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National Organic Standards Board
USDA-AMS-NOP
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Docket ID # AMS-NOP-21-0038

Re. MS: Excluded methods

These comments to the National Organic Standards Board (NOSB) on its Fall 2021 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

We are disappointed that the NOSB appears to be falling behind in addressing excluded methods. New genetic manipulation techniques are being introduced at an increasingly rapid pace. Organic stakeholders and accredited certifiers require clarity on this matter to ensure that all genetic techniques and methods are prohibited under the organic regulations as an excluded method. The NOSB and NOP must provide that clarity.

Over the years, the NOSB and the organic community have engaged in a reexamination of the excluded methods definition, which included discussion documents and proposed options for the NOSB review and evaluation. The NOSB acknowledged that this issue would require continuous work on their part to evaluate and provide recommendations to the NOP about new technologies as they emerge.

The framework put in place by the NOSB in the fall of 2016 should be formally adopted by the NOP and codified as a guidance document. The NOSB process of defining and clarifying what should be categorized as excluded methods builds on the current excluded methods definition in the organic regulations to encompass new technologies that have emerged since this definition was adopted in 1995.

Since 2016, the NOSB has clarified in unanimous recommendations that the following eleven methods are excluded in organic: Targeted genetic modification, gene silencing, accelerated plant breeding techniques, synthetic biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed via use of in vitro nucleic acid techniques, and induced mutagenesis through in vitro techniques. **NOP should codify the prohibition in organic for these eleven methods by publishing a guidance document for the NOP handbook to ensure clarity for all stakeholder groups.**

The unanimity of the NOSB recommendations on excluded methods since Fall 2016 reflects the organic community's united stance that *all* genetic engineering should be prohibited in organic. Genetic engineering is a threat to the integrity of the organic label. Both organic producers and consumers reject the inclusion of genetic engineering in organic production.

The NOSB has also passed unanimous recommendations that marker assisted selection, transduction, embryo rescue in plants, and embryo transfer in animals should be allowed in organic. **The NOP should codify that these four methods are allowed in organic by publishing a guidance document for the NOP handbook to ensure clarity for all stakeholder groups.**

The NOSB must continue to move ahead to determine the status for the 'to be determined' technologies and other GE technologies that emerge to provide clarity to all stakeholder groups. The NOSB must solicit input from scientists, plant breeders, and other organic stakeholder groups in making these determinations and publish it regularly for public comment. Failure to continue work in this area negatively affects organic plant breeders and the organic seed industry, who need certainty to advance plant breeding efforts that meet the needs of organic operations.

We urge the NOSB to move forward in evaluating the remaining technologies that have not yet been determined—using a transparent process that solicits input from key stakeholder groups and ensures that excluded methods are kept out of organic production. The NOSB should use the criteria that have been recommended in the past for determining whether methods should be excluded, with the proposed edits to #1. Allowable methods follow these guidelines:

1. 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~~ **synthetic** DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be an invasion into the plant genome.
2. The ability of a variety to reproduce in a species-specific manner has to be maintained, and genetic use restriction technologies are refrained from (e.g., Terminator technology).
3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.
4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g.,

utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences, or breeding processes) are refrained from.

With regard to our suggested change to the first sentence above, the genome does change in nature, and these changes may be genetically indistinguishable from changes made through human-induced methods, so the genome is a divisible entity in nature. We also suggest replacing “isolated” with “synthetic” to emphasize that sequences do not come from *de novo* synthesis.

Technical reviews of petitioned or sunset materials frequently mention the fact that a component or step in the manufacture of a material may involve genetic engineering. We need a clear statement that such materials are not acceptable in organic production. In some cases, an annotation to that effect may be necessary.

Replies to 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?*

The NOSB must prioritize moving ahead to determine the status for the TBD technologies. The NOSB must solicit input from scientists, plant breeders, and other organic stakeholder groups in making these determinations and publish it regularly for public comment. In the interim, these technologies must be prohibited as excluded methods. Failure to continue work in this area negatively affects organic plant breeders and the organic seed industry, who need certainty to advance plant breeding efforts that meet the needs of organic operations. When other GE technologies emerge, the NOSB must evaluate them to provide clarity to all stakeholder groups

We urge the NOSB to move forward in evaluating the remaining technologies that have not yet been determined—using a transparent process that solicits input from key stakeholder groups and ensures that excluded methods are kept out of organic production.

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?*

Cell fusion and protoplast fusion should not be allowed in organic systems. However, as noted by IFOAM, “Some varieties produced in this way may have been in use under organic systems for some time. Detection and replacement is potentially complex for reasons of identification and socioeconomic factors. Cultivars are used in organic farming, since they have been on the market for decades and are not subject to traceability and labelling requirements.”¹

¹ IFOAM – Organics International, 2017. Position Paper: Compatibility of breeding techniques in organic systems. https://www.ifoam.bio/sites/default/files/2020-03/Breeding_position_paper_v01_web_0.pdf.

Taxonomic families are broad entities, not necessarily reflecting a close relationship.² In fact, the only taxonomic level that could be supported as defining a difference in degree of relationship is the species. Cell or protoplast fusion used between plants of different species should be an excluded method. However, there must be a recognition of established cultivars that have been produced through cell/protoplast fusion. A time limit must be established for the allowance of such cultivars.

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?*

As noted in the quote from IFOAM above, it may be impossible to exclude cultivars in use historically. The determination of which cultivars should be allowed must be a transparent process using input from scientists, plant breeders, and other organic stakeholder groups, with draft findings published regularly for public comment.

Thank you for your consideration of these comments.

Sincerely,



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² <https://www.mobot.org/MOBOT/research/APweb/>.