



April 1, 2022

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

**Docket:** AMS-NOP-21-0087

**RE: Materials/GMO Subcommittee – Proposal on Excluded Methods Determinations**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Materials/GMO Subcommittee's Proposal on Excluded Methods<sup>1</sup> Determinations. The Subcommittee is continuing the work of identifying emerging excluded methods technologies. For this document, the subcommittee is addressing the terms 'cell fusion' and protoplast fusion' and clarifying the conditions that would make each one either an allowed or excluded practice under the regulatory definition of excluded methods.

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.

**Summary of OTA's Position:**

OTA is in full support the Subcommittee's Recommendation as written:

- ✓ NOP to develop a formal Guidance document to include the Definitions, Criteria, Excluded and Allowed Methods tables as developed by previous Board Proposals, with the additions of cell fusion and protoplast fusion:
  - Add **Cell Fusion** to the Guidance document as both an allowed and excluded method based on the conditions detailed in the proposal and our comments below
  - Add **Protoplast Fusion** to the Guidance document as both an allowed and excluded method based on the conditions detailed in the proposal and our comments below

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<sup>1</sup> *Excluded methods (§ 205.2 Terms defined)*. 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.

## Introduction

For the sake of the NOSB Spring 2022 record, OTA is carrying forward many of our comments from the Fall 2021 meeting. We recognize 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 and appreciative of the work being done in this area.

OTA supports the recommendations that have been made to date, and these include the clarification provided in the 2016 Recommendation that gene editing techniques such as CRISPR are currently prohibited under the NOP definition (7 CFR 205.1) of “excluded methods.” Further, we maintain that gene editing, gene silencing, synthetic biology and all of the other new and emerging techniques identified as ‘excluded methods’ in the terminology chart are prohibited in organic production and handling because they meet the NOP definition of ‘*excluded methods*.’

As we continue this discussion, it is important that we do not lose sight of the strength of our existing definition of ‘*excluded methods*,’ as per § 205.2, 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. NOP Guidance (adopted and placed in the NOP Handbook) to support the regulatory definition is important and helpful because it provides industry and certifiers with additional definitions and criteria to help guide evaluations and compliance decisions, and compiles more examples (new and emerging) that can be referred to and updated over time.

## OTA’s Position on the Spring 2022 Proposal

OTA agrees that cell fusion and protoplast fusion employed within taxonomic plant families (consistent with PM 13-1) be moved to the list of techniques that are allowed under the organic regulations (not Excluded Methods). The cell and protoplast fusion methods covered under this section of the list would be covered under the third sentence in the regulatory definition of ‘excluded methods’ as traditional breeding, hybridization, in vitro fertilization, and tissue culture. NOP Guidance that explicitly recognizes that cell and protoplast fusion are not excluded methods when the donor cells/protoplasts fall within the same taxonomic plant family, and when donor or recipient organisms are not derived using techniques of recombinant DNA technology, will further validate long-time NOP policy and secure the historical and future use of such techniques within traditional breeding programs. All other cell and protoplast fusion techniques would continue to be excluded methods per the NOP definition, and as further expanded upon in NOP Policy 13-1.

We also agree that cell and protoplast fusion involving recombinant DNA technology, techniques involving the direct introduction into the organism of hereditary materials prepared outside the organisms (such as microinjection), and use of donor cells or protoplasts that do not fall within the same taxonomic plant family should be added to the list of techniques as excluded methods.

To be clear, we are in full support of the subcommittee's recommendation as written:

- **Cell Fusion**

- The NOSB recommends the NOP add Cell Fusion to the table of Excluded Methods when the donor and the recipient cells are outside taxonomic plant families and/or when either is derived using techniques of recombinant DNA technology; with notes on the exception for use when donor and recipient cells are within the same taxonomic plant families.
- The NOSB recommends that Cell Fusion be added to the table of Allowed Methods with notes limiting the use to when the donor and recipient cells are within taxonomic plant families, and neither are derived from techniques of recombinant DNA technology.

- **Protoplast Fusion**

- The NOSB recommends the NOP add Protoplast Fusion to the table of Excluded Methods, when either the donor or the recipient cells are outside taxonomic plant families and/or when either is derived using techniques of recombinant DNA technology; with notes on the exception for use when donor and/or recipient cells are within the same taxonomic plant families.
- The NOSB recommends that Protoplast Fusion be added to the table of Allowed Methods with notes limiting the use to when the donor and recipient cells are within taxonomic plant families, and neither are derived from techniques of recombinant DNA technology

### **Continuous Improvement in Organic Seed Usage is a Top Priority**

OTA continues to express the critical nature of standards development and the need for USDA to modernize the organic standards to better reflect the growth and developments of the organic market. Since the regulations were implemented in 2002, the organic practice standards have been updated just twice (pasture regulations and residue testing) and only one of those updates (pasture regulations, completed in 2010) was the result of a NOSB recommendation.

