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

RE: Docket No. APHIS-2015-0057

Organic Seed Alliance (OSA) submits the following comments in response to the USDA's proposal to update regulations at 7 CFR Part 340 on the "Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms." We appreciate the opportunity to provide comments on the first comprehensive regulatory update to these rules since they were established 30 years ago.

OSA is a national organization that advances ethical seed solutions to meet food and farming needs in a changing world. We accomplish this mission through research and education with farmers and other agricultural professionals, and also through advocacy efforts that aim to protect the genetic integrity of seed used in organic farming systems. This demands close attention to the issue of genetic engineering (GE) and how these crops are regulated.

The organic community is increasingly challenged by the unwanted presence of GE material in organic seed and crops. Genetic engineering is an excluded method in the organic standards and yet organic farmers and handlers routinely find GE material in at-risk organic seed and crops. Ample evidence of the problem exists, and continues to pose economic and environmental threats to farmers, their markets, and the integrity of organic seed. Furthermore, in 2014 we conducted a national survey of US organic crop growers that included questions about GE crops. We found that the majority of respondents (71%) believe that federal regulations overseeing GE approvals aren't adequate for protecting their farm products from this excluded method.¹

New and improved regulations, coupled with stronger government oversight and enforcement, are long overdue. Unfortunately, this proposal as written takes US policy backwards and represents a departure from the USDA's mission to support the success of all forms of agriculture, including organic. What follows is our assessment of overarching problems with this proposal, especially in relation to APHIS's interpretation of its authority, and more detailed errors and gaps as we see them. These concerns are bulleted here and described in more detail below.

- APHIS interprets its mandated authority too narrowly.
- APHIS's narrow interpretation of its authority means real and potential risks associated with GE crops are dismissed as part of permit and deregulation decisions.
- APHIS should establish the process of genetic engineering as the trigger for regulation.
- APHIS's proposal will reduce the amount of GE crops that are regulated and therefore lessen oversight of GE crops in experimental trials.

¹ See: Hubbard and Zystro, State of Organic Seed, 2016, Organic Seed Alliance, at www.stateoforganicseed.org.

- APHIS should address “uncoordinated” aspects of the Coordinated Framework when regulatory gaps could be filled under its authority.
- APHIS’s proposal does not contribute to coherent coexistence policy.

APHIS interprets its mandated authority too narrowly.

Reading this proposal, we find APHIS’s approach and premise to be fundamentally flawed due to self-imposed restrictions on its authority. That is, despite being provided broad authority for regulating GE crops under the Plant Protection Act, APHIS continues to interpret its authority in an overly narrow manner and in so doing abdicates a more robust role in ensuring independent and proper reviews of GE crops. This proposal provides even weaker regulatory requirements and processes than already exist, a hands-off approach that supports the introduction of GE crops at the expense of other forms of agricultural production, including organic.

As indicated in the preamble of this proposal, no new law has ever been written to address the unique nature of agricultural biotechnology. Instead, agencies rely on their creative interpretation of their authority under existing laws – all of which predate the technology being regulated – that make up the Coordinated Framework for Regulating Biotechnology. The result is a patchwork approach (or a “mosaic,” as APHIS describes it) to regulating GE crops. More than 20 years of experience with GE crops in our fields and marketplace have shown us the consequences that result from a patchwork approach to regulation.

A genuine effort to improve 7 CFR Part 340 regulations in a manner that reflects sound public policy and the mission of the USDA is contingent upon a fundamental shift in this interpretation of authority. APHIS’s assertion that the regulations have been working well serves as evidence that its interpretation of their authority will remain narrow. The proposal states: “The Agency’s evaluations to date have provided evidence that most genetic engineering techniques, even those that use a plant pest as a vector, vector agent, or donor, do not result in a GE organisms that presents a plant pest risk.” The definition of a plant pest narrowly covers organisms that “directly or indirectly injure or causes disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.” Therefore, since the introduction of GE organisms, only impacts on other plants have been considered as part of risk assessments, dismissing numerous identified risks and damages associated with GE products. Unfortunately, this proposal provides a near guarantee that the broader risks and negative impacts associated with GE crops will continue to be overlooked, even with a new approach that includes reviewing GE crops in the context of noxious weeds.

