



April 11, 2015

Docket No. APHIS-2013-0047
Regulatory Analysis and Development, PPD, APHIS
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: U.S. Department of Agriculture Stakeholder Workshop on Coexistence (Mar. 30, 2015) (Federal Register Number 2015-07210) (APHIS 2013-0047-4184)

Dear Docket Clerk:

Thank you for the opportunity to provide comments on “NEW AND PROPOSED USDA ACTIVITIES IN RESPONSE TO RECOMMENDATIONS FROM THE USDA ADVISORY COMMITTEE ON BIOTECHNOLOGY AND 21ST CENTURY AGRICULTURE (AC21)”

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. It is the leading voice for the organic trade in the United States, representing over 7,000 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.

Reflections on the Raleigh meeting

OTA is still evaluating what transpired at the U.S. Department of Agriculture Stakeholder Workshop on Coexistence held at North Carolina State University and not entirely certain what to conclude about USDA’s coexistence facilitation capacity at this stage. OTA went into NC State workshop with fresh news about USDA’s action rescinding the proposed rule on part 340 and we were cautiously hopeful that this showed payoff of our investment in the previous AC21/coexistence process. However we are not feeling fully confident that there is a conducive platform for these discussions based on much of the tone and tenor that overshadowed what could have been a meeting focused solely on substance and solutions. The following example is intended to characterize what transpired. The invited lunch speaker, Dr. Pedro Sanchez presented the following logic as the center of his remarks:

- 1) ‘Africa is organic by default’ - There is no such thing as organic by default. Organic is by definition a practice standard, with a regulatory framework and as such is the opposite of agriculture by default and to conflate organic with subsistence, no input, farming is misinformed or deliberately misleading.

- 2) **‘The failure of Africa to adopt biotechnology, as opposed to organic contributes to poverty and starvation’** – In fact, there are twice as many acres in the continent of Africa under cultivation with GE crops than under organic certification.

These are of course the opinions of a speaker and we hope not those of USDA but the failure of USDA leadership, to either correct or disavow the statements in its official capacity became very counterproductive to the stated goals of the conference.

General Comments

OTA encourages USDA to keep open a continued comment period. This is an important public-private conversation, not tied to a specific rule-making deadline, and will benefit from an ongoing robust dialog.

OTA believes that restarting the rulemaking process for implementing the Plant Pest Act (aka Part 340), beginning with USDA’s upcoming webinars, is the most central component of a meaningful strategy for coexistence going forward. The limitations of the “plant-pest” paradigm will never prevent gene flow, co-pesticidal damage or secure diverse opportunity for U.S. crop production at home and abroad. The noxious weed authority in the Plant Pest Act was designed to address the full range of adverse agricultural, public health and environmental risks 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)]. We look forward to understanding the specifics of the process for stakeholder involvement to explore a broadened set of factors that USDA-APHIS could consider in its deregulation processes.

Of the ten new proposed USDA activities, OTA identifies the most significant as: those related to the Natural Resource Conservation Service (NRCS); Agriculture Research Service (ARS) practices for protecting germplasm collections; Data collection by Economic Research Service (ERS) and National Agricultural Statistics Service (NASS); and the potential use of Agriculture Marketing Service (AMS) Process Verified Program (PVP).

Additionally OTA proposes that USDA take up consideration of a new proposed activity related to coexistence: Utilize USDA testing laboratory capacity to provide no cost GMO testing for organic and IP growers and handlers in order to reduce the costs of coexistence on those stakeholders. USDA could perform these tests and provide test results directly back to the operator while aggregating confidential data sets to better inform USDA policy.

Specific Comments on Proposed Activities

1. **New Economic Research Service (ERS) study underway on the economic implications of coexistence** ERS is planning to publish a report this year that broadly examines the economic issues

related to coexistence of organic, genetically engineered (GE), and non-GE crop production and processing, including adoption trends for these crops and their identity-preserving differentiated product markets and labels. American consumers continue to fuel a fast-growing market for organic food, as well as a burgeoning market for non-GE conventional products, and there is continued strong domestic and international demand for commodity crop production, much of which involves GE crops. The potential for GE crop production to impose costs on organic and non-GE conventional production, via accidental pollination and other mechanisms, illustrates the problem of coexistence between GE-differentiated crops.

OTA supports the ERS commitment to publish a report on the economic impacts of coexistence this year, but hopes these efforts are adequately funded and maintain independent scientific integrity. The study analysis should take into account the extent/likelihood that coexistence failures have already inhibited the growth of non-GE production and markets. That is, the apparent current costs of coexistence failures may be misleadingly discounted due to the fact that some amount of non-GE production has already been foregone because non-GE market standards cannot effectively be met in certain parts of country, for certain crops. When the study is published, USDA should follow it up with specific meetings to review the findings and collect input for further actions based on the study. OTA further recommends the economic impact and risks to U.S. farmers for increasing overseas sourcing of organic grains be considered.