The arrested state of the recent NOSB recommendation on organic seed usage is a perfect example and one that is very relevant to this Proposal. Many of the excluded methods that NOSB and the organic sector are grappling with are seed breeding techniques. As we know, seed is a fundamental input of an organic system and organic seed *must be used* unless an equivalent organically produced variety is commercially unavailable. The commercial availability clause developed 20 years ago, opens the door to conventional seed use in organic systems. Thankfully, organic **and** non-organic seed used on a certified organic farm must be produced without the use of excluded methods, and certified operations are obligated to meet those requirements. 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 compliant with the organic regulations, but this can be challenging since its production falls outside of the organic certification and oversight system. Our best option for success is to focus on and regulate ORGANIC seed, and to put our energy into the

development of organic seed production and organic seed breeding. A focus on requiring and increasing organic seed usage will keep the oversight of excluded methods within the organic seed trade, ensure we have the best adapted varieties for organic growers and address the important environmental benefits of using seed produced organically rather than conventionally. **All of this points to the critical importance of USDA prioritizing and implementing the 2018 (rulemaking) and 2019 (guidance) NOSB recommendations to update and strengthen the organic seed and planting stock regulation.**

In addition to the organic seed recommendations, other NOSB proposals that are integral to this discussion but have not been acted upon by USDA include:

- Excluded Methods Prevention Strategy (2015, Guidance)
- Genetic Integrity Transparency of Seed Grown on Organic Land (2019, Instruction)
- Use of Excluded Methods Vaccines in Livestock Production (2019, Rulemaking)

On February 7, 2022, AMS-NOP released a [federal register notice](#) requesting input from stakeholders on upcoming standards development activities, including feedback about specific recommendations from the NOSB. In the notice, NOP described their current rulemaking priorities and its current thinking on outstanding NOSB recommendations that focus on practices standards. In the notice, NOP addressed the NOSB recommendation on Increasing Organic Seed Usage by saying:

NOP has not made this recommendation a regulatory priority because NOP believes the recommendation is already addressed by USDA organic regulations for commercial availability related to seeds and planting stock. Therefore, additional rulemaking is not needed. The NOP has completed training on organic seed sourcing as a practical, high-impact step; the training is available in the Organic Integrity Learning Center. The ACA has also published a Best Practice Document for certifiers to increase consistency. AMS invites comments on this prioritization.

OTA strongly disagrees with NOP's reasoning, and we feel it is important to flag the matter in the context of the Excluded Methods proposal, for the reasons we have described above. The 2018 NOSB recommendation is a simple yet critical revision to the regulations to require *continuous improvement* in using organic seed on an annual basis. Commercial availability does not require any specific improvement benchmarks and is sufficiently open ended to allow for farmers to use nonorganic seed as long as they demonstrate their search is valid. The pattern to use non-organic seed has flourished for decades despite the availability of organic seed. In the course of NOSB's public deliberations to update the 2013 organic seed guidance (NOP 5029), NOSB recommended that organic crop producers increase their organic seed usage over time, as a continuous improvement goal of the OSP. NOP rejected the recommendation and explained that the proposal for guidance went beyond the regulations. NOP explained that the regulations would need to be revised to support a requirement for increased organic seed usage, thus prompting the NOSB recommendation that was passed in 2018. Unfortunately, NOP is now saying that the NOSB recommendation is already addressed by the organic regulations. Further, while we appreciate the NOP training on organic seed sourcing and the ACA Best Practices to help support certifier consistency, these tools are *not* a substitute to a regulatory requirement to increase organic seed usage over time.

OTA continues to urge NOSB and organic stakeholders to call upon USDA to prioritize standards development and address the backlog of NOSB recommendations that were developed to clarify and update the organic standards through a stakeholder consensus process. Inaction by USDA is preventing unique



segments of the organic industry from developing or advancing and lending to inconsistent certification practices and consumer confusion about the value of the organic label.

In closing, 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. The list of techniques covered to date and the clarification provided are incredibly important and useful and are already assisting the organic sector with regulatory determinations. It is time to formalize this significant body of work by accepting the NOSB recommendations and finalizing the Guidance in the NOP Handbook.

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,

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Vice President of Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
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