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Organic trade association

June 22, 2015

Docket No. APHIS–2015–0036
Biotechnology Resource Services
USDA APHIS
4700 River Road, Unit 147
Riverdale, MD 20737–1238

RE: Docket No. APHIS–2015–0036
(7 CFR Part 340)

Dear Deputy Administrator Firko:

Thank you very much for this opportunity to provide comment.

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 organic businesses across 49 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

OTA appreciates the U.S. Department of Agriculture (USDA) decision to withdraw the 2008 proposed rule (7 CFR Part 340) to amend the regulations for genetically modified organisms. Refreshed stakeholder engagement in the regulation of biotechnology is essential to safeguard a diverse, thriving rural economy.

The Plant Protection Act (PPA) gives the Secretary of Agriculture authority to adopt regulations preventing the introduction and dissemination of plant pests [7 U.S.C § 7711(a)]. Consistent with that authority, APHIS regulates the introduction of organisms and products altered or produced through genetically engineering that are plant pests or believed to be plant pests, or regulated articles. The regulations covering GE crops are contained in 7 C.F.R. § 340. USDA, however, relies on an antiquated biotechnology crop regulatory system based on the Federal Plant Pest Act (FPPA) and other quarantine authorities that were repealed as part of the enactment of PPA in defining plant pests. Although a comprehensive overhaul of the biotech regulatory process was initiated through a Programmatic EIS (rulemaking) process in 2004 leading to the publication of Proposed Rules (APHIS-2008-0023), final regulations were never implemented, and USDA has withdrawn the proposed rule to re-engage stakeholders on the issue.

OTA continues to believe USDA has broader authority currently available that remains unexercised. The limitations of the "plant-pest" paradigm will never prevent gene flow or secure diverse opportunity for U.S. crop production at home and abroad. Unless this problem is solved, the high-value opportunities for organic and identity-preserved production will continue to migrate overseas where the pressures of gene flow, post-harvest mixing and the resulting market loss are kept in check. Relegating this opportunity overseas, without the ability of U.S. producers to participate, will weaken U.S. agriculture as a whole. These trends underscore the failure of the status quo—voluntary schemes—to prove adequate now and for the future.

1) Should APHIS regulate based on the characteristics of biotechnology products and the potential risks they may pose, or by the process by which they were created? In either case, what criteria should be used to determine what APHIS regulates? Are there products and processes APHIS should not regulate?

USDA should consider criteria related to the broader environmental and economic impacts of GE crops. The consideration should be crop and trait specific.

2) The Plant Protection Act gives APHIS the authority to protect plant health through regulatory programs. APHIS has implemented the plant pest authority as part of their biotechnology regulations. Should APHIS add noxious weed provisions to their biotechnology regulations and if so, how? What protection goals should APHIS consider?

Under the existing regulatory framework, USDA limits its inquiry to whether the inserted genetic material poses a plant pest risk, defined as ―*any living stage of any of the following that can directly or indirectly injure, cause damage to …any plant of plant product"* [7 U.S.C. § 7702(14)]. APHIS regulations similarly define plant pests as *"any living state of … bacteria … or any organisms similar to allied with the foregoing … which can directly or indirectly injure, cause disease or damage in or to any plants or plant parts thereof, or any processed, manufactured or other product of plants"*[7 C.F.R. § 340.1]. Those same regulations reference plant pest analysis as including *"indirect plant pest effects on other agriculture products*‖ [7 C.F.R. § 340.6(c)(4)].

The noxious weed authority in PPA was designed to address the full range of adverse agricultural, public health and environmental impacts associated with GE crops (7 U.S.C. § 7702 (10) in order to fulfill PPA's purpose to protect agriculture, the environment and economy of the United States [7 U.S.C. § 7701(1)]. This provides clear authority for USDA to consider the economic impacts to farmers in the deregulation decision-making process. Thus, USDA has legitimate statutory authority to protect U.S. farmers and agricultural economies, and should move swiftly to exercise it.

Recent USDA determinations have concluded that since no plant pest risk was involved, it was powerless to address economic and environmental consequences of gene flow. Adding noxious weed provisions to USDA's biotechnology regulations would enable USDA to:

- Impose isolation distances,
- Require regulatory restrictions,
- Establish/mandate management practices,
- Establish geographic restrictions, or
- Impose conditions to reduce impact to organic farmers.

These are exactly the types of stewardship parameters that must be codified on a crop-by-crop basis in order to deliver on USDA's stated goals for coexistence.

However, genetic drift is not the sole coexistence challenge. The co-pesticidal nature of dominant U.S. GE

cropping systems produces widespread negative effects (herbicide resistance, herbicide drift, increased toxicity of co-pesticidal technologies and other environmental damages).

4) What non-regulatory solutions or policy alternatives could or should be considered to complement APHIS's regulatory program?

- OTA welcomes the update of procedures and BMPs for preventing introgression of GE traits in plant germplasm and breeding stock. The review and revision of these germplasm protection practices is one the most important outcomes of the 2012 AC21 recommendations. We commend the deliberate actions by ARS to examine these issues and urge that USDA and OMB propose adequate budgetary resources to ensure ongoing success of the effort.
- Conflict Analysis prior to petitioning for deregulated status: OTA is skeptical of its potential efficacy if implemented as a voluntary option for applicants. However, depending on the structure it could begin to provide constructive opportunities for prevention of coexistence failures. To the extent that new GE events are increasingly exempted from USDA oversight, such voluntary Coexistence Analysis could just be an unused and therefore un-useful tool. Viewed as a parallel stream of work to substantive revisions of part 340, a CA analysis may prove useful.

Again, on behalf of our members across the supply chain and the country, OTA appreciates the opportunity to comment.

Respectfully submitted,

Laura Batcha
CEO / Executive Director
Organic Trade Association (OTA)