



September 30, 2021

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National Organic Standards Board
USDA-AMS-NOP
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Submitted via [Regulations.gov](https://www.regulations.gov).

RE: Docket #AMS-NOP-21-0038

NOSB Materials Subcommittee Discussion Document: Excluded Methods Fall 2021

Dear NOSB Members:

Thank you for the opportunity to provide comments on the Discussion Document on Excluded Methods, for Fall 2021. MOSA certifies approximately 2,050 organic operations throughout the United States. As a part of our certification decision-making quality system, we have a strong materials review program, including a database with information and decisions on some 13,000 materials.

We appreciate your ongoing work on excluded methods determinations, and your work is a basis for our excluded methods decision making. We have a couple of comments regarding the clarity of the tables in the document, and some responses to the questions for stakeholders.

The “Notes” columns in the tables need more clarity. Although we have a lot of experience with materials review, the notes for induced mutagenesis leave us with some decision-making uncertainty. Induced mutagenesis is on the excluded methods chart with the Notes saying, “Developed through in vitro nucleic acid techniques does not include mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress-causing activities.” This needs to be written with more grammatical clarity, and also so as to make the NOSB determination on those methods more evident. The same UV, chemicals, irradiation and induced stress methods are also listed on the third table as TBD. So, it’s not clear to us whether induced mutagenesis via these methods is deemed acceptable, or still needs to be determined.

Regarding your primary focus on cell fusion and protoplast fusion, to our recollection, we have not encountered any decision-making scenarios around these, including taxonomic family questions. For MOSA clients, we provide an Excluded and Prohibited Methods form to help MOSA clients provide information regarding materials they may be using. This form includes a general prohibition reference for cell fusion, and our policies clarify exclusions.

Regarding questions for the stakeholders:

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

We would prefer that work on additional criteria for excluded methods occurs in tandem with work on the TBD list. (Note our comment above regarding induced mutagenesis.) Both are important, and the Accredited Certifiers Association is relying on this work for its best practices.

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?

Above, we noted our limited experience in decision-making on cell fusion and/or protoplast fusion. We don't recall directly applying PM 13-1 in our work. We do have internal policy guidance on cell fusion, and cell fusion is generically noted as an excluded method on MOSA's Excluded and Prohibited Methods form. With this noted, we would like to see cell fusion added to the "excluded methods" and "NOT excluded methods" tables. Describe which types are allowed and prohibited and clear this from the TBD 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?

Yes. If a currently allowed product becomes prohibited due to newly defined excluded methods, then there SHOULD be a reasonable phase out period, based on the operator's use, the material input, and their supply. This is already our general policy, balancing enforcement and reasonable practicality. For example, for the induced mutagenesis example concerns noted above, where the same methods are on the tables as allowed and also as TBD, if we had allowed certain forms of induced mutagenesis and that changed, we'd likely inform operators of the new requirement and give them time to make adaptations. Then we'd verify the acceptability of their new material input and their implementation plan for using it.

We also have one other observation. We appreciate that the definition for Non-GMO speaks to the NOP's process-based standards. As we are looking at a number of NOSB discussion documents this comment period, this affirmation of process-based standards stands in contrast to some language in the Certification Accreditation and Compliance Subcommittee's Discussion Document on Oversight Improvements to Deter Fraud, which mentions "transitioning our current system from process-driven certification to data-driven certification with electronic verification." Process-based or Process-driven certification recognizes the presence of unforeseen variables and empowers organic operators to make adaptive management decisions that make sense for their operations. Data is important, but should not be relied-upon at the expense of our effective, process-based model.

Thank you for your perseverance on these tough technological issues. We greatly appreciate the work and the efforts to keep a current and complete excluded methods determinations list. We intend to continue to use your list as a basis for our MOSA excluded and prohibited methods form, which is used by many certified organic operations.

Respectfully submitted,

The MOSA Certification Team