of Sciences Press, 2010.

[129] Nichols et al (2010), op. cit.

HR weeds and increased use of tillage to control them. Only complex, multiple-tactic weed management can forestall the emergence of HR weeds, and GE HR cropping systems promote precisely the opposite approach.

APHIS assumes that the regulatory provisions of Alternative 3 would lead to lesser adoption of GE HR crops (PEIS, 4-31) than would occur under No Action (PEIS, 4-24) or the Preferred Alternative (PEIS, 4-29). If this is so, Alternative 3 would have numerous positive environmental impacts associated with reduced tillage and soil erosion, for instance improved water quality due to less runoff of sediment, fertilizers and pesticides,[130] which would in turn enhance biodiversity and wildlife habitat.

If Alternative 3 reduced adoption of GE HR crops, as APHIS assumes, additional benefits would accrue relative to the No Action or Preferred Alternatives. These include:

- Reduced use of environmentally toxic herbicides associated with new GE HR crops, such as 2,4-D and dicamba;[131]
- Improvements in air quality from reduced use of highly volatile herbicides like 2,4-D and dicamba;
- Improved human health through lesser use of, and exposure to, hazardous herbicides associated with GE HR crops, such as the probable human carcinogens glyphosate and isoxaflutole (the latter to be used with Bayer's isoxaflutole-resistant soybeans);
- Increased adoption of organic farming and non-chemical weed management techniques, such as cover cropping, which improve soil quality and benefit the environment and human health by reducing herbicide use. Interestingly, APHIS has in the past acknowledged that introduction of GE HR cropping systems "delay the adoption of non-chemical [weed] management strategies," and conversely that "cover cropping and crop rotation, both of which have shown promise in reducing weed pressure..." would increase more if they were not introduced.[132]

[130] Owen (2011), op. cit.

[131] Peterson RKD and Hulting AG (2004). A comparative ecological risk assessment for herbicides used on spring wheat: the effect of glyphosate when used within a glyphosate-tolerant wheat system. Weed Science 52(5): 834-44.

[132] CFS (2014). Comments to USDA APHIS on Dow AgroSciences LLC; draft Environmental Impact Statement for determination of nonregulated status of herbicide resistant corn and soybeans. Center for Food Safety, Docket No. APHIS-2013-0042, 3/11/14, pp. 34-35.