OHIO ECOLOGICAL FOOD OEFFA AND FARM ASSOCIATION

June 19, 2017

Regulatory Analysis and Development
Animal Plant Health Inspection Service
United States Department of Agriculture
4700 River Road Unit 118
Riverdale, MD 20737-1236

Docket # APHIS-2015-0057

Submitted electronically at www.regulations.gov

RE: OEFFA Comments on Docket # APHIS-2015-0057; Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms.

The Ohio Ecological Food and Farm Association (OEFFA) is a 501(c) 3 grassroots coalition of more than 4,500 farmers, gardeners, retailers, researchers, and others who share a desire to build a healthy food system that brings prosperity to family farmers and rural communities, meet the growing demand for local food, and safeguard the environment. OEFFA also operates one of the country's oldest and largest USDA-accredited organic certification agencies.

OEFFA represents the interests of organic producers, handlers and consumers choosing foods produced under the standards codified through the Organic Foods Production Act of 1990 and the National Organic Program as well as a significant constituency of non-GE producers. Of our farm members, approximately half are certified organic and most of the remaining operations grow without the use of GE technology. These producers incur substantial economic losses due to unintended presence of GE materials through product rejection and sales at below the costs of production. They also experience damage to their reputations and relationships both with buyers and within their communities.

While we appreciate USDA utilizing the noxious weed authority granted in the Plant Protection Act (PPA), the proposed rule exemplifies the one step forward two steps back approach to the regulation of biotechnology. OEFFA is concerned the USDA has not developed any means to prevent or mitigate the unintended presence of GE material in organic and non-GE seeds and products. Organic agriculture is the only segment of agriculture seeing double digit growth for more than a decade. In order for this vital and vibrant agricultural sector to continue to grow we must protect our ability to grow products without contamination from biotechnology. We ask that you utilize this opportunity to further improve the regulatory framework for biotechnology.

Sincerely,

Amalie Lipstreu

Policy Program Coordinator

1. *Addition of noxious weed authority to the review framework for the products of biotechnology.*

The 2000 PPA provides broad authority for the USDA to examine both the ***direct and indirect*** damage to crops, livestock, poultry, ***other interests of agriculture***, irrigation, navigation, the natural resources of the U.S., the public health or ***the environment*** (emphasis added). We appreciate the actions of USDA APHIS to utilize its noxious weed authority and broaden the scope of review. However, the proposal as issued does not go far enough in examining the comprehensive impacts of biotechnology or how these products affect "other"—namely organic and non-GE—forms of agriculture. Under the proposal APHIS has determined that a GE organism would only be regulated if it demonstrates a plant trait combination that causes it to act as a plant pest or noxious weed. According to APHIS' own assessment, almost all GE corn and soybean products brought to USDA to date would not be regulated.

One of the guiding principles of the coordinated framework asserts that the USDA will only apply federal resources where they will accomplish the greatest net beneficial protection of public health and the environment and that *oversight will be exercised only where the risk posed by the introduction is unreasonable.* What is considered unreasonable at the federal level and how does that filter down to organic and non-GE producers for which production choices are not their own and may be dictated by the risk of GE contamination? Should we not factor in ***other interests of agriculture*** and consider it an unacceptable risk to be hindering forms of production that operate under guiding principles that maintain and improve the resource base upon which all of agriculture depends? Should we not be protecting forms of agriculture increasingly sought out by the public and that contribute to the environmental and economic health of communities? Without thoughtfully considering these questions we are foreclosing a future for sustainable agriculture.

a.) OEFFA supports the USDA APHIS utilizing its noxious weed authority and request it consider long-term and indirect impacts.

b.) We ask the USDA not to base its internal evaluations solely on information provided by plant developers.

It is critical that independent scientific analysis be conducted to ensure proper objectivity. While potential conflicts of interests are disclosed, greater measures are needed to avoid bias in experimental design, data analysis and interpretation.

2. *Risk analysis process to determine which organisms would require a permit*

The concept of unreasonable risk is also employed in this proposal to create loophole for large categories of GE organisms. According to the proposal: "APHIS will no longer consider GE organisms to be regulated articles solely because of the donor, vector or vector agent used in engineering and will focus resources on the GE organisms that may present a plant pest and/or noxious weed risk." This will create new exceptions to product regulation based on similarity to previously approved organisms and does nothing to improve the oversight of biotechnology. In fact, this action is likely to exacerbate the indirect impacts of biotechnology on the environment and on other segments of the agricultural economy.

