



October 11, 2017

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-17-0024

RE: Materials/GMO Subcommittee – Excluded Methods Terminology (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee’s Proposal on Excluded Methods¹ 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 over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks the Materials Subcommittee for its diligence on this challenging topic. We have been pleased to have the opportunity to comment on this complex topic for the past several NOSB meetings, and we commend the work accomplished and the progress that has been made. In summary, OTA supports the process of clarifying the definition of “excluded methods.” However, we are challenged to support the proposal as its written because it does not include definitions for the terms and methods being considered. It also leaves the actual definition of “excluded methods” as written into the organic regulations out of the document entirely. The purpose of this work is to provide clear up-to-date definitions that will result in consistent determinations. We urge the Materials Subcommittee to continue its work on this topic but to improve the quality of the proposal by including definitions and descriptions that we can work with to ensure everyone is operating on the same page.

We offer the following more detailed comments:

The Materials Subcommittee is requesting comments from organic stakeholders on its proposal to update the NOP regulatory definition of “excluded methods” through guidance. This process is ongoing and for

¹ 7CFR205.2 (National Organic Program Regulations) - **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.

this particular October 2017 meeting, the focus is on the terminology chart and several of the “to be determined” methods that are listed.

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. For this reason, we continue to be supportive of the work being done to move forward a recommendation to NOP. We’re concerned, however, that the working document with the terminology chart and list of methods at this juncture, is lacking important background information and definitions for NOSB, NOP and stakeholders to uniformly work with.

The Regulatory Definition of Excluded Methods

OTA believes that any proposal moving forward needs to include and highlight the only definition for genetic engineering (excluded methods) we currently have in the organic regulation. Leaving it out of the document entirely actually makes the review of new technologies more difficult and may cause our work to stray further from the intent of the law. OTA believes the definition of ‘excluded methods’ includes a 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 not be lost. The Excluded Methods Terminology document of August 30, 2016, included the definition of ‘excluded methods’ right out of the gate. In order to best facilitate the process going forward and help newcomers to the conversation, OTA urges NOSB to continue to include the definition of ‘Excluded Methods’ as found under 7 CFR 205.2 of the regulations.

Cisgenesis, Intragenesis and Agro-infiltration

Based on the definitions OTA referenced on-line, we believe cisgenesis, intragenesis and agro-infiltration are methods used to genetically modify organisms consistent with the NOP definition of ‘excluded methods.’ We’re challenged, however, to support this proposal as written because it lacks critical information not only to adequately inform the reader’s position but also to support a clear recommendation to NOP. Specifically, the proposal does not provide definitions for the three methods designated as ‘excluded methods’ or for any of the other terms on the “to be determined” list. The comments made in the “notes” section of the proposal are helpful, particularly for agro-infiltration, but we believe clear scientifically referenced definitions are imperative. The definitions and explanations we looked at on-line may not be the same definitions the subcommittee used or the ones that various stakeholders used to inform their positions and comments.

One specific concern we noted when looking at various definitions and practices related to ‘cisgenesis’ is its relationship with “Cell Fusion within Plant Family,” as listed in the “TBD” section of the terminology chart and described in the NOP memo (NOP-13-1) released in 2013. The “notes” section of Discussion Document of August 30, 2016, described cisgenesis as a “very broad term that may need to be divided into some allowed and some excluded techniques.” If the subcommittee considered various techniques

and determined that the broad term is fine as is, those discussions are unknown to stakeholders. Our concern is that the classification of cisgenesis as an excluded method, without including a definition or further clarification in the proposal, could be confused to include cell fusion within the plant family that has been going on for decades and has been considered “conventional breeding” rather than genetic engineering (GE).

Our understanding is that "cisgenesis" refers to “the genetic modification of a recipient plant with a natural gene from a crossable—sexually compatible—plant. Such a gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.” (Shouten *et al.* (2006) Therefore, in cisgenesis, a single gene is being moved using GE techniques. Cell fusion within the plant family, on the other hand, involves merging many genes that fall within the same taxonomic plant family, e.g., the genome, and was allowed under the 2013 NOP memo because many Brassica crops are developed using cell fusion within the same plant family (*Brassicaceae*) and the donor or recipient organisms are not derived using techniques of recombinant DNA technology. The technique is a decade-long practice that has been considered conventional breeding. It is for this same reason that the Codex definition of "modern biotechnology" exempts cell fusion within a plant family. We believe the distinction is important, and needs further clarification in the Materials Subcommittee Proposal.

In closing, OTA continues to be extremely 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. In the case of this proposal, we would like to see it go back to the subcommittee and be revised to include the definition of ‘excluded methods’ as found in 7 CFR 205.2 as well as definitions and explanations for the terms being considered.

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