



September 30, 2021

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

**Docket:** AMS-NOP-21-0038

**RE: Materials/GMO Subcommittee – Discussion Document 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 Discussion Document on Excluded Methods<sup>1</sup> Determinations. The Subcommittee is continuing the work of identifying emerging excluded methods technologies, and for this document is seeking feedback on the To Be Determined (TBD) list terms 'cell fusion' and protoplast fusion.'

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**

For the sake of continuity, OTA is carrying forward many of our comments from the Spring 2021 meeting that we hold true and central to this topic. We recognize that the definition of "excluded methods" was based on the efforts of NOSB in 1995, and is now outdated.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

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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.

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. **Guidance 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.**

## Questions for Stakeholders

1. *Should the NOSB prioritize developing additional criteria for excluded methods determinations before continuing to work on the remaining TBD list techniques?*

No. To ensure consistency with the determinations that have been made to date, additional criteria should not be developed. If additional criteria were developed, it would likely delay if not set the process back, because all of the methods on the list would need to be revisited. We believe the regulatory definition of 'excluded methods' in conjunction with the definitions and criteria previously recommended by NOSB are adequate, and NOSB should focus on completing the chart and passing a final recommendation to NOP as soon as possible.

Although we do not support developing additional criteria, we agree with the Spring 2021 comments from the Organic Seed Alliance<sup>2</sup> on the need for a technical correction to the first criterion for scientific accuracy:

The genome is respected as an indivisible entity, and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g., through transmission of ~~isolated~~ **recombinant** DNA, RNA, or proteins). In vitro nucleic acid techniques are considered to be an invasion into the plant genome.

Finally, we recognize that the advances of modern agricultural biotechnology will continue, and so must the work of NOSB on this topic. Although we are not recommending additional criteria for the remaining TBD list, we expect an on-going evaluation process by NOSB to inform future updates to the guidance. We also see a need for additional information and resources that the organic certifiers

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<sup>2</sup> See Docket AMS-NOP-20-0089, Organic Seed Alliance comments (April 5, 2021), pg. 3

and inspectors can use to help determine where and when excluded methods may be applied in the production of any given input and/or in its supply chain.

To comply with the regulations and meet the promise of the organic label, it is critical that organic businesses, certifiers and other organic regulators have the necessary information to effectively inspect, certify and enforce the prohibition on excluded methods. At this point, perhaps our greatest challenge to upholding the prohibition on excluded methods is the lack of transparency around where and when the technology is being used and the shortcomings of current detection methods.

One solution is for NOSB, through the public comment process, to compile and create an electronic resource page - a one-stop shop - that the organic sector can use to find information on approved or pending GE crops, deregulated crops, GE food additives/processing aids and new and emerging technologies, etc. that are in use or in the pipeline. As a resource page, this could be updated periodically in a much simpler and more streamlined fashion than guidance and/or the regulations. 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 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 NOP webpage.

Another solution is to include an evaluation question in Technical Report that explores where and when genetic engineering may be used (generically) in the production of the National List input under review. Since accredited certifiers and Material Review Organizations (MROs) are the organizations that carry out excluded methods determinations, case-by-case at the brand-name level, the Technical Report could be a very helpful and valuable resource that certifiers and MROs could use to help inform their evaluation process.

The prohibition on genetic engineering in organic production and handling is not a choice, it's a regulatory requirement for those choosing to be certified. It is also an expectation of consumers who choose to buy organic products. OTA strongly urges USDA to support NOSB in its effort of creating greater transparency around when and where excluded methods are being developed, commercialized and employed.

- 2. Is Policy Memo 13-1 complete and applied consistently in organic systems, i.e., do cell fusion and protoplast fusion need to remain on the TBD list or can they be moved to the excluded method section with the notes that allowance is made for these techniques when employed within taxonomic plant families?*

OTA recommends 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 (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. A recommendation by NOSB 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.

For the sake of greater clarity, OTA also recommends 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 be added to the list of techniques that *are* excluded methods – the YES list.

3. *As the NOSB makes excluded methods determinations on the remaining TBD list techniques, should this organic system include allowance for historical use and a time frame for phasing out excluded uses?*

Consistent with our Spring 2021 comments, this question should be directed specifically to each individual TBD technique and the answer will depend on the decision. Generally speaking, the purpose of the NOSB recommendation should be to clarify the regulatory definition with updated examples of new and emerging technologies, not to change the definition or its meaning or change the prohibited or allowed status of GE techniques that have been in use by the organic sector for a long time. 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 policy). The recommendation is for Guidance to support the regulation and it should help inform sound decision-making *moving forward*. In the case of techniques that have long been employed under traditional breeding programs, such as certain cell and protoplast fusion techniques, the guidance will further support that which is already allowed, or prohibited. If all cell fusion were to be prohibited, full stop (inconsistent with PM 13-1), then a time frame for phasing out would be necessary given its historical use according to NOP policy. For emerging technologies, such as gene editing and synthetic biology, the Guidance will affirm their prohibition - given that the techniques did not exist and therefore were not included, *as examples*, when the regulatory definition of excluded methods was drafted and finalized in 2002.

## 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. 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.

**We urge NOSB to complete its work on the existing terminology list and push forward with a recommendation to NOP that encompasses the ‘package’ of excluded methods terminology recommendations passed to date.**

Finally, 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) was the result of a NOSB recommendation. This is unacceptable for a thriving \$60 billion industry that is 20 years of age.

The arrested state of the recent NOSB recommendations on organic seed usage is a perfect example and one that is very relevant to this Discussion Document. 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 implementing the 2018 and 2019 NOSB recommendations to update and strengthen the organic seed and planting stock regulation.**

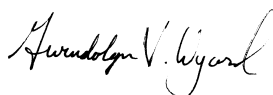
In addition to the organic seed recommendations, other NOSB proposals that are integral to this discussion but have not been acted upon by USDA include:

- 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)

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. Inaction by USDA is preventing unique segments of the organic industry from developing or advancing and leading to inconsistent certification practices and consumer confusion about the value of the organic label.

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