APHIS’s narrow interpretation of its authority means real and potential risks associated with GE crops are dismissed as part of permit and deregulation decisions.

APHIS’s proposal neglects significant environmental, social, and economic issues as part of their assessment of risk factors for GE crops. The most notable issues in need of APHIS’s regulatory inquiry include: (1) impacts to non-GE seed, crops, and markets; (2) the cumulative effects of herbicide-tolerant GE crops on the evolution of weed resistance; and (3) the increased use of herbicides and other chemical controls as a result of both this resistance and the proliferation of herbicide-tolerant GE traits generally. Regulatory inquiries that don’t include these impacts contribute to a lack of transparency and ultimately an erosion of public confidence in the process.

Therefore, improved regulations at 7 CFR Part 340 should reflect a broader and more appropriate interpretation of APHIS’s authority to account for the risks listed above. The Plant Protection Act provides APHIS broad authority through the noxious weed definition, which reads: “Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the

natural resources of the United States, the public health, or the environment.” Given the broad definition, it’s disappointing to read yet another narrow interpretation of APHIS’s authority and a hands-off approach to regulating GE crops. APHIS’s proposal states as much, and seems to outright dismiss the need to acknowledge noxious weed authority:

Historically, there has not been a significant need for such a noxious weed evaluation of GE plants. Most of the GE plants that APHIS regulated in the past, such as varieties of corn and soybeans modified with common agronomic traits, do not qualify as ‘noxious weeds.’² This is because most GE plants to date have been agricultural crops, and most agricultural crops are not biologically weeds prior to modification. Indeed, in order to domesticate a plant for crop production, farmers often had to deliberately eliminate weedy traits, such as seed shattering, thorns, and seed dormancy, from the plant using traditional breeding techniques. Moreover, the phenotypic traits that have historically been introduced into crops through genetic engineering do not confer weediness. Because the plants have not been weeds prior to genetic engineering, and genetic engineering has not introduced weediness, evaluating the plant solely for plant pest risk has not been problematic.

These statements provide a clear indication that APHIS doesn’t plan to interpret a noxious weed more broadly than the traditional understanding of “weediness” as it relates to other plants and farms. By asserting that “most of the GE plants that APHIS regulated in the past, such as varieties of corn and soybeans modified with common agronomic traits, do not qualify as ‘noxious weeds,’” APHIS is effectively making a policy statement that will result in the most widely used GE traits and crops escaping regulatory review under a broader and more appropriate interpretation of noxious weed impacts as provided by law, including newer traits that exhibit similar functionality as existing GE traits as well as already deregulated traits in different crops.

The proposal ignores the damage that GE traits have caused on markets and farmers’ livelihoods when gene flow results in unwanted traits showing up where markets reject them (e.g., organic, non-GE, and foreign markets where GE traits are rejected by buyers or, in some cases, unapproved). These statements also ignore the impacts of increased herbicide use on public health, the environment, and natural resources, and impacts to “other interests of agriculture” (such as organic), all areas included in the noxious weed definition and therefore suitable to include in risk assessments.

