April 5, 2021

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0089

RE: Materials/GMO Subcommittee – Discussion Document on Excluded Methods[1] Terminology

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Materials/GMO Subcommittee's Discussion Document on Excluded Methods Terminology. The Subcommittee is continuing the work of identifying emerging excluded methods technologies in the food sector and seeking to re-establish the community's understanding of the topic. In doing so, the subcommittee is seeking answers to several questions to aid in further development of its guidance to NOP on excluded methods terminology.

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 organic businesses across 50 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 organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Introduction
OTA recognizes that the definition of "excluded methods" was based on the efforts of NOSB in 1995, and is now outdated. Organic producers and handlers as well as Accredited Certifying Agencies (ACAs) and USDA's National Organic Program (NOP) must have clear and up-to-date definitions to make consistent and concrete determinations regarding compliance with the prohibition of GMOs in organic farming and handling. It is also critical that seed breeders have a clear understanding of the methods that are allowed and prohibited so they can confidently employ innovative and compliant seed breeding techniques and advance the development of organic seed used in organic systems. For this reason, we continue to be supportive of the work being done in this area.

OTA supports the recommendations that have been made to date, and this includes the clarification provided in the 2016 Recommendation that gene editing techniques, such as CRISPR, are currently prohibited under the NOP regulations per the existing definition of "excluded methods." We maintain that gene editing and the other methods that are listed as 'excluded methods' in the terminology chart are inconsistent with our existing definition and are therefore prohibited.

[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.

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As we continue this discussion, it is important that we do not lose sight of the strength of our existing definition ('excluded methods') and the first sentence that needs to be maintained and held central to our decision-making:

> "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."

Although the definition was written pre-2000, this first sentence provides a key foundation that should be applied to all new and emerging technology. The definition goes on to include *examples* of methods that are prohibited and allowed, but the list is not exhaustive. Guidance to support the definition is helpful because it provides additional examples that can be updated over time.

It is also important that we do not lose sight of the fact that the NOSB recommendation on Excluded Methods Terminology is one of over 20 final recommendations for "practice standards" that USDA has not completed rulemaking on (**see Appendix A**). The lack of progress and improvement in advancing and clarifying the organic standards is disrespectful to the NOSB process, it is harming and fragmenting the organic market, stifling continuous improvement within the industry and leading to inconsistent certification practices. The organic community has spent a tremendous amount of time and resources working together via the NOSB process to make recommendations to USDA on advancing the organic standards. Continuing to work on this proposal to USDA when there is such a significant record of inaction feels futile at best.

As we continue our work on Excluded Methods Terminology, OTA urges NOSB and organic stakeholders to call upon USDA to prioritize rulemaking and develop an action plan for clearing the NOSB backlog of recommendations. The future of organic depends on fixing this partnership and getting USDA to work better for the organic community.

Questions for Stakeholders

1. *What new emerging methods in biotech should be added to the TBD list? Please also describe the primary purpose and how far from commercialization for use in food processing and/or agriculture the method is in its development.*

   OTA is not aware of any new methods to add to the list. USDA's response[2] and overall inaction on this topic calls into question whether the on-going work to update the terminology chart is helping or hindering NOP's acceptance of the 2016 Recommendation. The most effective path forward at this juncture may be to complete this proposal at the fall meeting and focus energy on urging NOP to address the 'package' of excluded methods terminology recommendations passed to date. We also suggest asking NOP for clarification on the status of the NOP Handbook and what the plans are for issuing Guidance under this new administration. To the best of our knowledge, NOP has not worked on or advanced any Guidance in over four years.

2. *Please prioritize the remaining TBD list methods according to the definitions, principles and criteria established in the 2016 Proposal.*

   OTA does not have comments on prioritization at this time.

[2] The last response issued by NOP (August 12, 2019 "Memorandum to the National Organic Standards Board) refers to the on-going recommendations as "additional updates to the list of Excluded Methods that was put forth in its November 2016 recommendation." The consistent response is, "AMS is reviewing the NOSB's recommendation."

