

Formal Recommendation
From: The National Organic Standards Board (NOSB)
To: The National Organic Program (NOP)

Date: April 28, 2022

Subject: Excluded Methods Determinations

NOSB Chair: Nate Powell-Palm

The NOSB hereby recommends to the NOP the following:

Guidance Statement: X

Statement of the Recommendation:

The NOSB recommends the NOP develop a formal guidance document codified in the NOP Handbook, on the definitions, criteria, excluded, and allowed methods tables developed by this and preceding National Organic Standards Boards. In the Spring of 2022, the NOSB recommended adding cell and protoplast fusion to the excluded methods table. In the allowed methods table, the NOSB recommends an exception for when either technique is employed using donor and recipient cells within the same taxonomic plant families.

Rationale Supporting Recommendation:

The USDA organic regulations at 7 CFR 205.105(e) prohibit the use of excluded methods in organic production and handling. Beginning in 2016, the Board has produced definitions, criteria, and an extensive list of excluded and allowed methods in order to clarify the rapidly developing technologies that fall under the Excluded Methods provisions in terms defined. As per § 205.2, “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.” Cell Fusion is specifically listed as an example of an excluded methods at terms defined.

Cell and Protoplast Fusion are further clarified in NOP Policy Memo 13-1. Policy Memo 13-1 explains that certain traditional breeding techniques involving cell fusion should not be considered excluded methods, while those cell fusion techniques that involve recombinant DNA technology or cell fusion of plant cells from different taxonomic families are prohibited for use in organic production. Policy Memo 13-1 goes on to include protoplast fusion in the conclusions around when either is excluded or allowed.

Stakeholders were unanimous in support of this proposal. Commenters included, but were not limited to the Center for Food Safety, Friends of the Earth, National Organic Coalition, the Organic Trade Association, Organic Farmers Association, Organic Produce Wholesalers Coalition, Organic Seed Association, Bejo Seeds, Vitalis Seeds and Beyond Pesticides. One trade group supported the language of the proposal as written; most other sectors of the community suggested a technical correction to the language.

Due to the ubiquitous nature of stakeholder feedback, the Materials Subcommittee requested the NOP review the suggested language change. The NOP determined that the change is viewed as a technical correction, not a substantive change, and the NOSB voted unanimously at the Spring 2022 meeting to approve the proposal with the technical correction. Language from the original proposal and the technical correction are included below.

NOSB Vote:

Motion to accept the proposal on excluded methods determinations for cell and protoplast fusion. The NOSB recommends the NOP develop a formal guidance document to include the above definitions, criteria, excluded, and allowed methods tables as developed by previous Board proposals beginning in 2016, with the addition of the following:

1. Cell Fusion
 - The NOSB recommends the NOP add Cell Fusion to the table of Excluded Methods when the donor and the recipient cells are outside taxonomic plant families and/or when either is derived using techniques **of in vitro nucleic acid technologies** ~~of recombinant DNA technology~~; with notes on the exception for use when donor and recipient cells are within the same taxonomic plant families.
 - The NOSB recommends that Cell Fusion be added to the table of Allowed Methods with notes limiting the use to when the donor and recipient cells are within taxonomic plant families, and neither are derived from **in vitro nucleic acid technologies**. ~~techniques of recombinant DNA technology~~.
2. Protoplast Fusion
 - The NOSB recommends the NOP add Protoplast Fusion to the table of Excluded Methods, when either the donor or the recipient cells are outside taxonomic plant families and/or when either is derived using techniques **of in vitro nucleic acid technologies** ~~of recombinant DNA technology~~; with notes on the exception for use when donor and/or recipient cells are within the same taxonomic plant families.
 - The NOSB recommends that Protoplast Fusion be added to the table of Allowed Methods with notes limiting the use to when the donor and recipient cells are within taxonomic plant families, and neither are derived from **in vitro nucleic acid technologies**. ~~techniques of recombinant DNA technology~~.

