

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

**Date:** November 18, 2016

**Subject:** Excluded Methods Terminology Recommendation

**NOSB Chair:** Tracy Favre

**The NOSB hereby recommends to the NOP the following:**

Rulemaking Action:

Guidance Statement: X

Other:

**Statement of the Recommendation:**

The NOSB Materials/GMO subcommittee approves the three sections of this proposal:

1. Approve the definitions of Genetic Engineering (GE), Genetically Modified Organism (GMO), Modern Biotechnology, Synthetic Biology, Non-GMO, and Classical/Traditional Plant Breeding as written above.
2. Approve the Principles and Criteria above that will be used in the evaluation of new technologies and terminologies.
3. Adopt the Terminology chart proposed above and the listings in it as presented, with the removal of the Dupont Seed Production Technology term, recognizing that this will be added to as further deliberations occur in the future.

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

Excluded Methods are prohibited in the USDA organic regulations, but the definition in the regulation that was adopted in 1995 needs updating in light of new technologies and processes. The NOSB recommends that this set of supplemental definitions, criteria for review of new technologies, and terms that are included in the definition of excluded methods, be addressed in guidance on interpreting the excluded methods provision in the regulations.

**NOSB Vote:**

Motion by: Zea Sonnabend

Seconded by: Emily Oakley

Yes: 14 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion Passed

**National Organic Standards Board  
Materials/GMO Subcommittee Proposal  
Excluded Methods Terminology  
August 30, 2016**

## **Introduction and Background**

In April 2013 the project was started to grapple with the definition of "excluded methods" in the USDA organic regulations. This is the definition that appears in the rule (7 CFR 205.2; Terms Defined):

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. 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. (Federal Register / Vol. 65, No. 246 / Thursday, December 21, 2000 / Rules and Regulations p. 80639)

The definition was based on the best efforts of the NOSB in 1995 and has provided adequate guidance to prohibit the use of the most obvious genetically engineered crops such as herbicide-resistant corn and soybeans and Bt cotton, as well as prohibit processing inputs such as genetically engineered yeasts and enzymes. However, this definition is in need of re-examination and updating due to rapid advances in recombinant DNA biotechnology since 1995 that have resulted in gray areas for the organic standards regarding interpretation and enforcement.

In 2011 and 2012 a number of confusing issues came before the NOSB and to the NOP which made it necessary to revisit the definition. These include genetically engineered vaccines for livestock, the use of cell fusion within plant families to create male sterility in brassica hybrids, whether or not GMOs could be used in biodegradable bioplastic mulches, and the question of whether mutated algae might therefore be genetically engineered. The current definition is inadequate to clarify these issues. In the last few years the rise of gene editing with no insertion of foreign DNA, synthetic biology, and the genetically engineered insects that are starting to appear make this effort even more important.

The first NOSB Discussion Document on excluded methods in 2013,<sup>1</sup> discussed each of the terms in the above definition, defined and discussed other terms involved in traditional breeding, such as mutagenesis and conjugation, and brought up new terms that may be considered to be genetic engineering. No conclusions were suggested except that there is a need to do more work on the subject. The discussion questions posed asked commenters to suggest principles on which to base GE distinctions, to offer opinions on what terms were and were not excluded methods, and to bring forward new terms that may need consideration.

The second NOSB discussion document posted in September 2014 and in April 2015<sup>2</sup> analyzed the comments received and proposed several options for an updated definition, and principles and criteria to use when evaluating the various genetic modification issues. Additional terms were collected and the beginnings of some definitions were started. A structure was proposed similar to the one in use by the Research Institute of Organic Agriculture (FiBL) in Europe that involves an itemized chart with a yes/no column where the specific techniques could be itemized and evaluated. The Subcommittee made an informal recommendation, which was not voted upon, that these revisions to the definition and structure

for evaluating techniques be regulated through NOP guidance rather than additional rulemaking. Lastly it was acknowledged that there will be some unresolved issues that will need continued public discussion because they pose enforcement challenges, are totally hidden from view, or not enough is known about them yet.

Both a proposal and a discussion document were posted for the April 2016 NOSB meeting. While comment regarding the approach was generally favorable, there clearly was a need for some refinement of the definitions and criteria. There was also confusion about which techniques were part of the proposal and which remained to be discussed further.

