

National Organic Standards Board
Materials Subcommittee Discussion Document
Induced Mutagenesis
Fall 2025

Sacred seed. In many Indigenous cultures, the duty of selecting and preserving seed is a sacred one. All of our major food crops have been created by Indigenous cultures.

Introduction and Background

Scope & Definitions

This discussion document applies to both seed-propagated crops and clonally propagated crops such as many fruits and nuts. It uses the term “seeds” throughout for simplicity, which should be read to also include “propagules.” This document distinguishes three aspects of organic seeds:

- Breeding of organic seeds/varieties – that is, breeding seeds especially suited for organic production, ideally under organic conditions.
- Propagation of organic seeds – growing seed crops under organic conditions. Currently, organic seed can be produced starting with either organic or untreated, conventional seed (if organic is commercially unavailable), which is then grown under organic conditions.
- Production using organic seeds – growing crops under organic conditions. Organic seeds are required unless they are not available for the required traits or quantity, in which case untreated, conventional seeds can be used.

The scope of this discussion document is limited to seeds as distinguished above. It **does not** cover the use of induced mutagenesis (IM) in microbe or animal breeding.

Background & History

Current National Organic Program organic regulations (7 CFR 205.2 Terms defined) define **excluded methods** as:

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.

It is important to note that this definition refers to **means** not possible under natural conditions, not **results** not possible under natural conditions.

Excluded Methods Background

There are three key prongs to the excluded methods definition:

- (1) “methods used to genetically modify organisms or influence their growth and development”;
- (2) “by means that are not possible under natural conditions or processes”; and
- (3) “[by means that] are not considered compatible with organic production.”

The use of “and” to connect these prongs within the definition indicates that for a method to be excluded under the regulations, **all three elements must be met**. The phrases “natural conditions or processes” and “not considered compatible with organic production” were intended to be “subject to interpretation,” with the expectation that consumer and industry expectations may evolve over time and that the NOSB will help resolve questions arising with regard to specific techniques ([65 FR 13512](#), p. 13521). The NOSB has recommended that the lack of available testing methods to detect the use of a particular genetic modification technology should not prevent the NOSB from listing it as an excluded method if it otherwise fits the definition; rather, the NOSB should anticipate that appropriate testing or detection methods will develop over time.¹

PRONG 1: METHODS USED TO GENETICALLY MODIFY ORGANISMS OR INFLUENCE THEIR GROWTH AND DEVELOPMENT

An organism is considered “genetically modified” if it is created using genetic engineering (GE), which the NOSB has recommended defining as “[a] set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, organisms, cells and other biological units are altered and recombined.”² These synthetic processes “are designed to control nature at the molecular level, with the potential for unforeseen consequences.”³ IM is not considered a genetic engineering technique. By including techniques such as cell fusion in addition to recombinant DNA technology, the NOP meant “excluded methods” to include methods in addition to genetic engineering. A method that does not use GE may be considered an excluded method if it aims to “influence [an organism’s] growth and development” and satisfies the other two elements of the definition. Previously, the NOP convened the Vaccines Made With Excluded Methods (MWEM) Working Group which indicated that targeted genetic modifications are prohibited as an excluded method, while a method that causes random genetic modification followed by screening for a desired phenotype may be permitted if it fails to satisfy the other two prongs of the excluded methods definition.⁴ We request stakeholder input on Prong 1.

¹ NOSB, Formal Recommendation to the NOP: Excluded Methods Determinations April 2019, at 5 (Apr. 26, 2019).

² See, e.g., NOSB Formal Recommendation to the NOP: Excluded Methods Terminology Recommendation at 5 (Nov. 18, 2016); NOSB, Materials/GMO Subcomm. Proposal: Additional Excluded Methods to be Listed in the NOP Excluded Methods Guidance Document, NOSB Oct. 2017 Proposals and Discussion Documents at 170 (Aug. 22, 2017); NOSB, Formal Recommendation to the NOP: Excluded Methods Determinations, 4-5 (Spring 2022).

