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October 21, 2016

Ms. Michelle Arsenault, Advisory Committee Specialist
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.,
Room 2642-S, Mail Stop 0268
Washington, DC 20250-0268

RE: Docket AMS-NOP-16-0049
Materials/GMO Subcommittee – Excluded Methods Terminology Proposal and Discussion Document

Dear Ms. Arsenault:

Oregon Tilth thanks the Materials/GMO Subcommittee for their persistent and extensive work on improving the definition of excluded methods. We appreciate the opportunity to provide comment on this latest proposal and accompanying discussion document.

General comments and feedback
Oregon Tilth appreciates the time and effort this latest proposal represents. The list of ad hoc group participants contributing to both the definitions and criteria between the Spring and Fall NOSB meetings represents a good balance of stakeholders, offering diverse perspectives and expertise. It is also clear the subcommittee carefully considered public comments received in the Spring NOSB meeting. In particular, we appreciate that the practice of embryo transfer in animals has been re-categorized as "TBD" and moved to the accompanying Discussion Document, which identifies issues that will require further discussion at future meetings once the proposal for definitions and criteria is in place.

Overall, Oregon Tilth supports the proposal's three sections and approach. Establishing clear definitions, principles & criteria, and developing a terminology chart will help minimize confusion and uncertainty for certified operations, accredited certification agencies (ACAs), and consumers who look to the organic label for assurance that genetic engineering and its products have not been used. Being aware of approaches already taken by other countries is valuable to maintain harmonization of organic standards and practices at a global level. Oregon Tilth also agrees with creating this structure within the context of guidance instead of changes to regulations or the Act. Evolving and updating guidance as new technologies emerge is a more responsive and timely process, which is essential because the rapid development of new genetic engineering methods and techniques is outpacing the ability of our current regulatory framework to keep up.

The latest proposal reflects continued refinement of an approach to the prohibition of excluded methods based on *clearly defining what methods we want to prohibit*. This is helpful, but it is also a reactive position that places the organic sector in the role of constantly trying to stay abreast of the latest innovations in genetic engineering methods and techniques. As the subcommittee reaches an important milestone with this proposal, it should consider approaching the prohibition via a more proactive position. A proactive position

would attempt to *clearly define what methods we want to allow*. The proposed criteria to evaluate biotechnology processes and determine if they are excluded methods may serve as a strong foundation from which to further develop a more proactive approach.

Specific comments and feedback
We are pleased to see the definition of Genetically Modified Organism (GMO) explicitly state that the term "will also apply to products and derivatives from genetically engineered sources." This is an important declaration and is consistent with organic being a process-based standard. We are also pleased to see the definition of Non-GMO further emphasize that the NOP is a process-based standard.

Oregon Tilth believes it's important to codify a definition of Non-GMO, specifically to contrast it with the term "GMO-free" because the two terms are often conflated amongst ingredient buyers and consumers. As a point of information, there are some oils derived from genetically engineered (GE) corn, canola and/or soybeans that are so heavily processed that any genetic residue or marker of the source GE crop is removed. These oils are often marketed as verified "GMO-free" (supported by a non-detect test result) but they are still prohibited for use in certified organic products. Such claims are creating confusion in the marketplace.

As another point of information, Oregon Tilth has been collecting certified crop & product samples and testing for the presence of GMOs. In general, we see more positive test results than non-detect results. The vast majority of positive test results are at low levels indicative of drift or adventitious presence at the seed level, in spite of best management practices and efforts to prevent contamination. In this context, working with a process-based standard acknowledges that while preventive practices are in place to avoid GMO contamination, the possibility of inadvertent presence exists. This in-the-field scenario also emphasizes the importance of the subcommittee's proposed "Report to the USDA Secretary on Progress to Prevent GMO Incursion into Organic." As the proposed report indicates, effective and balanced "coexistence" is only possible if the USDA develops policies addressing shared responsibilities for GMO contamination and strengthens guidance on best practices to prevent incursion of biotech seeds, pollen and products into non-GE acreages and supply chains.

Verification and enforcement concerns
As Oregon Tilth has previously highlighted in our comments on this topic, a key consideration moving forward is ensuring reasonable access to information needed to verify compliance with and successfully enforce organic standards. Certified operators must be able to determine whether the seeds and processing inputs (such as yeasts & enzymes) they plan to use are the result of excluded methods. And certifying agents must be able to readily verify compliance via supporting documentation from the seed or processing input supplier.

We note with some concern that several of the genetic engineering methods included on the proposed terminology chart are described as hard to test for (i.e. targeted genetic modification) and not detectable in tests (i.e. accelerated plant breeding). In the absence of reliable testing protocols, the organic sector will need to rely on affidavits confirming the exclusion of prohibited genetic engineering methods and techniques. This approach is currently being used (most commonly in processing inputs) and works fairly well. However, it contributes to the often-cited paperwork burden of documenting compliance. It also relies on the knowledge and thorough understanding of individuals signing the affidavit. If information on affidavits becomes increasingly technical and complex, then the ability to find a qualified individual who is able to sign the affidavit in confidence may become a challenge – resulting in delays in acquiring the necessary signature. Furthermore, companies that create products via these newer excluded methods, especially those not subject to other federal regulatory frameworks beyond the USDA NOP, may view the specific techniques used as proprietary or confidential information, which may further hinder reasonable access to the information needed to verify compliance.

As a certifier, traceability and detectability are key components behind Oregon Tilth's ability to verify and enforce organic standards. While we support the subcommittee's desire to clearly identify the rapidly developing new biotechnology methods being used to genetically engineer organisms, we are struggling with how to verify and enforce compliance for specific techniques that are not readily traceable or detectable.

Finally, we are concerned about inconsistencies across different federal regulatory frameworks. As noted by the subcommittee, newer technologies (i.e. targeted genome editing) are emerging and being quickly adopted that clearly utilize genetic engineering techniques, but are not regulated by current federal government regulatory structures. This creates a situation where new biotech crops and inputs are commercialized and available in the marketplace that have not undergone any regulatory review or approval for genetic engineering, but are defined as a GMO under the USDA NOP. The definition of bioengineering in the new federal GMO labeling legislation further complicates efforts to create consistent definitions and regulatory oversight of genetically engineered organisms across government agencies. We recommend that the subcommittee's report to USDA Secretary Vilsack also highlight the need to align definitions across all federal regulatory structures involving genetic engineering.

On behalf of our certified clients and our members, Oregon Tilth thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering the growth and integrity of organic food and agriculture.

Respectfully submitted,
Oregon Tilth

Oregon Tilth is a leading certifier, educator and advocate for organic agriculture and products since 1974. Our mission to make our food system and agriculture biologically sound and socially equitable requires us to find practical ways to tackle big challenges. We advance this mission to balance the needs of people and planet through focus on core areas of certification, conservation, public health, policy and the marketplace.