### **Goals of This Proposal/Document**

The need for forward motion on this subject is more pressing every month. The fact that over 1000 pages of scientific references were submitted in public comment, with most of it consisting of research published since the NOSB GMO ad hoc Subcommittee was formed in 2012, indicates that the biotech community is rapidly outpacing any regulatory structure. The U.S. Department of Agriculture (USDA) has already ruled that certain plants produced with novel approaches to genetic manipulation will not be regulated in the United States<sup>3</sup> as genetically modified organisms. It is more imperative than ever that the organic community be very clear about where the line is drawn regarding genetic engineering.

Public Comment from the past two and a half years has indicated strong support for this effort on the whole, although there is not consensus on some details. Every organic stakeholder is clear that genetic engineering is an imminent threat to organic integrity. The NOSB must make, to the extent it can, every effort to protect that integrity. .

The Materials Subcommittee is putting forth a structure for reviewing new technologies, and disseminating the results of the review in a transparent manner. To this end, the proposal portion of this document includes supplements to the definition in the rule based on internationally accepted language, criteria to use in the reviews based on that definition, and a chart of those techniques that are clearly "excluded methods" based on the definition and criteria.

A separate discussion document contains the technologies, terms, and issues that the NOSB has not been able to agree on or on which it does not yet have enough information, or that pose challenges that have not yet been addressed. These items are put forth for discussion to collect further public comment, and will be reviewed at future NOSB meetings.

### **Definitions**

In the previous discussion document the NOSB suggested a couple of possible definitions that would update the text in the rule to be more comprehensive, and also be flexible enough to accommodate future technologies and terms. The Board favors the definitions in use by Codex Alimentarius that were also in the Cartagena Protocol.

During the course of public comment and subsequent discussion, it has become clear that more than one definition is important to the organic community, but that all the terms the NOSB suggests defining here would fall under the Excluded Methods definition in the rule and would not change, but would strengthen that definition. These definitions are to be used in guidance to supplement and update the definition in the regulations, while leaving the rule itself intact. It is important to adopt some definitions that are widely

accepted internationally and thus provide common ground with other countries who are concerned about GMOs in organics.

Based on public comment on the Spring 2016 proposal, we decided to add a definition for classical/traditional plant breeding. Traditional breeding is a term used in the Excluded Methods definition in the rule and is therefore important to clarify. . However because the other definitions and criteria are not unique to plants, we slightly changed the wording so that they are applicable to all organisms.

In October 2015 the International Federation of Organic Agriculture Movements (IFOAM) published a Discussion Paper on a proposed revision to their Position on Genetic Engineering.<sup>45</sup> Since other countries do not use the concept of "Excluded Methods", IFOAM proposed new definitions for three terms: Genetic Engineering (GE), Genetically Modified Organism (GMO), and Synthetic Biology. After examining their definitions, the Materials/GMO Subcommittee (MS) agrees that these three terms are important to define in the guidance it are proposing. However, we do not wish to use the old approach (that IFOAM is still using) of trying to capture all the methods and terms into one definition, in because it will be out of date as soon as the next round of new technologies arrives.

Instead we are proposing that the following definitions of terms and acronyms, with sources, be adopted by the NOSB as Excluded Methods<sup>1</sup>:

**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. (First sentence modified from IFOAM Position cited above)

**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 cited above)

**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<sup>6</sup>)

**Synthetic Biology**<sup>7</sup> – 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<sup>8</sup>)

**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. (Modified based on public comment from Spring 2016 NOSB)

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<sup>1</sup> Both definitions and criteria were worked on in between the Spring and Fall NOSB meetings by an ad hoc group with the following members: Julie Dawson, University of Wisconsin; David Gould, International Federation of Organic Agriculture Movements (IFOAM); Michael Hansen, Consumers Reports; Jaydee Hanson, Center for Food Safety; Kristina Hubbard, Organic Seed Alliance; Melody Meyer, United Natural Foods; James Myers, Oregon State University; Dana Perls, Friends of the Earth; Erica Renaud, Vitalis Organic Seeds; Dan Seitz, National Organic Standards Board (NOSB); Michael Sligh, Rural Advancement Fund International; Zea Sonnabend, Fruitilicious Farm and NOSB; Jim Thomas, ETC Group; William Tracy, University of Wisconsin; Gwendolyn Wyard, Organic Trade Association.