

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

**National Organic Standards Board
Materials Subcommittee Proposal
Genetic Integrity Transparency of Seed Grown on Organic Land - Instructions to Certifiers
August 13, 2019**

I INTRODUCTION

The USDA National Organic Program (NOP) regulations do not allow the use of materials developed using “excluded methods” in certified organic production. The USDA defines “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...” (7 CFR 205.2). These organisms include, but are not limited to, seed, bacteria, insects, animals and vaccines. According to the most [recent National Agricultural Statistics Survey](#) (NASS), at least 94% of soybeans, 92% of corn, 94% of cotton, 75% of Hawaiian papaya, 98% of sugar beets, and 90% of canola are genetically engineered. This proposal will address seed planted on organic land that may have a Genetically Engineered (GE) equivalent.

II BACKGROUND

The National Organic Standards Board (NOSB), in separate recommendations in [2016](#), [2017](#), [2018](#), and [2019](#), defined terms used when describing gene altering technologies and the subset of those methods deemed to be excluded methods. This list is continually under review, with new methods being added periodically. The list of those excluded methods are as follows:

- 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
- RNA-dependent DNA methylation (RdDM)
- Silencing via RNAi pathway RNAi pesticides
- Reverse breeding
- Genome elimination
- FasTrack
- Fast flowering
- Creating new DNA sequences
- Synthetic chromosomes
- Engineered biological functions and systems
- Somatic nuclear transfer
- Plastid transformation
- Cisgenesis
- Intragenesis
- Agro-infiltration
- Transposons-Developed via use of in vitro nucleic acid techniques

Currently in the U.S., testing is not required to verify if seeds planted on organically certified farms were

produced using an excluded method. Organic farmers plant both organic and non-organic seed (when the organic seed is not commercially available in the form, variety, or quantity required). Some, but not all, certification agencies perform genetically engineered (GE) testing on a farmer client's harvested crop. Proposed here is an additional step; certifiers should recommend that their farmers request information on any GE testing performed on seed they may purchase.

To meet the current certification standard, farmers are required to provide documentation that the seed they plant was not produced using excluded methods. This standard is met in one of two ways. 1) Certified organic seed breeding companies must verify excluded methods were not used in the production of certified organic seed. 2) For non-organic seed, a non-GE affidavit is required if the crop has a genetically engineered equivalent in the marketplace. Affidavits typically state "to the best of the seed supplier's knowledge, the seed was not produced using excluded methods"; however, the affidavit does not address the issue of possible contamination of the seed lot with seed produced using excluded methods. The *intentional* use of seed produced by an excluded method is prohibited. Non-GE affidavits have been accepted as proof by organic certifiers that the seed is acceptable in organic systems.

In a previous discussion document the Material's Subcommittee discussed a proposed requirement that all field corn seed planted on organic land be accompanied by a statement detailing any presence of GE within specific percentages, such as .1%, .9% etc. levels. While many farmers, consumers, advocates, and certifiers liked the transparency this would have provided, there was significant concern from all groups, especially seed breeders, that there could be unintended negative consequences from this requirement. These potential negative consequences included added cost of disseminating this information, loss of germplasm and seed varieties to organic producers if there is significant presence of GE in the seed, loss of genetic diversity available to organic farmers, and more. This proposal recommends the NOP provide an instruction to certifiers informing producers they can request the results of any testing for presence of genetic engineering in the seeds they purchase.

In the development of this proposal, NOSB members and the public, specifically the Organic Seed Alliance, reached out to numerous suppliers of field corn seed that typically serve the organic market. This includes both organic and nonorganic seed growers. The vast majority of seed suppliers reported that they already test their field corn seed for detectable levels of genetic engineering, and, when asked, are willing to provide this testing information to those who buy their seed.. Most farmers are not aware that this testing is being done, and consequently, most do not currently request this information.

If farmers don't know what they are starting with, it puts them in a compromised position when they sell their crop; after all, they are committed to producing GE-free grains, fruits, and vegetables. On the other hand, the organic marketplace, or the "back end" of the food system, has developed a fairly robust testing protocol for organic foods intended for human consumption as well as livestock feeds. Various tolerance levels of genetic contamination must be met in order to sell into specific markets. Knowing the purity of the seed farmers plant on the "front end" is critically important for several reasons. The level of contamination at the beginning of the season will not decline and can only worsen by cross-pollination and post-harvest seed handling. To meet organic market demand and to provide farmers with what they need to make informed decisions when choosing seeds, transparency of GE contamination levels and the knowledge of the adventitious presence of genetic engineering in their seed has become a necessity.

