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National Organic Standards Board
Spring 2013 Meeting
Portland, OR

Re. GMO Ad Hoc: Excluded Methods Discussion Document

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

We want to thank the GMO Ad Hoc Subcommittee for addressing the issue of definitions of terms. There certainly needs to be more clarity around the meaning of words used in connection with excluded methods. We urge the subcommittee to consider vehicles in addition to the regulatory definition for increasing clarity. Is a guidance document appropriate? An appendix to the Policy and Procedures Manual (PPM)? It appears that more discussion than is allowed in a regulatory definition would be helpful.

In response to the subcommittee's questions, we offer the following thoughts:
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.
The core of the current definition –"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"—captures the reasoning behind "excluded methods." It is consistent with the CODEX definition and public expectations. Terminology in this field is changing with continual adoption of new methods, and because of that some of the terms in the definition are not very clear. However, because the change in technology and associated vocabulary is rapid and ongoing, a change in the regulatory definition does not seem to be the best way to address it. Instead, it could better be addressed through the issuance of guidance or other means that can be more easily updated.

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"?

First of all, we agree with the suggestion in the discussion document that some methods that do not fit under "excluded methods" might still be inappropriate for producing organic seeds. Chemical and radiation mutagenesis are examples. Therefore, we suggest that it is not appropriate to make the distinction simply between "excluded methods" and "permitted methods." Rather, the distinction should be made among "excluded methods," "methods not permitted in organic production," and "permitted methods."

A question related to #2 was posed in the text of the discussion document: "What exactly is it about a genetic modification process that is objectionable in an organic context?" There are many ways to approach this question. Organisms used in organic production should be part of an (agro)ecosystem. Evolutionarily and ecologically, they should belong to the system in which they are grown. We don't mean to imply that varieties need to be native, but the NOSB Principles of Organic Production and Handling, adopted October 17, 2001, state that organic agriculture "tak[es] into account that regional conditions require locally adapted systems." Locally-adapted varieties are advantageous because they have a suite of characteristics that allows them to succeed in the diversity of conditions to which a plant might be subjected in the locale. Genetically engineered organisms, on the other hand, are created to have certain specific traits, ignoring both pleiotropic effects of the genetic manipulations and the robust genetic background that evolves through the selection of whole organisms.

One general comment. Sometimes terms are confusing with respect to their inclusion as "excluded methods" because the terms are really relating to endpoints rather than processes. Thus, even though we talk about the process of "mutagenesis" or "cell fusion," those terms really encompass everything resulting in mutation or fused cells—both natural and otherwise. It is more helpful in the organic context to talk about the processes rather than the endpoints — such as mutation through exposing cells to toxic chemical or radiation, or protoplast fusion.

While definitions of genetic engineering vary, they all involve direct manipulation of genes independent of normal reproductive processes. The direct manipulation of genes is something common to genetic engineering in plants, animals, and microorganisms, and is a criterion that may be included in guidance to further clarify specific cases. While "natural conditions" and "traditional breeding" may not be terribly precise, they do accurately portray public expectations.

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

In such a rapidly growing field, there are new terms continually being added that the organic community may need to know. Again, this is a reason for putting them in guidance rather than the regulations.

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

We do not recommend changing the regulation at this time. However, building on the existing regulatory framework and language, guidance should use numerous examples to define the

extent and boundaries of the excluded methods term. It should focus on processes rather than outcomes of those processes—for example, “hybridization by cross-pollination” might be given as an example of a non-excluded method, but not simply “hybridization,” which is an endpoint achievable through both genetic engineering and traditional breeding. Examples that are included in the definition should be selected to cover the range of methods to be covered by the definition (as of this time), and the boundaries between genetic engineering and traditional breeding techniques.

There may be breeding methods that are incompatible with organic production for reasons other than fitting under the definition of "excluded methods," and the Board should address these separately.

The parameters to include under the guidance:
Definitions of genetic engineering all involve direct manipulation of genes independent of normal reproductive processes. Processes that should be included, therefore, are direct alteration of DNA/RNA through cutting and splicing of their molecules, molecular cloning, insertion and deletion of nucleic acid sequences, and transformation of bacterial cells through the transfer of foreign DNA. This may not be a complete list.

Boundary processes:
Cell fusion may be achieved by different means. Some may be regarded as direct manipulation of genes —for example, protoplast fusion or somatic hybridization. Others may occur by natural means —fertilization, for example. The difference between the direct manipulation and natural cell fusion is a good distinction for defining a boundary of “excluded methods.”

Mutagenesis may occur through different means. It may occur through exposure of the organism to radiation or toxic chemicals. This should be a prohibited method because it is inconsistent with OFPA, but not an excluded method because it does not involved the direct manipulation of genes. Insertional mutagenesis, on the other hand, is clearly direct manipulation of genes, and should therefore be an excluded method. This looks like another boundary distinction.

Conjugation, is another boundary —some processes being genetic engineering, some not.

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?
The excluded methods prohibition should go “all the way” back. It is really only possible to say this because “all the way” is not all that far.

On the other hand, the prohibition against “prohibited methods” that are not “excluded methods” does not need to go as far back, and should apply only to the producer of the organic seeds or other products —as long as they are not using excluded methods.

6. [Suggested new question] Outside of the regulatory definition of excluded methods, what terminology needs to be clarified and how?
There is a need for further guidance about both the general principles and specific methods. The current definition does not limit excluded methods to the list given, nor state all breeding methods that are not excluded. It would be impossible to do so, and such a list would soon be out-of-date. The methods listed in the guidance should illustrate the kinds of methods that are excluded and also look at terms on the boundaries of the set of processes covered by the term.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board member