Motion by: Mindee Jeffery

Second: Logan Petrey

Yes: 15 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Motion Passed

**National Organic Standards Board
Materials/GMO Subcommittee
Excluded Methods Determinations Proposal Spring 2022
February 8, 2022**

Introduction and background

At the November 18, 2016, in-person National Organic Standards Board (NOSB) meeting, the NOSB recommended that the National Organic Program (NOP) develop a formal guidance document for the determination and listing of excluded methods. The 2016 recommendation, entitled “Excluded Methods Terminology,” clarifies excluded method definitions and criteria in response to the increasing diversity in the types of genetic manipulations performed on seed, livestock, and other biologically based resources used in agriculture. Genetic engineering is a rapidly expanding field in science. To be responsive to this rapid expansion, the NOSB will continue to list new methods for review and will determine over time if the methods are or are not acceptable in organic agriculture. In addition to the 2016 recommendation, a discussion document provided a “To Be Determined (TBD) list” of technologies needing further review to determine if they should be classified as excluded methods or not; this proposal continues the work established in 2016. The organic community, as well as the NOSB, has voiced a consistent, unanimous stance that direct manipulation of genes through in vitro nucleic acid techniques should be considered as excluded methods.

Cell Fusion is listed specifically in the regulations under (7 CFR 205.2) under terms defined as an excluded method. In 2013, Policy Memo 13-1 clarified cell and protoplast fusion as mimicking natural phenomenon with the limiting factor of [use when the original cells are within the same taxonomic plant family. In the October 2021 NOSB meeting, the Board put forth a discussion document to clarify whether cell and protoplast fusion are excluded methods when the techniques are employed within taxonomic plant families. Note that in recent years, protoplast fusion is the scientifically preferred term for cell fusion as used in plant breeding. This document will continue to distinguish them as is necessary for the purpose of clarity.

Goals of this proposal/document

At the October 2021 NOSB meeting, a discussion document was presented for public comment for the two items covered in this proposal: cell fusion and protoplast fusion. This proposal addresses these two items which have remained on the TBD list, despite cell fusion’s appearance in terms defined, and the clarification in Policy Memo 13-1. This Proposal seeks to clarify the position of cell and protoplast fusion, taking into consideration all previous NOSB work on the topic and current public comments.

Public comment at numerous NOSB meetings over the years continues to stress the view that technologies used to manipulate the genetic code in a manner that is outside traditional plant and animal breeding should remain prohibited in organic production. Among organic stakeholders, there is a strong belief that 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. This document represents the continuing work of the NOSB to clarify which methods in the expanding field of genetic engineering can or cannot be used under the USDA organic seal.

The Materials Subcommittee recognizes the topic of genetic engineering and evaluation of excluded methods will remain on our work agenda to determine if emerging technologies do or do not meet our current definitions. We may need to incorporate additional criteria to evaluate new and unique technologies as they become commercially available as potential inputs to organic supply chains.

The NOSB is aware that specific laboratory tests may not be available to detect the presence of excluded methods in organic systems and will continue to emphasize the power of this process based, systems approach to evaluating agriculture and food processing. Until such a time as higher regulatory authorities provide organic systems with definitions and transparency of methodologies organic systems view as prohibited, the Materials Subcommittee will continue to evaluate, define, and assist organic stakeholders in determining the presence of excluded methods in organic systems as they emerge.

Definitions and Criteria

Under the National Organic Program organic regulations, methods that employ genetic engineering techniques are excluded from use in organic production. The current regulation (7 CFR 205.2 Terms defined) defines an excluded method 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.

The NOSB previously recommended the use of the following definitions to determine whether or not a method should be/is excluded.

Genetic engineering (GE) – 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.

Genetically Modified Organism (GMO) – A plant, animal, or organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources. (Modified slightly from IFOAM Position)

Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. (From Codex Alimentarius)

Synthetic Biology – A further development and new dimension of modern biotechnology that combines science, technology, and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity)

Non-GMO – The term used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with process-based standards of the NOP where preventive practices and procedures are in place to prevent GMO contamination while recognizing the possibility of inadvertent presence.

Classical/Traditional plant breeding – Classical (also known as traditional) plant breeding relies on phenotypic selection, field-based testing, and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include the following: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.

Criteria

Below are the criteria listed in the 2016, 2017, 2018 and 2019 NOSB recommendations to determine if methods should be excluded.

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 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.

Excluded Methods:

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Targeted genetic modification (TagMo) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	Sequence-specific nucleases (SSNs) Meganucleases Zinc finger nuclease (ZFN) Mutagenesis via Oligonucleotides CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes TALENs (Transcription activator-like effector nucleases) Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System	YES	1, 3, 4	Most of these new techniques are not regulated by USDA and are currently difficult to determine through testing.
Gene Silencing	RNA-dependent DNA methylation (RdDM) Silencing via RNAi pathway RNAi pesticides	YES	1, 2, 4	
Accelerated plant breeding techniques	Reverse Breeding Genome Elimination FasTrack Fast flowering	YES	1, 2, 4	These may pose an enforcement problem for organics because they are not detectable in tests.
Synthetic Biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and systems	YES	1, 3, 4	
Cloned animals and offspring	Somatic nuclear transfer	YES	1, 3	
Plastid transformation		YES	1, 3, 4	
Cisgenesis	The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.	YES	1, 3, 4	Even though the genetic manipulation may be within the same species, this method of gene insertion can create characteristics that are not possible within that individual with natural processes; it can have unintended consequences.