³ NOSB, Policy and Procedures Manual, App. 1, #1, Foundations: NOSB Principles of Organic Production and Handling, § 1.11 (May 1, 2024).

⁴ See NOSB Formal Recommendation to the NOP: [Livestock Vaccines Made with Excluded Methods](#) at 9-11 (Oct. 30, 2014).

PRONG 2: BY MEANS THAT ARE NOT POSSIBLE UNDER NATURAL CONDITIONS OR PROCESSES

The phrase “natural conditions or processes” was specifically chosen to align with the NOSB and American Organic Standards (as developed by the Organic Trade Association) definitions that were created through consultation with organic industry and consumer stakeholders (65 FR 13512, p. 13521). Under the regulations, “natural” and “nonsynthetic” are synonymous; a nonsynthetic substance must be “derived from mineral, plant, or animal matter,” and must not have undergone any synthetic processes (7 CFR 205.2). Naturally occurring biological [processes]” are not considered synthetic (7 U.S.C. 6502(22)). Additionally, natural processes must not use any chemical process to formulate or manufacture a new substance, or use any “process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources” (7 U.S.C. 6502(22)).

The NOSB has emphasized the importance of the genome’s integrity as an indivisible entity, prohibiting technical or physical insertions, deletions, or rearrangements in an organism’s genome, as well as in vitro nucleic acid techniques,⁵ which aligns with international standards. Under the Canadian standards, “synthetic biology” is defined as “the design and construction of novel artificial biological pathways, organisms or devices, or the artificial redesign of existing natural biological systems.”⁶ IFOAM’s guidance is similar to the NOSB’s, although IFOAM also stresses the cell’s integrity as an “impartible entity,” and prohibits “[t]echnical interventions into an isolated cell on an artificial medium.”⁷

In the preliminary discussion of induced mutagenesis (IM) at the Fall 2024 meeting, the NOSB stressed that the definition of excluded methods “refers to *means* not possible under natural conditions, not *results* not possible under natural conditions.” This aligns with the U.S.’s fundamental approach to organic systems: “[t]he emphasis and basis of these standards is on process, not product” (65 FR 80548, p. 80549). A 2017 NOSB recommendation indicates that genetic manipulation within the same species may not be permissible if the method of genetic manipulation “can create characteristics that are not possible within that individual with natural processes and can have unintended consequences,” or if “[t]he resulting plants could not have been achieved through natural processes and are a manipulation of the genetic code within the nucleus of the organism.”⁸ According to the 2024 technical report, IM uses synthetic chemicals or high levels of radiation to achieve mutation rates hundreds of times higher than those found in nature. We request stakeholder input on Prong 2.

⁵ NOSB, Formal Recommendation on Excluded Methods Determinations to the NOP (Spring 2022) at 5.

⁶ CAN/CGSB-32.310-2020, https://publications.gc.ca/collections/collection_2020/ongc-cgsb/P29-32-310-2020-eng.pdf.

⁷ IFOAM NORMS for Organic Production and Processing § III(B)(4.8) (July 2014), <https://ifoam.bio/sites/default/files/2020-09/IFOAM%20Norms%20July%202014%20Edits%202019.pdf>.

⁸ NOSB, Formal Recommendation: Excluded Methods Terminology to be listed in the National Organic Program Excluded Methods Guidance Document (Nov 2, 2017), <https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethodsFinalRec.pdf>.

PRONG 3: BY MEANS THAT ARE NOT CONSIDERED COMPATIBLE WITH ORGANIC PRODUCTION

Compatibility with organic production is determined based on the NOSB's longstanding internal guidance.⁹ Organic production systems are designed to enhance and conserve genetic and biological diversity; promote ecological balance, biological cycles, and soil biological activity; foster cycling of resources; maintain long-term fertility; and should aim to be ecologically, socially, and economically sustainable.¹⁰ To achieve this, these systems prioritize the use of management practices to respond to regional and site-specific conditions, and use cultural, biological, and mechanical methods, where possible, rather than using off-farm inputs and synthetic materials to satisfy particular system functions.¹¹ The NOSB has recommended that new varieties must maintain their ability to reproduce in a species-specific manner, and genetic use restriction technology, such as Terminator technology, must be avoided.¹² Additionally, methods compatible with organic production must not introduce novel proteins and other molecules produced from modern biotechnology into the agro-ecosystem.¹³ Finally, organic production must comply with the Organic Foods Production Act and the NOP regulations.