Making matters worse, APHIS writes that in order to determine whether a GE plant could function as a noxious weed, the agency will have to “rely on its own independent evaluation of the plant itself, based on information provided by the plant’s developers.” The word “independent” is misleading because in the same sentence APHIS is committing to business as usual practices, where it bases its risk assessments of new GE crops solely on the petitioner’s own data. The lack of truly independent risk evaluations is a major weakness of this proposal. GE crop evaluations should be based on data and assessments from uninterested parties, and should include potential direct and indirect impacts as already discussed. This includes a full assessment of social implications, which have largely been ignored. In fact, a 2010 National Research Council report on biotechnology emphasizes the need:

² This sentence is misleading in calling novel GE traits that allow plants to survive heavy doses of agricultural chemicals (among other GE traits) “common agronomic traits.” They are only “common” in so far as they have been widely used by plant developers and planted by farmers for more than 20 years, but far from common in the history of crop improvement, production, and technologies that introduce new risks (i.e., increased herbicide use, unprecedented weed resistance, and market impacts caused by gene flow). Indeed, it’s this reference to “common agronomic traits” that underscores another faulty premise of this proposal: that GE crops don’t introduce new risks compared to their conventional (non-GE) counterparts.

The use of GE crops, like the adoption of other technologies at the farm level, is a dynamic process that both affects and is affected by the social networks that farmers have with each other, with other actors in the commodity chain, and with the broader community in which farm households reside. However, the social effects of GE-crop adoption have been largely overlooked.³

APHIS should establish the process of genetic engineering as the trigger for regulation.

APHIS should regulate biotechnology based on the process by which they are created, using genetic engineering as the trigger for regulatory review. Process-based regulations are appropriate for overseeing new technologies, as recommended by the National Academy of Sciences. Characteristics of biotechnology products and their potential risks should still be included in process-based assessments, but adhering only to product-based criteria leaves it up to industry to determine which products should be regulated – a clear regulatory weakness that, among other concerns, would engender mistrust among the public and our trade partners. APHIS should ensure that it retains exclusive authority to determine whether its regulations apply to a particular organism, rather than allowing developers to decide whether their GE products are subject to these regulations.

Furthermore, there are no categories of GE products that should go completely unregulated. Strong regulation is needed to protect farmers, the environment, and the public. We have learned a lot about the impacts of biotechnology since APHIS first developed regulations to oversee these new technologies 30 years ago. For example, the evolution of weed resistance due to the adoption of GE crops that encourage dramatic increases in herbicide use is one example that showcases an environmental nightmare that has fallen through gaps of the Coordinated Framework. The USDA should include known impacts of GE organisms, including increased herbicide use, herbicide-resistant weeds, impacts to non-target organisms, contamination of organic and other non-GE crops, among others, in risk assessments, and the agency should apply its regulatory authority to monitor, mitigate, and prevent negative impacts associated with GE organisms. This includes preventing the spread of GE traits to seed, fields, and markets where they're avoided or not allowed. We also urge APHIS to strictly regulate GE crops that produce experimental pharmaceutical or industrial compounds. These crops present risks beyond those just mentioned, and should never be grown outdoors without stringent permits and oversight.

When assessing risk, APHIS's proposal states that "the agency has discovered that the expressed phenotype of the regulated organism provides the most reliable indicator of the organism's potential for deleterious effects on plants and plant products." Generally that may be true, but phenotypes are clearly not the only way to assess risk, and shouldn't be the exclusive approach. A phenotype won't always reveal the distinctions of a plant's interaction with its environment, whether it's an important disease resistance trait or a risk factor. Similarly, we know that a plant's phenotype isn't fixed, especially in different environments. There's also the factor of how field trials and risk assessments are designed, and if risks are part of the original trial design. For this and other reasons, comprehensive and independent assessments of risk are needed.

APHIS's proposal will reduce the amount of GE crops that are regulated, therefore lessening oversight of GE crops in open-air experimental trials.

Perhaps most problematic in this proposal is seemingly less oversight of GE crop field trials. Given the history of contamination events at the field trial stage, market disruptions, and potential risks to

³ National Research Council. 2010. "The Impact of Genetically Engineered Crops on Farm Sustainability in the United States." Washington, DC: The National Academies Press.

sensitive markets, this is one of the most concerning components of APHIS's proposal.⁴ While we're supportive of doing away with notifications, we oppose any plan that aims to require less of GE crop developers in the way of field trial data collection and submission, including as part of the petition/deregulation process.

