

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

Date: April 26, 2019

Subject: Excluded methods determinations April 2019

NOSB Chair: Harriet Behar

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Statement of the Recommendation:

This recommendation continues the ongoing work to determine whether or not specific technologies should be considered excluded methods using the current regulatory definition of an excluded method and the 2016 NOSB formal recommendation entitled “Excluded Methods Terminology”. This proposal covers various methods that could result in transposons, and provides information on what transposons are as well as further clarification on the definitions of cisgenesis and intragenesis, which were voted as excluded methods at a previous NOSB meeting.

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

One small change was made to the chart within the document, to clarify that “Transposons developed via use of invitro nucleic acid techniques” was the method that should be considered to be excluded. There was no change made to the proposal motion voted out of subcommittee, since that language was already present. This determination is consistent with the NOP final rule and with the NOSB recommendation which helps to determine which technologies should be excluded under the organic label.

NOSB Vote:

Motion to accept the proposal on excluded methods determinations April 2019

Motion by: Harriet Behar

Second: Dave Mortensen

Yes: 14 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Motion Passed

National Organic Standards Board
Materials/GMO Subcommittee Proposal
Excluded Method Determinations April 2019
February 12, 2019

Introduction and background

At the November 18, 2016, in-person 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,” clarified the excluded methods definitions and criteria in response to 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. The NOSB recognizes the need to continually add methods to the list for review and to determine if the methods are or are not acceptable in organic agriculture. In addition to the 2016 recommendation, a [discussion document](#) provided a list of technologies needing further review to determine if they should be classified as excluded methods or not. At the Fall 2017 NOSB in-person meeting, the NOSB passed a [recommendation](#) to add three technologies as excluded methods to the NOP guidance document. In Fall 2018, the NOSB recommended one technology be added to the list of methods that are not to be excluded in organic production.

Goals of this proposal/document

This proposal addresses three more items on the “To Be Determined” list found in the November 2016 discussion document. Using the NOSB’s proposed improved definitions of excluded methods, the NOSB Materials Subcommittee has clarified what type of technologies used to cause transposons should be excluded methods in organic agriculture and what type of activity should not be excluded.

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 all of the 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.

Criteria

Below are the criteria listed in the previous 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.

The NOSB has voted and determined these to be 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	<ul style="list-style-type: none"> • 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 and can have unintended consequences.
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 and 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.

The following genetic engineering methods were found by the NOSB NOT to be excluded methods.

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.

Discussion

The Materials Subcommittee recognizes the topic of genetic engineering and evaluation of excluded methods will remain on our work agenda to determine if new technologies do or do not meet our current definitions. We may also need to incorporate additional criteria to evaluate new and unique technologies.

We are aware that specific laboratory tests are not currently available to detect the use of several new excluded genetic modification technologies in organisms. However, we still believe that the technology should be listed as an excluded method, when appropriate, and anticipate tests or other methods will be developed over time to detect the presence of these technologies. The Materials Subcommittee may put forward another discussion document in the future to aid the NOP in determining how to enforce this prohibition when there is no means to detect an excluded method that may have been used in production.

In the Fall 2018 discussion document, there were descriptions assigned to both cisgenesis and intragenesis. These descriptions are still valid, and in this document we would like to add the following to further clarify these two technologies. There is no further clarification for agroinfiltration proposed.

- 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.
- 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.

The following methods will continue to be researched in future NOSB proposals.

Terminology				
Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Protoplast Fusion		<i>TBD</i>		There 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.
Cell Fusion within Plant Family		<i>TBD</i>		Subject of an NOP memo in 2013. The Crops Subcommittee will continue to explore the issue of detection and testing.
TILLING	Eco-TILLING	<i>TBD</i>		Stands for “Targeted Induced Local Lesions In Genomes.” It is a type of mutagenesis combined with a new screening procedure.

Doubled Haploid Technology (DHT)		<i>TBD</i>		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		<i>TBD</i>		This is a very broad term and needs to be classified based on what induces the mutations, such as chemicals, radiation, or other stresses.
Transposons		<i>TBD</i>		Produced from chemicals, ultraviolet radiation, or other synthetic activities considered to be a method of “induced mutagenesis”
Embryo transfer in animals	Embryo rescue in animals	<i>TBD</i>		FiBL distinguishes embryo rescue in plants from animals. A technique used in animal breeding, FiBL involves inducing superovulation of the donor with gonadotropins (glycoprotein polypeptide hormones), artificial insemination, recovery of embryos, isolation and storage of embryos, and transfer of embryos into an animal, which results in a pregnancy and hopefully a birth of a live animal at maturity. More research is needed to clarify if use of hormones is essential to this technique.

Transposons

- Transposons are jumping genes that can occur in nature and are responsible for mutations through mobile genetic elements. Transposon activity can be modified through stress or genetic engineering to increase mutation rates. Changes or mismatches to the individual nucleotides occurs, altering the cell’s genetic identity and genome size. When the transposon cleaves from its original location to another location, there is also a change to the genetic makeup at the site where it no longer resides.
- Transposons are responsible for mutations when moving around within a genome. Various forms of environmental stress, such as heat, cold or drought, as well as stress caused by chemicals or exposure to irradiation, can increase the movement of naturally occurring transposons which then results in higher mutation rates.
- Transposons can also be developed in a laboratory using in vitro nucleic acid techniques to then be introduced into plants or animals.
- IFOAM’s 2018 position paper on Techniques in Organic Systems considers transposons caused by physical stress to be compatible with organic systems.
- Transposons, when produced from chemicals, ultraviolet radiation, or other synthetic methods, are considered to be a method of “induced mutagenesis”. Further research and discussion are needed to determine if induced mutagenesis methods, both those that are random or targeted, should be considered excluded from organic production, or not.

The method below has been determined to be an excluded method based upon the criteria listed above.

Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Transposons developed via use of invitro nucleic acid techniques		YES	1, 3, 4	Developed via use of in vitro nucleic acid techniques

~~The method below has been determined to **not** be an excluded method based upon the criteria listed above.~~

Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Transposons		NO		Developed through environmental stress, such as heat, drought, or cold

The method below needs further review.

Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Transposons		TBD		Produced from chemicals, ultraviolet radiation, or other synthetic activities considered to be a method of "induced mutagenesis"

Future Work on this Topic

The Materials Subcommittee has developed a discussion document for the April 2019 NOSB meeting to encourage public input on embryo transfer in animals and the various methods of induced mutagenesis.

Subcommittee Proposal

The NOSB recommends the NOP add the following to the table of excluded methods, in NOP excluded methods guidance.

- 1. Transposons - Developed via use of in vitro nucleic acid techniques.**

The NOSB recommends the NOP add the following to the table of "not excluded" methods, in NOP

excluded methods guidance.

2. **Transposons - Developed through environmental stress, such as heat, drought or cold.**
3. **Add these two definitions to the excluded methods terminology chart for Cisgenesis and Intragenesis**
 - 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.
 - 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.

Subcommittee Vote

Motion to accept the proposal on excluded methods determinations April 2019

Motion by: Harriet Behar

Second: Dave Mortensen

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

Approved by Emily Oakley, Materials Subcommittee Chair, to transmit to NOSB February 13, 2019