August 5, 2019

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

Docket: APHIS–2018–0034

RE: Proposed Rule on Movement of Certain Genetically Engineered Organisms

Thank you for this opportunity to provide comment on the USDA Animal and Plant Health Inspection Service (APHIS) proposed rule entitled *Movement of Certain Genetically Engineered Organisms*.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

USDA National Organic Program regulations prohibit the use of genetically engineered organisms (GMOs) in the production of agricultural products marketed as organic in the U.S. This prohibition applies to a broad range of emerging technologies such as gene editing. Nevertheless, the usage of GMOs and regulatory framework for GMOs are of upmost importance to the organic industry, because organic producers are required to protect their products from contamination by prohibited materials such as GMOs. Even inadvertent contamination by GMOs can jeopardize the organic status of an otherwise compliant organic product, and lead to loss of markets and significant industry disruption. Organic farms that experienced crop loss from presence of GMOs between 2011-2014 reported an average loss of $70,000 per farm (2014 USDA Organic Survey).

For many years, the Organic Trade Association has been actively engaged in the national discourse on biotechnology, and has advocated for policies that protect organic agriculture and trade while preserving farmer and consumer choice. We have submitted numerous comments to USDA on proposed regulations related to the regulatory framework for genetically engineered organisms and other issues related to biotechnology.

Throughout our history of engagement on these issues, we have emphasized the need for a more robust regulatory framework for federal oversight of GMOs that includes an evaluation of economic, environmental and trade impacts.

As USDA continues to explore and potentially implement a new regulatory framework for GMOs, the agency must consider how it will address the needs of USDA-certified organic operations to prevent contamination from GMOs. Such considerations are not addressed in the current proposed rule, but will be essential for USDA to effectively implement final regulations in a manner that protects all types of
farm operations under USDA purview including organic and identity-preserved production. Below, we highlight two key issues for the organic industry that USDA must manage under its authority to regulate GMOs.

Detection of GMOs and other products of biotechnology

The USDA organic regulations require that agricultural products are produced and handled without the use of excluded methods\(^1\). This prohibition applies to emerging technologies such as gene editing. USDA-certified organic operations must implement contamination prevention measures across the supply chain to ensure compliance with the organic standards. USDA-accredited certifiers are also required to conduct periodic residue testing of organic products to verify that contamination prevention measures are effective.

Testing is a critical monitoring tool that the organic sector uses to evaluate whether an organic operation has adequate measures in place to prevent contact with GMOs. USDA-accredited certifiers are currently testing for GMO contamination and industry is voluntarily testing as well. However, some genetic engineering technologies cannot be detected by existing testing methodologies. This poses a significant challenge for organic operations to monitor and detect presence of prohibited material. **USDA must manage its regulation of GMOs with the need for industry (organic and identity-preserved) to monitor and detect the presence of GMOs.**

The proposed rule exempts gene edited and other broad categories of genetic engineering technologies that are **prohibited** under the USDA organic standards. Without a transparent registration and approval process and no possibility of testing to detect the use of these prohibited technologies, USDA will force an unsurmountable burden on farmers who exercise their choice of producing non-GMO agricultural products. Visibility of the type and prevalence of GMO material is essential for farmers to implement proper contamination prevention measures, and trace back contamination to its source.

International Trade and Market Requirements

Organic is a global industry, with many U.S. organic business active in international markets. Nearly 44% of U.S.-based companies export at least some of their organic products. Many countries have GMO testing and labeling laws that are applied to imported products including USDA-certified organic products. International markets will reject U.S. organic products that do not meet their country’s legal standards. Thus, U.S. organic farmers and processors who rely on sensitive international markets must adapt their practices, including monitoring and testing to comply with international market requirements. Relegating GMO standards overseas, without the ability of U.S. producers to participate, weakens U.S. agriculture as a whole. **USDA must manage its regulation of GMOs with the need for industry to comply with international markets that are sensitive to GMO contamination.**

\(^1\) **Excluded methods.** A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (7 CFR 205.2)
On behalf of our members across the supply chain and the country, we thank the USDA Animal and Plant Health Inspection Service for the opportunity to comment, and for your commitment to protecting the health and value of American agriculture and natural resources.

Respectfully submitted,

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cc: Laura Batcha
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