A prior NOSB recommendation on determining whether a substance is consistent with organic farming and handling requires consideration of the following factors¹⁴:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- Is the substance made from renewable resources? If the source of the product is nonrenewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?

⁹ NOSB, Policy and Procedures Manual, App. 1, # 2, Foundations: NOSB Guidance on Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling (May 1, 2024).

¹⁰ 7 CFR 205.2; NOSB, Policy and Procedures Manual, App. 1, §§ 1.1–1.2, 1.5 (May 1, 2024).

¹¹ 7 CFR 205.2; NOSB, Policy and Procedures Manual, App. 1, § 1.1 (May 1, 2024).

¹² NOSB, Formal Recommendation on Excluded Methods Determinations to the NOP (Spring 2022) at 5.

¹³ NOSB, Formal Recommendation on Excluded Methods Determinations to the NOP (Spring 2022) at 5.

¹⁴ NOSB, Policy and Procedures Manual, App. 1, § 2 (May 1, 2024).

- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

We request stakeholder input on Prong 3.

IFOAM provides further guidance that may be helpful when determining whether a method is compatible with organic production. The IFOAM NORMS prohibit the use of any ingredients, additives, or processing aids that are derived from GMOs, and require tracing these back “one step in the biological chain to the direct source organism from which they are produced to verify that they are not derived from GMOs.”¹⁵

Induced Mutagenesis Current Status

Currently, varieties bred using IM are allowed for organic production, since in vivo IM is on the NOSB’s “TBD list” of excluded methods. This is a list of potentially excluded methods which are controversial and have not yet had recommendations from the NOSB. Stakeholders, particularly organic seed breeders and producers, have pushed for resolution of TBD methods since the list was established in 2016. This discussion document is part of an effort to gather information to make a recommendation regarding in vivo IM.

Discussion: Mapping Scenarios & Implications

In Fall 2024, the first Discussion Document on Induced Mutagenesis engendered thoughtful feedback from organic stakeholders. Many commenters concurred that exposing plant materials to toxic chemicals and radiation is not consistent with organic principles. Many commenters also expressed concern about losing access to existing IM varieties and/or restricting future variety development through IM techniques. The solutions proposed varied significantly.

The following discussion attempts to untangle the various routes the NOSB could take to make recommendations that will address the concerns elevated around IM. The first step in this ‘detangling’ is to describe impacts that would occur under three recommendation scenarios - limited to seed production for the purposes of this discussion:

1. IM is an excluded method;
2. IM is not an excluded method;
3. IM is not an excluded method, but should be restricted.

Each of these scenarios is discussed below.

¹⁵ The IFOAM NORMS for Organic Production and Processing § 2.3 (July 2014), <https://ifoam.bio/sites/default/files/2020-09/IFOAM%20Norms%20July%202014%20Edits%202019.pdf>.

It is worth noting that similar considerations may apply to the status of gene editing and other new, difficult to identify, and possibly excluded methods entering into the crop seed supply. However, the scope of this document is limited to IM.

1. NOSB recommends IM *is* an excluded method

Rationale: IM could be classified as an excluded method, because IM influences growth and development of plants with chemicals, processes, and speed that some consider incompatible with organic production. There are also a number of criteria regarding the compatibility with organic that are potentially relevant, including the impact on soil health.¹⁶

Impact: Seeds that are the product of IM are currently in use in organic production, including as organic seed. If the NOSB recommends that IM should be considered an excluded method, there would be significant adjustments to the way producers and handlers avoid using and prevent contamination from excluded methods in their crops and products. Classifying IM as an excluded method for seed production would require certified operations and certifiers to dig into seed breeding and supply chains to determine where IM was used, work to find alternatives to seeds produced with IM, and adjust their production systems accordingly. Some standard varieties known by consumers would not be available as organic products (e.g., ruby red grapefruit, many modern wheat varieties, some brassica hybrids). Some varieties that farmers rely on for disease resistance would also be disallowed.