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Intragenesis	The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant.	YES	1, 3, 4	Even though the genetic manipulation may be within the same species, this method of gene rearrangement can create characteristics that are not possible within that individual with natural processes; it can have unintended consequences.
Agro-infiltration		YES	1, 3, 4	<i>In vitro</i> nucleic acids are introduced to plant leaves to be infiltrated into them. The resulting plants could not have been achieved through natural processes and are a manipulation of the genetic code within the nucleus of the organism.
Transposons- Developed via use of in vitro nucleic acid techniques		YES	1,3,4	Does not include transposons developed through environmental stress such as heat, drought or cold.
Induced Mutagenesis		YES	1	Developed through in vitro nucleic acid techniques does not include mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress-causing activities.
Cell and Protoplast Fusion	donor and/or recipient cells are outside taxonomic plant family; and/or recombinant DNA technology is employed	YES	Terms Defined 205.2	See NOP Policy Memo 13-1.

Methods Allowed:

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Marker Assisted Selection		NO		
Transduction		NO		
Embryo rescue in plants		NO		IFOAM's 2018 position paper on Techniques in Organic Systems considers this technique compatible with organic systems.
Embryo transfer, or embryo rescue, in animals		NO		*Use of hormones not allowed in recipient animals.
Transposons		NO		Developed through environmental stress, such as heat, drought, or cold.
Cell and Protoplast Fusion	Recipient and/or donor cells are within the same taxonomic plant family; must be achieved without recombinant DNA technology	NO		NOP Policy Memo 13-1; Definition of Modern Biotechnology

TBD list:

Terminology				
Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
TILLING	Eco-TILLING	TBD		Stands for “Targeted Induced Local Lesions in Genomes.” It is a type of mutagenesis.
Doubled Haploid Technology (DHT)		TBD		There are several ways to make double haploids, and some do not involve genetic engineering while some do. It is difficult or impossible to detect DHT with tests.
Induced Mutagenesis		TBD		Induced mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress.
Transposons		TBD		Produced from chemicals, ultraviolet radiation, or other synthetic activities.

Discussion and Public Comment

Under the NOP organic regulation, cell fusion is, by definition, an excluded method at §205.2. In 2013, NOP Policy Memo 13-1 provided further context for the use of cell fusion which included protoplast fusion. Both were deemed by the Policy Memo to be excluded methods except when either technique was employed within taxonomic plant families. The Policy Memo defends this assertion that this limited use mimics natural phenomena and is therefore allowed. In response to the 2021 Discussion document on this subject, a stakeholder provided historical context that indicates the NOSB’s support for the Policy memo:

“At the time the policy memo 13-1 came out, the NOSB was just starting to work on Excluded methods and there was a lot of controversy over the memo. That has since died down, and the definition of “Modern Biotechnology” that was adopted in the 2016 recommendation essentially codifies the approach in that memo by citing the international definitions that allow it within plant families.”

Furthermore, in February 2013, the NOSB Discussion Document on Excluded Methods Terminology references the Policy Memo explaining “that cell fusion techniques are considered an ‘excluded method’ when the donor cells/protoplasts do not fall within the same taxonomic family. Cell fusion is also an ‘excluded method’ when the donor or recipient organism is derived using techniques of recombinant DNA technology and techniques involving the direct introduction into the organism of hereditary materials prepared outside of the organism.”

As the NOSB continued its work around issues of Excluded Methods, both cell fusion and protoplast fusion were included on a list of techniques that needed consideration for allowance/prohibition (see Appendix for NOSB Proposal and Discussion Document April 2016). The TBD list included cell fusion with the note column giving the explanation “[s]ubject of an NOP memo in 2013. The Crops Subcommittee will continue to explore the issue.” Protoplast fusion was included in the TBD list with the note “[t]here are many ways to achieve protoplast fusion, and until the criteria about cell wall integrity are discussed and developed, these technologies cannot yet be evaluated.”

