National Organic Standards Board
Materials/GMO Subcommittee
Excluded Methods Terminology – Third Discussion Document
August 30, 2016

Note: The Materials Subcommittee is posting the same discussion document from February 2016 with one change. Embryo transfer in animals has been added to the terminology chart with a "TBD", after public comment from the Spring 2016 meeting indicated that it should be considered as allowed in organic livestock. This and all the issues within this document will warrant further discussion at future meetings once the proposal for definitions and criteria is in place. If you submitted comments to the Spring 2016 posting, you do not need to send them again.

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 made for gray areas for the organic standards regarding interpretation and enforcement.

Please see the Excluded Methods Terminology Proposal from this same date for a full elaboration of the background and progress to this point.

This Discussion Document contains the technologies, terms, and issues that we have not been able to agree on or do not yet have enough information on or that pose challenges that we have not yet taken up. These items are put out for discussion to collect further public comment. They will be reviewed at future NOSB meetings.

Discussion
There are several areas for future discussion and work on this subject:

- Additional criteria for evaluating technologies that need to be considered.
- How to detect those technologies that are excluded but may not provide detectable genetically engineered DNA when tested.
- Enforcement of the excluded method provisions of the rule when they are not traceable and undetectable.
- Additional technologies and terms that may not be clearly prohibited as excluded methods.

- Whether the concepts adopted in the proposal should or could lead to Organic Plant Breeding standards and the regulation of the term "Organically Bred Variety (or Animal)"

Once the proposal section in the accompanying document is voted on the structure will be in place to continue looking at these issues. We are interested in input from the organic public on these issues and will continue to have a transparent process to keep excluded methods out of organic production.

A. Additional Criteria

In the 2015 publication on Plant Breeding from FiBL[i], the Research Institute for Organic Agriculture from Switzerland, there are several more criteria mentioned than we have adopted in our proposal. These include:

- The cell is respected as an indivisible functional entity and technical/physical invasion into an isolated cell on growth media is refrained from (e. g. digestion of the cell wall, destruction of the cell nucleus through cyto-plast fusions).
- A variety must be usable for further crop improvement and seed propagation. This means that the breeders' exemption and the farmers' right are legally granted and patenting is refrained from, and that the crossing ability is not restricted by technical means (e.g. by using male sterility without the possibility of restoration).
- The creation of genetic diversity takes place within the plant specific crossing barriers through fusion of egg cell and pollen. Forced hybridization of somatic cells (e.g. through cell fusions) is refrained from.

B. Detection and testing

Many in the organic community have proposed that there be some testing of at-risk seeds and crops for the presence of GMOs and a threshold beyond which the crop could not be sold as organic. Consumers throughout the world clearly want to know if their food has been genetically engineered. These tests are reliable indicators of DNA that has had foreign components introduced at the genome level.

However, in the newer gene splicing and gene editing technologies there is no foreign DNA introduced. The DNA in the genes has been moved around, or sequences introduced from within the same genome that change the expression of certain traits. Many if not most of these methods are not detectable with the existing tests for GMOs. While it is likely that such testing may be developed in the future, it becomes very challenging for the National Organic Program (NOP) and Accredited Certifying Agents (ACA) to determine if any new variety was produced with one of the newer excluded technologies.

Ideas for addressing this have included creating a website for plant varieties that are excluded, or some sort of affidavit system for ACAs to use for varieties known to be introduced from these methods. Any workable ideas for accomplishing a way to tell which varieties are excluded are welcome.

C. Enforcement

Hand in hand with the above detection issue is the question of how to enforce the exclusion of new technologies when they cannot be detected. Enforcement needs to be equal across all ACAs and there has to be adequate training for ACAs in how to recognize newer strains of GMOs and what to do about them. The same process that could be developed for detection could also tie into enforcement, but some creative approaches are needed for these issues since they are not being addressed by the USDA as a whole.

D. Additional technologies and terms

The chart presented in the Proposal document has a number of terms that are marked "TBD" in the Excluded Methods column. These are the ones that need further discussion to determine which of these should be added to the chart and which may not be appropriately deemed an excluded method. Some may be excluded for some uses but not others depending on exactly how the technique is carried out. They are repeated below, with a few notes:

Terminology Chart			
Method and synonyms	Types	Excluded Methods	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.
Cisgenesis		*TBD*	A very broad term that may need to be divided into some allowed and some excluded techniques.
Intragenesis		*TBD*	Similar to cisgenesis but gene sequences may be re-arranged.
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 think this is not excluded but more study of the methods is needed.
TILLING	Eco-TILLING	*TBD*	Stands for Targeted Induced Local Lesions In Genomes. It is a type of mutagenesis combined with a new screening procedure.
Agro-infiltration		*TBD*	*In vitro* nucleic acids are introduced to plant leaves to be infiltrated into them. More study needed.
Doubled Haploid Technology		*TBD*	There are several ways to make double haploids and some do not involve genetic engineering but some do.
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.

E. Organic Plant Breeding

Some groups in Europe are moving ahead with developing a full set of organic plant breeding standards. If this become regulation there, then a label could be given for an "Organically Bred Variety". This is far from being able to be achieved in the U.S.A. with a very different approach to seed regulations as a whole. However, it is a potential next step and may be appropriate to tie into the discussion of some of the remaining terms above. For more information about this see the FiBL dossier cited above.

For instance a variety created with a cell fusion event for brassica male sterility might be allowed as seed in organic farming (as it is now) but prohibited from being used in a variety labeled as "Organically Bred Variety" with an organic breeding standard.

Discussion Questions

1. Are there any additional criteria for evaluating technologies that need to be considered?

2. Do you have any insights on how to detect those technologies that are excluded but may not provide detectable genetically engineered DNA?

3. Please offer any suggestions for enforcement of the excluded method provisions of the rule when they are not traceable or detectable.

4. Opinions are welcome on the terms in the chart above that may or may not be clearly prohibited as excluded methods.

Subcommittee Vote
Motion to adopt the third discussion document on excluded methods

Motion by: Zea Sonnabend
Seconded by: Emily Oakley
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

[i] [i] FiBL Research Institute of Organic Agriculture 2015. Dossier No. 2 Plant Breeding Techniques: an assessment for organic farming.