In addition, organic handling operations would be required to verify that any nonorganic ingredients used in organic products were not produced with IM, which could be challenging or impossible for some ingredients and could cause disruptions in broad categories of organic products.

Short of a list (discussed below), it is difficult to see how farmers and certifiers could readily and accurately determine allowed varieties if IM is an excluded method, because there are no labeling requirements to identify use of IM in seed.

2. NOSB recommends IM is *not* an excluded method

Rationale: IM could fall outside the definition of an excluded method, because IM does not explicitly appear in the definition of ‘excluded methods,’ and it has been considered by some to be a classical plant breeding technique. It is possible to draw a distinction between direct manipulation of the genome

¹⁶ Publications show the effect of genetic manipulation/changes in plants on the plant microbiome. See, for example, Kayla M. Clouse & Maggie R. Wagner, Plant Genetics as a Tool for Manipulating Crop Microbiomes: Opportunities and Challenges, *Frontiers in Bioengineering and Biotechnology* 9 (2021), <https://doi.org/10.3389/fbioe.2021.567548>. Changes in plant microbiome eventually impact the soil microbiome. The focus is on the impact of the genetic change on plant microbiome and not the method by which the genetic change is achieved. There are a number of other publications that show that genetic changes in plants cause changes in plant microbiome. Another article discusses how exudates released from plant roots impact the rhizosphere microbiome and soil microbiome in general. V.A. Seitz et al., Cover crop root exudates impact soil microbiome functional trajectories in agricultural soils, *Microbiome* 12, 183 (2024), <https://doi.org/10.1186/s40168-024-01886-x>. Genetic changes in plants may cause changes in phytochemicals released into the soil. This in turn may change the chemical and biological properties of the soil.

versus exposure to stressors that cause mutations. Some may also consider IM compatible with organic production.

Impact: If the NOSB recommends that IM is not an excluded method and does not add any additional restrictions on seed produced using IM, the status quo would continue. Seeds produced using IM are understood to be in use currently, and certified operations and certifiers would continue with current processes for verifying that organic crops, livestock, and products are produced without excluded methods. There would not be any disruptions to the availability of plant genetics, livestock feed additives, or organic product ingredients. Harmful chemicals and other techniques used in IM would remain in use, and there would continue to be no consumer-facing label that indicates crops and food products are produced without IM. Consumers would retain access to organically produced versions of popular crop varieties that are the products of IM.

3. NOSB recommends that IM is **not** an excluded method, but should be restricted in some manner

Regardless of whether IM is or is not an excluded method, there remains significant concern among NOSB members and the organic community around the use of toxic chemicals and radiation as a plant breeding technique used in organic production. These harmful substances are clearly not allowed for use on organic farms or in contact with organic products, and it is warranted to consider how the organic regulations could restrict the use of these techniques if they are not determined to be excluded methods. A number of the possible approaches to restricting seed varieties that are the product of IM are detailed below:

a. "Positive" list that includes all allowed seed varieties

The NOSB or NOP could maintain a "positive" list that includes all seed varieties allowed in organic agriculture. It would have the advantage of specificity and avoiding the problem that a disallowed variety might elude discovery simply by being renamed. However, it would be highly restrictive and might not include many valuable varieties. Many farmers are in the process of creating their own highly adapted varieties, and a positive list would put these efforts in jeopardy. However, if they could verify that their breeding lines are all from approved variety sources, they could still comply. In this case, they would be considered breeders as well as crop producers.

b. "Negative" list that includes all varieties disallowed

The NOSB or NOP could maintain a "negative" list that identifies all seed varieties disallowed in organic agriculture. This approach would allow farmers more freedom to choose varieties, but would be subject to the problem of incompleteness. If a variety was determined to be disallowed after the list had been in use for several years, organic breeding and crop production based on it would be disrupted. It would also be challenging to keep such a list current, as new varieties are developed.