- 2. Gathering information from farmers about actual economic losses incurred as a result of unintended GE presence** The 2014 Organic Survey is a collaborative effort between USDA's National Agricultural Statistics Service (NASS) and its Risk Management Agency (RMA). The population of interest is those producers certified as meeting the USDA standards for organic production, those exempt from certification, and those transitioning to certified organic production. In the survey, among many other questions, respondents are asked to answer questions related to economic losses received from unintended presence of GMO material in an organic crop produced for sale. Results from the survey will be published on August 31, 2015.

OTA applauds this important and overdue step and if the survey return rate is sufficiently representative it will be a positive accomplishment for USDA's coexistence efforts. USDA should be making a number of plans now for release of the survey results, within which this question will have particular significance. With only one question devoted to a complex set of questions about risk of loss from coexistence failure, there's a lot that this first attempt to collect such data won't immediately tell us. Follow up planning should begin now for analysis, collection of further data and framing of policy questions derived from the data. Budget allocation proposals for these follow-up activities should be put in place immediately. Of particular note, the current survey does not provide for collecting data on costs incurred to reduce the risk of GE contamination. This additional information will be particularly important to integrate into USDA policy analysis.

- 3. Development of a USDA Coexistence Education and Outreach Strategy** USDA has developed a draft USDA Coexistence Education and Outreach Strategy. The goal of the strategy is for all producers

to recognize the interconnectivity of their cropping practices. In addition, several USDA agencies and the private sector have personnel with experience in promoting local voluntary solutions that address gene flow at the county and community level. ... USDA will be inviting input and collaborators for the strategy as it is finalized.

OTA supports the stated goal of this activity. It could be a successful strategic anchor if it truly encompasses cropping *systems*, including “interconnectivity” of the embedded practices and technologies associated with GE crops. 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) which must also be addressed by coexistence education and outreach.

- 4. Development of updated procedures and best management practices for GE traits in plant germplasm and breeding stocks** The Agricultural Research Service (ARS) is in the process of revising and updating Agency-wide procedures and practices for handling GE traits and unintended presence of the latter in USDA/ARS crop breeding stocks and genebank collections. The procedures and practices focus on the five major crops with widely cultivated varieties that incorporate deregulated GE traits: cotton, maize, soybean, alfalfa, and sugarbeet. These procedures and practices will encompass five major elements: 1. Well-documented, reviewed, and accessible best management practices (BMPs) for maintaining seed purity in both breeding and genebank programs. 2. Testing for purity at critical control points. 3. Mandatory purity testing of new varieties or enhanced germplasm prior to formal release. 4. Guidelines for mitigating the effects of unintended presence of GE traits in breeding stocks and germplasm accessions. 5. Communication strategies for disseminating information about Agency procedures and practices and for handling future occurrences of unintended presence of GE traits.

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 of 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.

We recommend that USDA communicate opportunities to comment on these specific plans and resource allocations, under ARS stakeholder process and/or the proceedings of the National Genetic Resource Advisory Council (NGRAC).

- 5. Work with seed industry on providing additional information to farmers at the point of seed sale.** USDA is working with the American Seed Trade Association: to ensure the availability of seed to meet grower demand for the GE, identity-preserved non-GE, and organic markets; and to provide additional information to seed purchasers about best production practices for coexistence at the time of seed purchase.

OTA applauds these general goals and the apparent commitment of USDA to begin addressing the extremely difficult specifics. However it is not sufficient for USDA to identify ASTA as the only cooperator in this endeavor. The seed sector is the core challenge for coexistence and should be considered as a primary focus for further efforts, e.g. the next charge to an AC21 or its successor.

- 6. Provision of informational materials describing voluntary and outcome based strategies for facilitating production of all types of identity preserved products** Information will be provided about the use of pinning maps, grower zones, screenable markers, pollen-excluding traits, and procedures in place in the organic industry to prevent commingling and unintended presence.

While USDA collation of this information can be a useful product, OTA is uncertain how effective this can be in making serious improvements in coexistence performance. Information on organic growers' practices to reduce contamination risk IS widely available. However they lack matching efforts by GE crop producers and developers to prevent transmission of unintended presence. As stated in prior comments by OTA, extensive effort on merely providing informational materials should not be a high priority. Resources would be better allocated to actual development of new knowledge and more effective practices for markers, pollen-exclusion, etc.

The intent of a paper concerning market thresholds is unclear. Is it primarily for general public knowledge or is it specifically a query for development of public policy options? In either case, it should be based on an extensive canvass of market participants to provide an accurate picture of testing practices and the role of thresholds. Underscoring that coexistence is intended to meet a market preference, exploration of thresholds should be based on just that.