Current field trial oversight is already inadequate for monitoring GE crop experiments generally, and, for preventing and identifying the spread of unapproved GE traits specifically. At a time when investigative bodies have called for more transparency, monitoring, and restrictions on outdoor trials, APHIS is proposing to regulate fewer GE crops because the method will no longer be the main trigger for regulatory oversight. For example, we strongly oppose the "functionally equivalent" approach, where a trait that has a mechanism of action that is functionally equivalent as an already deregulated trait (e.g., a specific herbicide tolerance) wouldn't be regulated even if it was derived from a different donor organism. APHIS's proposal also eliminates the requirement for GE crop developers to submit field trial data as part of the petition/deregulation process.

This proposal must take seriously the recommendations from two USDA Office of Inspector General (OIG) audits, a Government Accountability Office investigation, and language in the 2008 Farm Bill, all of which called for stronger oversight of GE crop field trials. The OIG's most recent audit (2015) found ongoing severe shortcomings with the agency's monitoring and tracking of field trials, concluding that "there is reduced assurance that APHIS can prevent an inadvertent release of regulated GE crops into the environment" and "APHIS still does not have adequate controls in place to account for and sufficiently monitor all field trial locations."⁵ The audit points to recommendations from a previous audit (2005) that still need to be addressed.

APHIS should address "uncoordinated" aspects of the Coordinated Framework when regulatory gaps could be filled under its authority.

Herbicide-tolerant crops, which are planted to nearly all of the GE crop acreage in the US, provide the best available example for making a case for more synchrony between APHIS and other regulatory agencies, especially the EPA. As acknowledged in the proposal, the EPA registers herbicide products used on herbicide-tolerant crops but does not regulate herbicide-tolerant crops themselves. Second generation herbicide-tolerant crops now in our fields and marketplace showcase a failure in coordination. Newer herbicide-tolerant GE crops are developed to survive more toxic and antiquated chemicals that volatilize and drift. Some of these varieties are now stacked with several GE traits, all of which confer tolerance to different agricultural chemicals. This is all to say that risks to non-GE production are only increasing on account of these new seed and chemical packages, yet no single agency is regulating the package, despite the combination being the ultimate goal and purpose for introducing the GE crop.

APHIS asserts that it's not in its authority to restrict the sales of an herbicide-tolerant crop before the registration review of the accompanying herbicides is complete. We challenge this assertion given the consequences of this gap in regulatory oversight, where in 2016, thousands of acres of soybeans, cotton, vegetables, fruits, and ornamental trees were damaged by illegal applications of dicamba. The

⁴Unapproved GE traits have been discovered in harvests even years after experimental trials ended, including in wheat and rice, two significant export markets for US producers. Perhaps more alarming is that there's no system in place to test surrounding fields to ensure trial containment measures are successful; meaning, there could potentially be more instances where unapproved traits enter markets where they're not allowed. The lack of monitoring, tracking, and inspections – all noted as weaknesses by USDA's Office of Inspector General – creates enormous risk for US producers, especially in light of stronger GE regulations and testing abroad.

⁵ See: USDA Office of Inspector General. 2015. "Controls Over APHIS' Introduction of Genetically Engineered Organisms Audit Report 50601-0001-32."

investigation is ongoing, but many suspect that farmers who planted dicamba-tolerant GE seed in the region sprayed dicamba illegally.⁶ These applications were considered illegal at the time because the EPA had not yet registered the use of specific formulations of the herbicide on these crops. Chemical drift is an inevitable problem that comes with pesticides, especially those that easily volatilize. Currently, risks associated with drift are not a part of APHIS's risk assessments because of its narrow interpretation of its authority over plant pest and noxious weed risks. At the very least, APHIS should seek any required changes (including statutory changes if need be) to remedy this gap in regulatory oversight. A 2015 White House memo, entitled "Modernizing the Regulatory System for Biotechnology Products," called for improved coordination among agencies where there's overlapping jurisdiction.⁷