c. Grandfathered list that freezes time

The NOSB could recommend grandfathering of IM-derived varieties currently in use, but prohibiting any new varieties produced by IM in the future. Presumably, this would require dropping any of the current IM-derived varieties from organic breeding programs. This approach would require a list similar to the

ones described above, with a listing of all IM-derived varieties for use by breeders, and a subset of conventional IM-derived varieties released after the rule came into effect, to be used by producers and certifiers. A determination would need to be made regarding how far back in lineage it is necessary to look for use of IM.

d. Limiting, but not prohibiting, IM in organic crop production

IM could be prohibited in organic plant breeding and organic seed propagation, while being allowed in organic crop production via the use of untreated, non-organic seed when organic seed is not commercially available. The use of such non-organic seed is meant to be reduced over time.

This approach is supported by the International Federation of Organic Agriculture Movements (IFOAM) in their Compatibility of Breeding Techniques in Organic Systems Position Paper. In it, they say that IM should be phased out of organic seed breeding, and that IM varieties have been “tolerated” in organic production thus far. They note that IM is currently not used in animal breeding. They further say:

A positive list of organic varieties and breeds should be built and maintained on an ongoing basis, with a corresponding body established for this purpose. Said body can also list acceptable varieties/breeds that have not yet been bred under organic conditions and suggest control protocols.

Discussion of potential approaches to restriction

The European Union already has a list of crop varieties allowed for commercial production, so creating a smaller list of varieties allowed in organic production is not too difficult. There is no such list in the U.S., and cogent reasons for this to continue. This makes creating a U.S. list of allowed organic varieties problematic. The U.S. has many crop varieties, and it would be a significant effort to identify and include them all. The onus might best be placed on seed companies to submit verification information to a material review organization for inclusion on the list. It is possible that sophisticated genetic methods can be used to trace specific gene-trait combinations and identify IM-derived varieties. Some of this information may be recorded in patent applications.

It would be challenging to maintain seed lists, and it is not clear who else could host, maintain, or pay for such a list. Fees for inclusion on a positive list, paid for by seed companies and breeders, could potentially contribute to covering the costs.

If IM-derived varieties were allowed for organic production but not for organic seed, it may set a precedent for other unrelated decisions. It may also provide both an incentive and a disincentive for farmers to use organic seed. The incentive value could be from either better performance¹⁷ from the organic seed, or a recognition by consumers that the farmer is strictly adhering to organic principles. It is

¹⁷ Non-IM varieties may be free of yield drag or depression caused by deleterious genes carried through from the IM process. However, under high fertility conditions, IM-derived varieties might benefit if the IM process had made ecosystem-fitting pathways inoperative; i.e. not fixing as much N as a wild type, thus saving energy for growth. Research is needed on these questions.

not clear whether either of these will apply in practice. The disincentive would be loss of specific valuable varieties from use, and lack of these crops in the organic marketplace.

Under a grandfathering approach, organic producers could lose opportunities to adapt to changing environmental conditions in the future and adopt other innovations in seed. However, over the long run, if use of organic seed increases, IM-derived varieties would be phased out of organic production. Ideally, IM decisions should dovetail with provisions encouraging more use of organic seed.

Questions for Stakeholders

1. If you believe IM is an excluded method, please describe **how it meets all 3 prongs** of the excluded methods definition.
2. If you believe IM is not an excluded method, please describe **which prong(s) of the excluded methods definition it does not meet.**
3. Is a list of allowed or disallowed varieties feasible? Why?
4. What other specific approaches could be used to balance the competing goals of reducing the use of harmful chemicals in the seed supply chain and keeping a wide range of seed varieties available to organic producers and organic consumers?
5. How can the approach to IM be dovetailed with increased use of organic seed?
6. What feedback do you have on the process and approach that the NOSB is taking on considering IM? Would you make any adjustments to this process for the NOSB to use in considering the TBD list?

Subcommittee Vote

Motion to accept the discussion document on induced mutagenesis.

Motion by: Brian Caldwell

Seconded by: Franklin Quarcoo

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2