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a) *Would methods newly determined to be excluded by the NOSB/NOP be retroactive for commercial varieties already in the marketplace?*

This question is best answered when tied to concrete examples. Our understanding is that the Guidance primarily applies to new and emerging technologies and the situation described should be minimal to none. The NSB recommendations are to clarify the regulatory definition with updated examples of new technologies, not to change the definition or its meaning. We do not want to see this discussion, or a resulting recommendation, move the goal post on what is currently considered an excluded method (per the NOP definition), or what is currently allowed. The recommendation is for Guidance that supports the regulation and it should help inform decision-making moving forward. It is important to note that Guidance does not have the force and effect of law. It is non-binding. This is why we need to stay tethered to, and reference, the USDA organic regulatory definition of "excluded methods."

b) *Should the NOSB grandfather in methods that have long been used in organic plant breeding (e.g., double haploids) and focus its energy entirely on new and emerging technologies?*

Again, we would want to answer this question with a concrete example. Double haploid methods that involve genetic engineering should remain prohibited. A better understanding of the distinction between the various double haploid methods involved will be helpful. In accordance with the definition of 'excluded 'methods,' the use of traditional breeding, conjugation, fermentation hybridization, in vitro fertilization and tissue culture are not considered excluded methods and such practices should continue to be allowed.

Yes, we think the Guidance should focus on clarifying new and emerging technologies. The definition of 'excluded methods' in conjunction with all of the methods in the terminology chart provide solid direction for where we stand today.

c) *How do we regulate technologies used to develop new seed varieties that companies are otherwise under no obligation to disclose?*

Organic certification is voluntary, and companies that sign up to be a part of the system are making a decision to obtain and/or disclose the necessary information and documentation to demonstrate compliance. Seed is a fundamental input of an organic system and it falls under scrutiny to the requirements of the organic regulations. Organic and non-organic seed used on a certified organic farm must be produced without the use of excluded methods. Certifiers and certified operations are obligated to comply with the organic regulations. That said, it is difficult if not impossible for the organic sector to regulate the conventional seed sector. Organic operations are obligated to ensure conventional seed is complaint with the organic regulations, but this can be challenging since its production falls outside of the organic certification system. Our best option for success is to regulate ORGANIC seed and to put our energy into the development of organic seed production and organic seed breeding. This points to the importance of USDA implementing the 2018 and 2019 NOSB recommendations to update and strengthen the organic seed and planting stock regulation.

3. *Are unintentional excluded methods hiding in organic systems when the actual material produced and used has no trace of excluded method in the final organic product? Do we have the inspection, testing, and enforcement tools to keep prohibited methods out of the organic marketplace?*

The Organic Trade Association believes we have many of the inspection, testing and enforcement tools necessary to prohibit the *intentional* use of excluded methods and monitor the success of contamination prevention. Refinement is undoubtedly needed and must be on-going. First and foremost, and to the credit of

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this Discussion Document, the organic sector needs a clear understanding of the definition of "excluded methods," and the "variety of methods" covered under this prohibition so we can definitively articulate the requirements of organic certification. Second, organic certification is process-based, so we need to continue to focus on prohibiting the intentional use of genetic engineering and developing best practices to prevent inadvertent contamination. Third, testing is a critical tool that should be used to monitor the effectiveness of GMO contamination prevention measures and the authenticity of non-GMO practices and claims. Testing is critical, and it is also the area that needs the most development and refinement. Finally, with a clear understanding of the "variety of methods" that are prohibited under the organic regulations, certifying agents should be able to further develop or advance the non-GMO declarations / affidavits used to communicate and verify the prohibition. The use of a "non-GMO affidavit" often falls under scrutiny and is thought of as being less than ideal. However, a "non-GMO affidavit" is a legally binding document, and most people and companies understand the seriousness of such a contract. The construct of the affidavit and the information contained therein, is really where the rubber hits the road. The more specific the affidavit is, the more effective it will be in keeping excluded methods out of organic systems.

4. *Given the lack of transparency around emerging technology entering food and agricultural systems, how can Organic producers, handlers, certifiers, and this Board, etc. stay educated on emerging methods and the potential for contamination?*

   Since excluded methods are prohibited under the USDA organic regulations, it seems reasonable that USDA could provide NOSB with technical support in this area. NOSB could also request information and resources from the organic community on an annual basis, compile it into a resource document and request that it be posted and maintained on the NOSB webpage. USDA should support NOSB in this effort.

Conclusion

OTA remains supportive of moving recommendations forward to NOP that will not only improve the practices used to keep GMOs out of organic seed, feed and crops, but will also clarify the standards and terminology used for making clear and consistent compliance determinations. Our priority, however, at this time is to ensure that the backlog of NOSB recommendations (including this one, strengthening organic seed usage and GMO contamination prevention) are address by USDA and implemented by a final rule or final guidance.

