



October 3, 2019

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

Docket: AMS-NOP-19-0038

RE: Materials Subcommittee – Excluded Methods Terminology (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee’s Proposal on Excluded Methods Terminology. The Subcommittee is requesting comments from organic stakeholders on its proposal to clarify the excluded method status of “induced mutagenesis” and “embryo transfer (embryo rescue)” in animals.

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.

The Organic Trade Association recognizes that the definition of “excluded methods¹” was based on the efforts of NOSB in 1995, and several new technologies have emerged since that time. As a result, it is extremely helpful for organic producers and handlers as well as Accredited Certifying Agencies (ACAs) and USDA’s National Organic Program (NOP) to have guidance including clear and up-to-date terminology to make consistent and concrete determinations regarding compliance with the prohibition of excluded methods. For this reason, we continue to be supportive of NOSB’s work on a terminology chart that complements and provides additional detail to the existing regulatory definition of “excluded methods.”

The Organic Trade Association 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 National Organic Program regulations per the existing definition of “excluded methods.” The the term ‘bioengineering,’ as defined by USDA, does not and

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.

should not affect the definition of “excluded methods” or any other definition under USDA’s National Organic Program. 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.

As we continue to work on a terminology chart, it is important that we do not lose sight of the existing strength of our definition of ‘excluded methods’ and the first sentence that needs to be maintained and held central to these discussions:

“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 emerging technology. The Guidance is extremely helpful because it provides additional examples beyond the ones that are included (but not limited to) in the regulatory definition of ‘excluded methods.’

With respect to the recommendation for this fall 2019 meeting, we support a full board recommendation to add the following to the NOP excluded methods guidance as proposed by the subcommittee:

Induced mutagenesis – Developed via use of in vitro nucleic acid techniques

- Add as an “**excluded method**” – “YES” in the chart

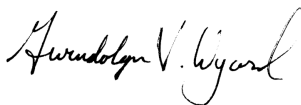
Embryo transfer, embryo rescue, in animals

- Add as **NOT an excluded method** – “NO” in the chart

The Organic Trade Association continues to be 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.

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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Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association