In the Fall 2021 Discussion Document preceding this proposal, stakeholders were asked if additional criteria for excluded methods determinations are necessary before work on the remaining terms can be addressed as indicated in the TBD list notes. Stakeholders were also asked if Policy Memo 13-1 is complete and being applied consistently in organic systems. These questions were intended to establish whether the conversation around cell and protoplast fusion is complete or if more discussion is needed.

In response, except for consistent suggestions for an edit to the language of the first criteria for scientific accuracy, stakeholders expressed overwhelming support for the criteria developed for evaluating Excluded Methods as they stand. One commenter captured the tone of many with the following assertion:

“We do not support or see a need for additional criteria for excluded methods determinations at this time. It is imperative to the integrity of the NOSB’s process that the same criteria be applied to all methods that have been reviewed and those still under review by the NOSB.....[i]t is important to first recognize that cell fusion is already clearly listed as an excluded method per the regulatory definition (7 CFR 205.2). What the NOP Policy Memo 13-1 deems an allowable method is cell fusion and protoplast fusion within taxonomic plant families. “Cell fusion and protoplast fusion within the same taxonomic family” should be moved to the list of methods determined to NOT be excluded. This is consistent with Policy Memo 13-1 and clarifies that this method – again, when employed within taxonomic families – is viewed as traditional plant breeding and not genetic engineering.”

Stakeholders were consistent in response to the Policy Memo 13-1, asserting that the regulatory definition in conjunction with the Policy memo provide necessary clarity. The subcommittee appreciates that public comments were united and practical. One commenter reflected:

“...organic plant breeders, organic seed companies, organic growers, and organic certifiers find Policy Memo 13-1 remains an important touchstone for guiding their decisions. Upholding Policy Memo 13-1 is essential to the success of organic operations, especially when considering the extensive use of cell fusion and protoplast fusion within taxonomic plant families”

Additionally, an organic seed producer provided the following:

“...Policy Memo 13-1 adequately defines the instances under which cell fusion and protoplast fusion can be used in organic and ties the logic directly to the first sentence of the Regulatory definition of an ‘excluded method’ wherein methods which could be achieved in nature are compatible with organic production; also, the third sentence of the definition wherein traditional breeding and hybridization are listed allowable.

*We would prefer that these methods be moved to the *Excluded Methods -NO - List with a note that ‘Except when used outside of taxonomic plant families’. If kept on the Excluded Methods -YES -list, with the note ‘Except when employed within taxonomic plant families’ we would then prefer that the above mentioned (*) of NO list also be honored in order to clearly define and underscore that certain usages of cell fusion and protoplast fusion, in cases within taxonomic plant families, are acceptable for on farm use.*

For the sake of discussion, we would further raise the idea of updating the Guidance table on Excluded Methods to be renamed Allowed Methods or similar positive prose.”

The Materials Subcommittee did not see the need to address issues of phasing out the use of either cell or protoplast fusion at this time, for these specific techniques. The policy memo was established in 2013 and public comment expressed overwhelming support for the forward motion of this proposal as a validation of long-standing NOP Policy and the will of previous NOSB decision making on excluded methods.

Subcommittee Vote:

Motion to accept the proposal on excluded methods determinations for cell and protoplast fusion. The NOSB recommends the NOP develop a formal Guidance document to include the above Definitions, Criteria, Excluded and Allowed Methods tables as developed by previous Board Proposals in 2016, with the addition of the following:

1. Cell Fusion
 - The NOSB recommends the NOP add Cell Fusion to the table of Excluded Methods when the donor and the recipient cells are outside taxonomic plant families and/or when either is derived using techniques of recombinant DNA technology; with notes on the exception for use when donor and recipient cells are within the same taxonomic plant families.
 - The NOSB recommends that Cell Fusion be added to the table of Allowed Methods with notes limiting the use to when the donor and recipient cells are within taxonomic plant families, and neither are derived from techniques of recombinant DNA technology.
2. Protoplast Fusion
 - The NOSB recommends the NOP add Protoplast Fusion to the table of Excluded Methods, when either the donor or the recipient cells are outside taxonomic plant families and/or when either is derived using techniques of recombinant DNA technology; with notes on the exception for use when donor and/or recipient cells are within the same taxonomic plant families.
 - The NOSB recommends that Protoplast Fusion be added to the table of Allowed Methods with notes limiting the use to when the donor and recipient cells are within

taxonomic plant families, and neither are derived from techniques of recombinant DNA technology.

Subcommittee Vote:

Motion by: Mindee Jeffery

Second: Logan Petrey

Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB February 15, 2022.