NOSB plays a critical role in advising USDA on the development of organic regulations. When Congress created NOP housed under USDA nearly 30 years ago, the industry envisioned a process by which public and private stakeholders would work together via the NOSB to make recommendations to USDA on advancing and developing the organic standards. We envisioned a process that would be able to evolve the standards and ensure that the organic label would continuously improve. Unfortunately, this process is stalled. OTA acknowledges all of the National List Recommendations that USDA has addressed, and the incredible dedication and work NOP is accomplishing around organic enforcement and oversight. Now it is time to focus on updating and clarifying the organic standards, and to call upon USDA to commit to an action plan for prioritizing and addressing the NOSB backlog of recommendations

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

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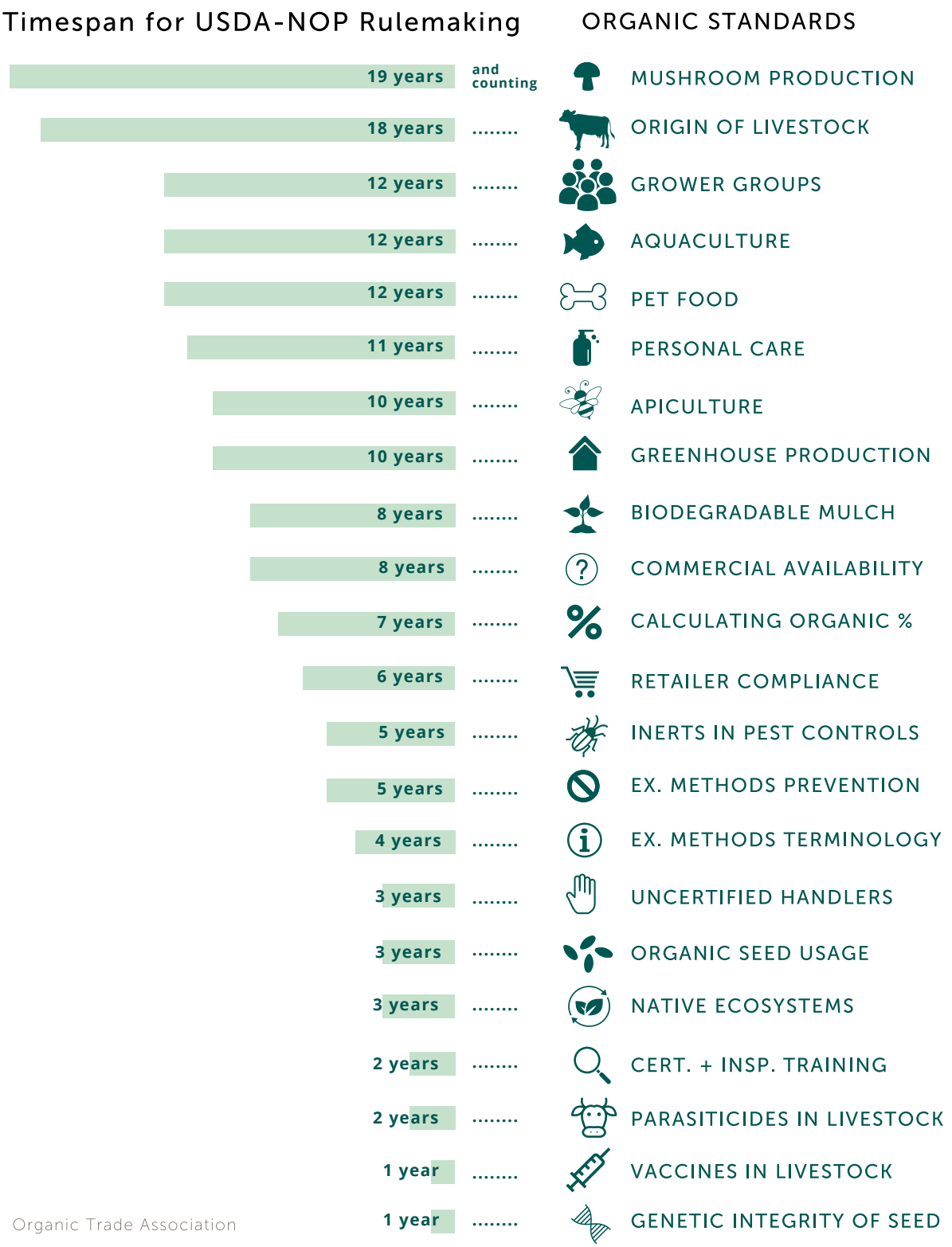
Appendix A: Backlog of NOSB recommendations that have not been implemented



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