- 7. Toolkits providing resources that encourage communication, planning, and crop-specific practices to reduce unintended gene flow or post-harvest mixing, as well as information on contract issues and incentives** USDA will host a new Web site devoted to informational resources about coexistence. The site will consolidate and present coexistence-related information and resources from across all USDA agencies, as well as partners in the States, industry, and scientific communities. Content on the site will help support continued discussion and engagement regarding agricultural coexistence. A series of new factsheets that define agricultural coexistence, explain its importance, and highlight key aspects supporting coexistence in different sectors of U.S. agriculture will be added to the site in the near future. Beyond that, USDA will explore developing additional toolkit products for the Web site that will support ongoing dialogue about coexistence and encourage adoption of best practices. USDA looks forward to expanding the information and resources for the Web site, as well as ideas about additional toolkit products that are needed to help advance coexistence.

Although this was general concept was endorsed by the AC21 consensus, it still lacks specificity of content. OTA is unsure if there is sufficient useful (and not already easily accessed) content to justify a large use of resources for the outcomes that such “toolkits” might provide.

8. **Potential use of AMS Process Verified Programs to verify non-genetically engineered crops/processes** The USDA Process Verified Program provides companies that supply agricultural products or services the opportunity to assure customers of their ability to provide consistent quality products or services. It is a fee for service program and is limited to programs or portions of programs where specified process verified points are supported by a documented quality management system. The specified process verified points are identified by the supplier. Companies with approved USDA Process Verified Programs are able to make claims associated with their process verified points and their verified process points are documented and available for public view on the AMS website. The USDA Process Verified Program does not relieve the company of meeting regulatory requirements issued by other Federal Departments or USDA Agencies.

OTA is extremely interested in this proposal as it has many potential ramifications, including for the AMS-National Organic Program. Verification of “non-GMO/GE” claims is a highly dynamic marketing phenomenon in its own right. We strongly urge immediate further dialogue on this topic.

First and foremost USDA must not set or allow to be set a standard for “non-GMO” status below the bar which is already set by the National Organic Program in regards to exclusion of GMO technologies. OTA cannot more strongly state our advice to the department in this regard.

The AMS Process Verified Program can and does often provide meaningful and effective services for consumer transparency and supply chain validation, but we are not sufficiently clear on all aspects of its operation so as to fully evaluate its potential role in this context. For example:

- We lack information on the oversight and accountability of the AMS PVP.
- How is quality control of the AMS PVP program reviewed and maintained?
- How is the fee for its services determined?
- How are overarching criteria established to set baselines for processes that may have multiple parties entering into agreements?

In addition to these questions, we find it problematic that USDA would engage in fee-for-service verification of such claims while parts of USDA (notably FSIS) will still not readily recognize the validity of “non-GMO” claims under the provisions of USDA’s own National Organic Program Standard. Those agency inconsistencies need to be resolved before AMS proceeds on any PVP services for “non-GE/GMO” protocols.

9. **USDA’s Animal and Plant Health Inspection Service (APHIS) initiative to encourage analyses of, and means to address, coexistence challenges for new products** APHIS could encourage applicants to provide a conflict analysis (CA) prior to or concurrent with submitting a petition for determination of



non-regulated status of genetically engineered (GE) plants. The CA could be used by USDA in developing the socio-economic impact portion of a NEPA analysis, helping both to facilitate timely NEPA analysis, and to address a broad range of potential conflicts...

OTA is very interested in this proposal and we believe it is worth further discussion. We are 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 Coexistence Conflict Analysis may in fact prove valuable.

10. Potential use of conservation programs in some instances to facilitate farmers' measures to promote coexistence Although AC21 recommended that USDA encourage the development and use of joint coexistence plans by neighboring farmers through crop insurance or conservation incentives, USDA may not currently have the legal authority to directly support and monitor such activities as a general matter. In addition, conservation programs administered by Natural Resources Conservation Service (NRCS), and the practices used to implement conservation, must focus on natural resource concerns. Although genetic isolation is not a natural resource concern, there may be occasional opportunities where producers can mutually achieve conservation and coexistence goals.

OTA looks forward to detailed participation in the examination of potential uses of NRCS programs to facilitate coexistence. Functional coexistence must include addressing the collateral, non-genetic unintended negative effects of GE crop systems. These collateral effects (e.g., increased, more toxic co-pesticidal applications; increased herbicide resistance in weeds) certainly do impact NRCS natural resource concerns (air, water, wildlife, climate) and proactive prevention of these effects should be a clear NRCS priority. OTA believes this is an important discussion to pursue, despite narrow assumptions stated here about NRCS programs' potential utility. Further, while "genetic isolation" is not necessarily an NRCS resource concern, genetic *diversity* is very arguably relevant to NRCS resource concerns. The negative effects of GE cropping systems on genetic diversity of wildlife and habitat is another important but so far neglected aspect of coexistence that USDA should be exploring.

Conclusion

Once again, on behalf of our members across the supply chain and the country OTA appreciates the opportunity to provide comments on "NEW PROPOSED USDA ACTIVITIES IN RESPONSE TO RECOMMENDATIONS FROM THE USDA ADVISORY COMMITTEE ON BIOTECHNOLOGY AND 21ST CENTURY AGRICULTURE (AC21)"

Respectfully submitted,

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Organic Trade Association

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Organic Trade Association