The NOSB put forth discussion documents and proposals addressing the issue of clarity around genetic purity of the seed supply in 2013, 2014, 2015, 2016, 2017, and 2018. The strong response from the public in the form of many comments clearly demonstrates the importance of this issue for organic farmers,

processors, and consumers.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

Detection and Testing Requirements: Under the NOP residue testing requirements, products from certified organic operations may require testing when there is reason to believe that certified products have come into contact with prohibited substances or have been produced using excluded methods. This requirement is specified in Subpart G (Administrative) of the regulations:

§205.670 Inspection and testing of agricultural product to be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or post-harvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

NOP Policy: The NOP issued a Policy Memo on April 15, 2011 (Policy Memo 11-13) on genetically engineered organisms. The memo clearly states that the use of genetically engineered organisms is prohibited and goes on to address questions that have been raised concerning the use of these organisms and how to minimize their presence in organic production and handling. The memo emphasizes that organic certification is a process-based standard, explaining the presence of detectable GMO residue alone does not necessarily constitute a violation of the regulation.

IV RESPONSE TO PUBLIC COMMENT

Public comment from most seed suppliers and producers, did not favor tolerance levels due to concerns that this approach would narrow the availability of needed crop traits and the overall crop choice. Concern was also raised that strict tolerance levels could result in the unintended consequences such as damage to the growth and integrity of organic agriculture, as well as negative impacts to organic growers and seed breeders. This proposal does not set tolerance levels that could prohibit the planting of seed that exceeds any specific tolerance. Instead, this proposal seeks to encourage certifiers and farmers to seek out the currently available information before planting seed that has a GE equivalent on organic land.

There are no current restrictions that would prevent a farmer from taking a sample of hybrid corn seed (a non-GMO variety) or other seeds they purchase and having them tested for the presence of GE. There are agreements that seed breeders might encounter when purchasing the foundation seed for building their own hybrid varieties that could restrict them from testing that seed for the presence of GE. However, this proposal only requires testing of the seed that would be planted by an organic producer who has no legal impediments to this testing. Farmers would not be required to do GE testing of their seed, but if their seed supplier does not provide GE contamination test results for their seed, this option is open to the farmer.

In addition, it is a good practice for farmers to retain seed samples of seed they plant on organic land, and certifiers can suggest this to farmers as another step in finding the source of GE contamination in case their crop is rejected by a buyer at harvest time.

The previous discussion documents on the issue of genetic integrity transparency of seed, focused only on field corn seed. This proposal addresses all seed or planting stock that has a GE equivalent in the marketplace. There is no specific requirement, other than for certifiers to instruct their clients about the option to request GE contamination test results from their seed and planting stock providers.

The NOSB continues to request that the NOP fund a task force that would collect information on the genetic integrity of seed planted on organic land so the organic community - from farmers to consumers - would have statistical information detailing GE contamination issues. This task force would be empowered to collect data for multiple years, since growing conditions and crop production issues change from year to year, and in order to collect useful information, numerous years and regions must be tracked. We know there are issues with some crops in some regions, but there has not been a comprehensive review of data to provide a clear picture of the problems. Without this information, the organic community cannot develop solutions.

V Proposal

The NOSB recommends the NOP provide an “Instruction to Certifiers”.

The purpose of this instruction is to have certifiers inform their producers that GE contamination of seed or planting stock is being tested regularly by those suppliers who are at risk for GE contamination of their products. Producers are encouraged to discuss GE contamination with suppliers willing to share the results of the GE testing they are currently doing but typically do not disseminate, unless requested by the buyer of the product.

Certifiers should be proactive in encouraging their farmers who grow organic crops according to the USDA organic regulations, and who could be at risk of having crops rejected by their buyers due to presence of GE contamination, to obtain information from their seed or planting stock suppliers about any GE contamination found. Certifiers can request this GE contamination information from their organic producers, and they may choose to maintain that information in the client’s organic certification records. Farmers can then make informed decisions about which seed or planting stock to use based upon the requirements of their buyers and their production situations that may or may not result in GE contamination in their fields. Obtaining this GE contamination information before planting can be beneficial in lessening the risk of significant economic losses due to GE contamination when that crop is sold. The discussion between growers and seed suppliers may also demonstrate there is a demand for seed with low GE contamination levels.

1. In order to aid producers in their goal of low-to-no detection of GE contamination of their organic crops (seed and planting stock) that have GE equivalents in the marketplace, certifiers should provide the following information to their organic farmers:
 - A. Producers who are growing crops from seed or planting stock that could be subject to Genetic Engineering contamination of that seed or planting stock, can contact their suppliers to obtain GE contamination test results.
 - B. The vast majority of seed and planting stock suppliers whose crops have GE equivalent varieties that could cause contamination are already doing GE contamination testing and are supplying information, at the request of the buyer of their seed or planting stock, of any GE contamination and the levels present.
 - C. Certifiers may choose to obtain this information at the organic inspection. If presence of GE

contamination is found on the finished crop by the certifier in their testing program or by a buyer of the finished crop, this seed GE contamination information will be useful in determining the cause of the GE contamination.

- D. Certifiers can inform farmers who wish to test seed they grew or test seed or planting stock they purchased, that they are legally allowed to test for GE contamination. A wide variety of laboratories around the U.S. and the world supply this testing service. This information could be provided to the organic certifier as well.

Subcommittee vote:

Motion to accept the “Genetic Integrity Transparency of Seed Grown on Organic Land Instructions to Certifiers” Proposal

Motion by: Harriet Behar

Seconded by: Dave Mortensen

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

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