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National Organic Standards Board
Fall 2014 Meeting
Louisville, KY

Re. MS/GMO: Excluded Methods Definitions Discussion Document

These comments are submitted on behalf of 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, Beyond Pesticides 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.

The Tasks of Defining "Excluded Methods" and Related Terms are Important and Urgent

It is apparent that there are two definitional tasks being addressed in this discussion document. First, there is the regulatory task of defining "excluded methods." The second is the common lexicographic task of defining various methods of genetic manipulation and related terms.

The first, regulatory, task depends in part on agreement on principles, such as those contained in the FiBL criteria, and a general understanding, such as that contained in the definitions of the Cartagena Protocol and Dag Falck's comments. It also requires the accomplishment of the second task, in order to apply the principles and general understanding to specific cases.

Having a clear definition of "excluded methods" and the limits of its application is critical to ensuring that organic food meets consumer expectations. Other urgent projects of the NOSB – including identifying vaccines made with excluded methods, protecting seed purity, and preventing the contamination of organic fields and food with genetically engineered organisms—all depend on having a regulatory definition of "excluded methods" that stands up to scrutiny. The development and adoption of that definition –whether it is in changed regulations or clarifying guidance—depends on the organic community having a clear understanding of the language used in the discussion. It is the responsibility of the NOSB to develop this guidance, and the job cannot be delegated to the NOP.

Regulatory Definition of Excluded Methods

We use the term "regulatory" here without taking a position regarding whether the outcome of this task should be regulation or guidance. We think that guidance may become regulation as clarity and consensus are achieved. 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.

Definitions must be process-based.

We agree that the definition of "excluded methods" should be process-based. This is the approach taken by OFPA, and it is implied by the term "excluded methods."

Ethical criteria, such as those suggest by FiBL, are important to a regulatory definition. They might be used in grouping terms as we recommend below, to establish relevant distinctions among methods.

While we believe that this common understanding is pretty well encompassed by both the Cartagena Protocol and Dag Falck's definition, we offer a warning when using the phrase, "beyond the taxonomic family." While taxonomists are pretty well in agreement about the meaning of "species," as those organisms that are naturally capable of interbreeding or exchanging genes, the use of terms representing taxonomic groups above the level of species is not consistent and does not necessarily correspond to the degree of reproductive compatibility. If the aim is to capture the difference that would exclude natural interbreeding, then the natural distinction is that of species, not family. Since some degree of natural hybridization does occur between some species, an allowance for gene transfer between species that are known to hybridize could be added.

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.

In 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.

"Excluded Methods" is not necessarily the same as "not allowed in organic."

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."

Defining Types of Genetic Manipulation

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.

The task of defining the constantly increasing number of terms relating to genetic manipulations is overwhelming. We suggest that grouping terms that apply to similar processes (rather than endpoints) would make the terminology much easier to understand and would allow a more robust discussion of the definition of excluded methods.. We also suggest that one outcome of this task might be a glossary that could become an appendix to the Policy and Procedures Manual, like the "Basic Chemistry" summary.

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 of Directors