Another example of the "uncoordinated" nature of the current regulatory framework is the case of herbicide-resistant weeds. These weeds are now an epidemic in regions where Roundup Ready (glyphosate-tolerant) crops have been continuously grown.⁸ As mentioned, APHIS regulates the GE crop and the EPA regulates the companion herbicide separately, and no single agency is regulating the seed-chemical package. Yet it's this package that is responsible for the epidemic of resistant weeds, which leads to the increased application of agricultural chemicals generally; higher production costs for farmers; and economic, environmental, and human health risks associated with the application of more pesticides. Given that these impacts fall through the regulatory gaps of the Coordinated Framework, APHIS's evaluations must include a fuller assessment of potential impacts to the environment, human health, and the interests of agriculture as part of any decision to permit or deregulate a GE crop, as mandated by its noxious weed authority.⁹ This is one example where regulatory gaps can be filled under APHIS's existing authority.

APHIS's proposal does not contribute to coherent coexistence policy.

The introduction of GE crops more than 20 years ago elevated the policy question of whether agricultural biotechnology and organic (and other non-GE forms of) agriculture can coexist. Landmark lawsuits challenging the introduction of GE crops have brought this question into sharp relief. Yet neither proponents nor opponents of these technologies believe litigation will result in meaningful policy. Unfortunately this proposal fails to address this need, ensuring that economic, environmental, and social risks associated with GE crops will likely worsen, and that the burden to protect the organic industry – the fastest growing sector of agriculture – will remain on the shoulders of producers who strive to avoid the presence of GE material in their seed, crops, and products. This proposal also threatens to further the pattern of regulation by litigation, because US policy, including

⁶ Charles, Dan. 2016. "How Monsanto And Scofflaw Farmers Hurt Soybeans In Arkansas," NPR, August 1.

⁷ In July 2015, the White House issued a memo with the following message: "Federal agencies that regulate biotechnology products should continually strive to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements. It is critical that these improvements: maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection; establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement."

⁸ See: Mortensen, D.A., J. F. Egan, B.D. Maxwell, M.R. Ryan, and R.G. Smith. 2011. Navigating a critical juncture for sustainable weed management. *BioScience* 61:75-84.

⁹ It's important to note that EPA's regulations governing insect-resistant GE traits (or Plant Incorporated Protectants) require data addressing a host of factors, including non-target organisms, the environment, the potential for gene flow, and the need for management plans to avoid insect resistance. APHIS doesn't require the same data, evaluations, and plans despite having authority over the vast majority of GE crops introduced.

this proposal, continues to be supportive of the introduction of GE crops even in instances where risks to the integrity of organic and non-GE farming systems have been identified.¹⁰

Conclusion

APHIS has ample authority to address the broad agricultural, environmental, economic, and social harms associated with the proliferation of GE crops. These harms include contamination of organic (and other non-GE) seed and crops, the evolution of herbicide-resistant weeds, crop damage from herbicide drift, and impacts from increased herbicide use, among others. APHIS must carefully assess the impacts of GE crops and use its authority to adequately monitor their development and oversee their commercial release. We ask that APHIS develop a new proposal that incorporates the recommendations made in these comments to protect all forms of agriculture and to strengthen public confidence in the regulatory process. As part of a new proposal, we also ask that APHIS include a fair compensation mechanism that addresses economic losses and other harms experienced by farmers who, despite their best efforts, can't always avoid the market impacts of GE crops.

Sincerely,

A handwritten signature in black ink that reads "KHubbard". The signature is written in a cursive, slightly slanted style.

Kristina Hubbard
Director of Advocacy

¹⁰ See: Hubbard, Kristina and Neva Hassanein. 2013. "Confronting coexistence in the United states: Organic agriculture, genetic engineering, and the case of Roundup Ready alfalfa, *Agriculture and Human Values* 30(3): 325-336.