It should be a basic right for farmers to choose what to produce and how, which markets in which to operate and to make those decisions freely and independent of the choices of other farmers or

industries. OEFFA works with farmers that take all possible precautions to prevent contamination. Despite their efforts, which require significant expense—including pulling land out of production for buffer strips, delayed planting and more—many farmers have experienced the unintended presence of GE materials and have had loads of grain rejected.

A survey conducted by OEFFA in the fall of 2016 asked producers if they experienced contamination from genetic material and/or had product rejected. Approximately 4.3% of respondents had product rejected due to contamination. Follow-up phone interviews revealed the actual level of contamination to be much higher. Farmers experiencing contamination are at a distinct disadvantage in that they are required to prove contamination. This is difficult as causation can occur at multiple points in the process, from purchasing seed through delivery. Buyers also use different testing methodologies. Farming requires a tremendous skill set, one that should not need to include forensic science.

The burden of contamination prevention, proof of causation and any mitigation is borne solely by organic and non-GE producers. This is a very real impact of GE crop production systems that must be addressed by the USDA under its noxious weed authority.

a.) **<u>All products should be made available for independent scientific review that examines all risks, including long-term risks, direct and indirect environmental harm.</u>**

b.) **<u>USDA needs to account for the direct and indirect impact to organic and non-GE producers, and if additional regulatory authority is necessary, it should be requested.</u>**

3. Elimination of the notification process in favor of permitting.

The determination by APHIS that it would have better regulatory oversight, enforcement and improved transparency if all regulated movements are authorized under the permitting procedure is sound.

<u>OEFFA supports removing the current notification provisions from the regulations and requiring that all authorizations for movement be conducted under permit.</u>

However, the self-imposed reduction on the number of regulated articles will likely result in far fewer permits requirements in the future. Additionally, the new regulations will not include requirements for field trial data. This provides little incentive for the developer community to provide a public record of trials leaving the agency and the sustainable agriculture and environmental community with no base of information should there be future impacts.

4. Suggestions for ways to smooth the transition to new regulations.

The proposal for allowing non-regulated status for previously approved traits may also lead to an increased pace stacking of traits and contribute to the reliance on herbicides, the proliferation of herbicide-resistant weeds, and progression of the pesticide treadmill. Environmental and economic impacts will be felt by farmers that become even more dependent on pesticide products and use of these new herbicides will have harmful effects on human health, the environment and farm operators.

There are also concerns about how the proposed regulations may leave farmers that sell into foreign markets vulnerable. The Viptera corn lawsuits are emblematic for the types of problems producers may face, especially given the expansion of whole classes of non-regulated organisms. Other countries

scrutinize products of biotechnology more closely than the United States, putting domestic producers at a distinct disadvantage.

a.) <u>OEFFA asks USDA APHIS to re-propose this rule with the inclusion of recommendations from the organic and sustainable agriculture community.</u>

Please consider the recommendations of the organic and broader sustainable agriculture community, the long-term, direct and indirect impacts of this technology. Create a re-proposed rule that utilizes the broad authority laid out in the PPA which will facilitate a smooth transition to regulations that are truly representative of the entire agricultural community.

5. Additional Feedback

This proposal states that if APHIS determines federal regulation of a GE plant is not capable of mitigating noxious week risk, the plant would not be regulated. This sets up scenario where the introduction of bioengineered products could become so pervasive resulting in damage to crops, livestock, and broad interests of agriculture, natural resources the public health and/or the environment. A lack of any action would be an abdication of responsibility by the USDA.

Before proceeding with a final rule, USDA APHIS must ensure that previous OIG audits recommendations are fully implemented including:

- GPS coordinates of all field test sites;
- Scientific protocols or study designs from applicants prior to authorizing a field test of a GE organism;
- Legislative authority to require applicants to provide proof of financial responsibility in the event of an unauthorized release;
- Develop risk based criteria for conducting inspections and exercising oversight of field tests for the release of GE organisms; and
- Provide more explicit guidance regarding how to terminate a field test and document.

OEFFA reiterates recommendations related to the improvements of the regulatory framework for biotechnology to ensure:

- Biotech companies are liable for the costs of contamination and the costs of mandatory contamination prevention strategies that should be promulgated in the near term;
- Post-market monitoring and comprehensive risk assessment tools are included;
- The effects on organic and agroecological systems are considered; and
- A complete review of agricultural chemicals used in conjunction with GE products are conducted and considers low-dose, endocrine-mediated, and epigenetic effects.

We appreciate the USDA giving thoughtful consideration to OEFFA's comments as well as other organizations that directly serve small farmers that make up the majority of agricultural producers throughout the U.S.