DISCUSSION DOCUMENT:

EXCLUDED METHODS TERMINOLOGY

SUMMARY

A clarification of the term "excluded methods" is needed, and additional time should be allowed for comments on this subject.

It is essential to provide adequate time to involve the organic community in this process of clarification of the term "excluded methods." We request that Discussion Documents be kept open for comments for a longer period of time than the petitions.

The public was given three weeks for comments on the entire slate of agenda items for this meeting. This Discussion Document, in particular, was completely new and highly technical. It deserves in-depth review. Although we understand the short time frame for items that will be voted on, we also believe that a longer time frame is essential for discussion items. Possibly discussion could be open until 30 days after the NOSB meeting. This may result in more thoughtful and complete responses.

DISCUSSION QUESTIONS

1. **Does the definition of "excluded methods" in the Organic Rule need to be revised? Please provide reasoning for either a "yes" or a "no" answer.**

Yes, the definition of the term "excluded methods" needs to be clarified, because the definition includes the terms "natural conditions" and "traditional breeding." Those two terms have been subject to different interpretations. The current phrase—"A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions—is a workable definition, but only if we use a narrow definition of the term "natural conditions." Similarly, the Discussion Document states, "It is not clear at what point traditional breeding techniques are divided from modern or non-traditional breeding techniques."

2. **On what general principle(s) should practical and consistent distinctions be made between "excluded" and permitted methods of breeding that could apply to plants, animals and micro-organisms? Under such general principles should we further define or replace terms such as "natural conditions" and "traditional breeding"?**

"A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions" is a workable definition, if we use a narrow definition of the term "natural conditions." We suggest that the term "traditional breeding" can be defined as "methods used to change the genetics of a plant or animal by means that are only possible under natural conditions." This is straightforward in the case of sexual reproduction in higher organisms.

The term "traditional breeding" does not really apply to microorganisms, because they do not require male and female genders for mating. The definition of permitted methods must take into account the fact that reproduction of bacteria, fungi and viruses is significantly different from that of plants and animals. It must also consider the uses of a genetically modified organism. Some methods may be prohibited for plants and animals, but allowed for microbes. Examples might include viruses used for vaccines (if viruses are killed before injecting them into an animal).

3. **Are there other terms beyond those discussed here that should be addressed in the context of excluded methods?**

At this time, we have no additional terms to suggest. However, we request that the NOSB allow more time for review of this document so that organic stakeholders can participate in the upcoming public discussion and then submit additional comments. We also note that the science of genetic engineering changes rapidly. There should be some mechanism to evaluate new techniques as they are developed.

4. **Of the terms and practices discussed here, which ones should be in the definition of excluded methods and which not included? Why?**

Most of the terms and practices that are currently included in the definition of "excluded methods" should be retained. In particular, the term "cell fusion" should be retained. Cornucopia disagrees with the Policy Memorandum issued by the NOP on February 1, 2013, which states:

> *The NOP further concludes that cell fusion (including protoplast fusion) is not considered an excluded method when the donor cell/protoplasts fall within the same taxonomic plant family …*

The memo says that cell fusion is natural, as in an egg and sperm. In that case, cell fusion within a species, which could occur under natural conditions, should be allowed**. Cell fusion between two different species, even if they are in the same taxonomic family, should not be allowed**.

The technique used in plant breeding could not occur under natural conditions. It involves chemical removal of cell walls, and chemical or electrical fusion of nuclei.

Why is cell fusion used? It is used to overcome "sexual incompatibility." In other words, it is used to produce a hybrid between two plants that would never cross in nature. The organic regulations specifically prohibit "methods used to genetically modify organisms … that are not possible under natural conditions." The only genetic recombination that is natural in higher organisms is that within a plant (or animal) species.

An example within the family Solanaceae:

- Tomato breeds with tomato = within species (Solanum lycopersicon). This is "possible under natural conditions."
- Tomato breeds with pepper, potato, or eggplant = within taxonomic family, but not within species. These crosses are not possible under natural conditions.

Demeter, the biodynamic certifier, prohibits the use of protoplasmic cell fusion. They maintain a list of about 400 varieties that have been created with this technique. Furthermore, Europe considers protoplasmic cell fusion to be genetic manipulation.

The only terms that could be removed are fermentation and gene doubling. Gene doubling should be removed because it can occur in nature, at least in plants. It should be clarified that gene doubling for organisms other than plants remains prohibited. Fermentation should be removed because it is not a method of genetic engineering; it is a method of production of fungal or bacterial biomass, or production of a metabolite. Fermentation should be allowed in organic agriculture. After all, composting and mushroom production on compost are often referred to as "solid-state fermentation."

Some of the emerging breeding strategies discussed in part B need to be added to the recitation of "excluded methods." Microinjection and biolistic transfer should be added; others may need to be added after the organic community has had time to review the Discussion Document in more detail.

5. **How far back into the development or manufacture of a substance, or in the development of vaccines, or in the lineage of a breeding line, should the excluded methods prohibition apply? How far back is practical and verifiable?**

This question is three questions in one.

- In the development or manufacture of a substance, the prohibition on excluded methods should cover the **entire** development or manufacture of that substance. Once an organism is modified through an excluded method (genetic engineering) all of its progeny remains "novel."
- In the development of vaccines, the prohibition on excluded methods should cover the **entire** development and manufacture of the vaccines.

- In the lineage of a breeding line, the prohibition on excluded methods should go as far back as possible.