

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

Date: October 25, 2019

Subject: Excluded Methods Determinations - Induced Mutagenesis and Embryo Transfer

NOSB Chair: Harriet Behar

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement: X

Other:

Statement of the Recommendation:

The NOSB recommends that induced mutagenesis be considered an excluded method and therefore be prohibited in organic production. Additionally, the NOSB determined that embryo transfer in animals does not qualify as an excluded method and therefore would not be excluded in organic production. Numerous public commenters reinforced the statement in the proposal, that eggs or sperm from cloned animals are not allowed when using embryo transfer methods.

This recommendation to the National Organic Program is a continuation of the NOSB's review of various technologies and methods to determine if these methods should be considered an excluded method. The NOSB's recommendation of 2016 on this same subject clarified the definition and terminologies used in the expanding field of genetic engineering. In order to clarify what is allowed and what is not under the National Organic Program regulations, current and future NOSB's are providing proposals to the NOP on specific technologies and whether they should be excluded from organic production.

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

Two methods were discussed and voted upon in this proposal. Induced mutagenesis through invitro nucleic techniques and embryo transfer in animals. The induced mutagenesis method was found to meet the definition of an excluded method, and the embryo transfer in animals did not. Public commenters supported the NOSB's recommendation, and reinforced the statement in the proposal that eggs or sperm from cloned animals are not allowed when using embryo transfer methods.

NOSB Vote:

Motion to accept the proposal on excluded methods determinations October 2019 -
Induced Mutagenesis and Embryo Transfer

Motion by: Harriet Behar

Second: Dan Seitz

Yes: 13 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Outcome: Motion Passed

National Organic Standards Board
Materials/GMO Subcommittee Proposal
Excluded Methods Determinations October 2019
August 13, 2019

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 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. In April 2019, one more method was added to the list of methods to be excluded. The organic community, as well as the NOSB, has voiced a consistent stance that direct manipulation of genes through in vitro nucleic acid techniques should be considered an excluded method. This would include gene editing techniques such as CRISPR, which was determined to be an excluded method by the NOSB in November 2016. The NOSB will continue to review and determine various methods and technologies to provide clarity to the organic community on which methods could be allowed and which ones are excluded.

Goals of this proposal/document

This proposal addresses two more items on the “To Be Determined” list found in the November 2016 discussion document. At the April 2019 NOSB meeting, a discussion document was presented for public comment for the two items covered in this proposal: induced mutagenesis and embryo transfer in livestock.

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 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.

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 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.

Below are the criteria listed in the 2016, 2017, 2018 and 2019 NOSB recommendations to determine if methods should be excluded. The table includes the NOSB vote in April 2019, to add transposons developed via use of in vitro nucleic acid techniques as an excluded method.

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	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.
Transposons- Developed via use of <i>in vitro</i> nucleic acid techniques		YES	1,3,4	Does not include transposons developed through environmental stress such as heat, drought or cold.

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.

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
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
TILLING	Eco-TILLING	<i>TBD</i>		Stands for “Targeted Induced Local Lesions In Genomes.” It is a type of mutagenesis
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
Induced Mutagenesis		<i>TBD</i>		Induced mutagenesis developed through exposure to UV light, chemicals, irradiation or other stress
Transposons		<i>TBD</i>		Produced from chemicals, ultraviolet radiation, or other synthetic activities

Discussion and Public Comment

Induced Mutagenesis

The April 2019 NOSB discussion document covered a variety of methods that could result in induced mutagenesis. Public comment overwhelmingly stated that environmental or other stresses that induce mutagenesis need more deliberate discussion. Impact on current plant breeding methods needs to be carefully considered, as well as consistency with what is allowed and not allowed, in organic agriculture. Having clear definitions and accessibility in determining which items may or may not have been developed through stress induced mutagenesis is needed to provide seed breeders and companies, certifiers, and producers the information they need to meet any possible restrictions discussed in the future.

However, it was clear that induced mutagenesis developed through in vitro nucleic acid techniques meets the criteria to be determined as an excluded method. Information is accessible in the marketplace to determine if the induced mutagenesis was produced through this method. This proposal adds this type of in vitro nucleic acid technique induced mutagenesis to the excluded

method table and keeps induced mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress-causing activities on the “To Be Determined” list for future discussion and review.

Embryo transfer, or embryo rescue, in animals

This technique used in animal breeding, involves inducing superovulation of the donor animal with gonadotropins (glycoprotein polypeptide hormones), artificial insemination of the donor animal, recovery of embryos from the donor, isolation and storage of embryos, and transfer of embryos into a recipient animal (either with or without hormones to synchronize estrus), which results in a pregnancy and hopefully a birth of a live animal at maturity. Many organic certifiers stated they currently allow this method of embryo transfer in organic agriculture. In nonorganic agriculture, the recipient animal may also be given hormones to improve the success of the embryo transfer, but no organic certifiers allowed the use of these hormones in the recipient animal to synchronize estrus.

In response to the question of whether this technique might narrow the genetic pool in livestock, commenters were sympathetic to this concern but felt that organic farmers would be careful in choosing embryos that would result in genetic diversity in their livestock. There were no concerns expressed for the health of the nonorganic donor animal after repeated use of hormones to produce multiple embryos, nor possible future health issues in the animals grown from those embryos. While embryo transfer was not found to be a necessary method by the public, numerous commenters stated it is a useful tool that should be allowed.

Future Work on this Topic

The NOSB encourages the public to continue the dialogue on the various methods that cause induced mutagenesis and provide information on which methods, chemical, UV light, irradiation, or others should or should not be considered excluded for organic production.

Subcommittee Proposal

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

1. Induced mutagenesis - 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 the NOP excluded methods guidance:

2. Embryo transfer, or embryo rescue, in animals. Use of hormones not allowed in recipient animals.

Subcommittee Vote:

Motion to accept the proposal on excluded methods determinations October 2019

Motion by: Harriet Behar

Second: Dan Seitz

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

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