National Organic Standards Board
Materials/GMO Subcommittee Proposal
Additional Excluded Methods to be listed in the
National Organic Program Excluded Methods Guidance Document
August 22, 2017

Introduction and background

On November 18, 2016, the NOSB sent a recommendation to the National Organic Program (NOP), recommending the NOP develop a guidance document to improve the definition of excluded methods as applied to the use of genetically engineered materials used in agriculture. This recommendation provided improved definitions and attempts to address the increased diversity in types of genetic manipulations performed on seed, livestock and other inputs used in agriculture. It is understood that genetic engineering is a rapidly expanding field in science at this time, and that the NOSB and the NOP will need to continually review new technologies to determine if they would or would not be acceptable in organic agriculture. In addition to the recommendation passed by the NOSB in November 2016, providing a new framework of definitions for determining a genetic manipulation as an excluded method, there was also a discussion document that listed numerous technologies that needed further review to determine if they were within the definition of prohibited or excluded methods.

Goals of this proposal/document

This proposal for the October 2017 NOSB meeting addresses three of the "To Be Determined" methods listed in the discussion document voted upon in November 2016. Using the NOSB's proposed improved definitions of GE excluded methods, the NOSB Materials Subcommittee was able to determine if certain technologies should be considered an excluded method and therefore the products of these type of technologies would not be allowed in NOP organic agricultural production.

Public comment at numerous NOSB meetings over the years, continues to stress the desire 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.

Criteria

The NOSB previously recommended that biotechnology processes will be reviewed to the following criteria to determine if they are excluded methods:

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 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.

Definitions

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

A. 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.

B. 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.

C. 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.

D. 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

E. 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.

F. 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: 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.

It is this series of definitions and terminology was used to as the basis to determine the status of the many of the previously "To Be Determined" materials.

The NOSB voted on the methods listed below during its April 2016 meeting, and determined these to be excluded methods.

Terminology Chart				
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* TALENs** Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System	YES	1, 3, 4	Most of these new techniques are not regulated by USDA and are hard to test for.
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	YES	1, 3, 4	
Cloned animals and offspring	Somatic nuclear transfer	YES	1, 3	
Plastid Transformation		YES	1, 3, 4	

* CRISPR-Cas = Clustered regularly interspaced short palindromic repeats and associated protein genes.

** TALENs = Transcription activator-like effector nucleases.

The following genetic engineering methods were found to be NOT an excluded method, under the proposed new definitions.

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Marker Assisted Selection		NO		
Transduction		*NO*		

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 into our current definitions in order to evaluate new and unique technologies.

We also understand that many of the new technologies do not lend themselves to testing. . However, we still believe that the technology should be listed as an excluded method. The Materials Subcommittee may put forward another discussion document to aid the NOP in determining how to enforce this prohibition when there is no means to test and prove an excluded method was used in production.

Proposal

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

Terminology				
Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Cisgenesis		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		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	*In vitro* 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 methods will continue to be researched.

Terminology				
Method and synonyms	Types	Excluded	Criteria Used	Notes
Protoplast Fusion		*TBD*		There are many ways to achieve protoplast fusion and until the criteria about cell wall integrity is discussed, these technologies cannot yet be evaluated.
Transposons		*TBD*		Used in animal vaccines. May be excluded in some situations but not others.
Cell Fusion within Plant Family		*TBD*		Subject of an NOP memo in 2013, the issue of detection of these varieties needs to be addressed before further policies can be adopted.
Embryo rescue in plants		*TBD*		Many sources including FiBL[1] think this is not excluded but more study of the methods is
TILLING	Eco-TILLING	*TBD*		Stands for Targeted Induced Local Lesions In Genomes. It is a type of mutagenesis combined with a new screening procedure.

[1] Research Institute of Organic Agriculture (FiBL) http://www.fibl.org/en/switzerland/location-ch.html

Doubled Haploid Technology		*TBD*		There are several ways to make double haploids and some do not involve genetic engineering but some do. Difficult to impossible to find using tests.
Induced Mutagenesis		*TBD*		This is a very broad term and needs to be divided and classified based on what induces the mutations, chemicals, radiation, or other stresses.
Embryo transfer in animals	Embryo rescue in animals	*TBD*		FiBL distinguishes embryo rescue in plants from animals.

Subcommittee Vote:
Motion to accept the two sections of this proposal as stated above.
Motion by: Harriet Behar
Second: Dan Seitz
Yes: 5 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Harriet Behar, Subcommittee Chair, to transmit to NOSB August 22, 2017