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

RE: Docket AMS-NOP-15-0085
Materials/GMO Subcommittee – Excluded Methods Terminology
Materials/GMO Subcommittee – Next Steps for Improving Seed Purity

Dear Ms. Arsenault:

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

Excluded Methods Terminology – Proposal & Discussion Document
The rapid development of new genetic engineering methods and techniques is outpacing the ability of our current regulatory framework and definitions to keep up. This can lead to confusion and uncertainty for certified operations, accredited certification agents (ACAs), and consumers who look to the organic label for assurance that genetic engineering and its products have not been used.

This proposal is a good step forward in closing the gap between new methods and regulatory frameworks. We support the goal of establishing a structure that is flexible enough to evaluate newly developed methods and techniques in the future for adherence with specified principles and criteria.

The Subcommittee's approach to creating this structure is sound – establishing clear definitions, principles & criteria, and developing a terminology chart. 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 of the essence both now and in the future.

Verification and enforcement concerns
As highlighted by the Subcommittee in its discussion document, 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 prohibited methods. And certifying agents must be able to readily verify compliance via supporting documentation from the seed or processing input supplier.

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). Further, companies that create products via these methods 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. As such, we are struggling to offer viable suggestions for enforcement of excluded methods provisions for specific techniques that are not traceable or detectable.

We offer the following input on some ideas for addressing these issues included in the discussion document:

Creating a website for plant varieties that are excluded

A centralized repository or listing of excluded plant varieties is a good concept, but will only be as good as the system designed to acquire and maintain it. The system needs to be comprehensive and avoid situations where some varieties are listed but others that use prohibited excluded methods are not listed because of lack of knowledge or disclosure. Ideally, a centralized listing would be supported by mandatory disclosure requirements for companies creating products using excluded methods. Further, the system would need funding for the resources necessary to consistently and reliably track and update the list over time.

Affidavit system for ACAs

This would be used for varieties known to be introduced from excluded methods. Oregon Tilth currently relies on a system of affidavits to verify compliance with prohibited excluded methods, most commonly in processing inputs. This approach works fairly well, albeit 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. Another possible (and even worse) unintended consequence, is having people sign affidavits without really understanding what they're confirming (which could result in inaccurate affidavits).

Embryo transfer in animals

The inclusion of embryo transfer in animals under the terminology chart of excluded methods came as a surprise to Oregon Tilth and the organic community. While this process is not used on many livestock operations, it has the potential to improve the health and welfare of animals on organic operations. We are concerned that the NOSB may be relying too much on FiBL, the Institute for Organic Research in Switzerland's published paper and public comment rejecting the use of embryo transfer in animals, in vitro fertilization (IVF) and sperma sexing. OTCO has observed use of all of these practices on organic livestock farms. In their 2013 comments to the NOSB, FiBL supported classifying embryo transfer in animals as an excluded method, citing the damage to egg cells, selection being determined by technology and the danger of the gene pool narrowing. Oregon Tilth asserts that these concerns are largely unconvincing, that these technologies do not fit within the proposed definition of excluded methods, and we would advise the National Organic Standards Board to look beyond these comments to formulate an independent and well-vetted decision on how to best classify these practices.

First, the terms used in the FiBL document and in the NOSB proposal for Excluded Methods Terminology are not consistent with general terminology used in the industry. The NOSB proposal only includes a definition of embryo transfer/rescue. Upon review of the FiBL document, it appears that these terms are being used in

conjunction with and perhaps interchangeably with IVF, due to the fact that embryo transfer is not included in their table of methods. The term "embryo rescue" is typically reserved for plant breeding techniques. The process for embryo transfer in animals is typically different than in vitro fertilization (IVF). In cattle, embryo transfer refers to the process of inseminating the donor cow, and flushing out the resulting embryos for implantation in the surrogate cow. In contrast, in vitro fertilization occurs with both an egg and sperm in a laboratory setting, rather than in a live animal. It is important to note that the current Excluded Methods definition in the NOP Organic Regulations clearly states that in vitro fertilization *is not* an excluded method.

Next, the additional information cited in the NOSB proposal only describes the process of superovulation used in embryo transfer. Organic operations are unable to use this process due to the use of synthetic hormones to stimulate the release of more eggs than are normally produced by the cow in her estrus cycle. However, while it would be more expensive because less embryos can be produced, it is possible to skip the superovulation step and therefore avoid the use of synthetic hormones in this procedure. Likewise, in vitro fertilization without the use of hormones does not produce more eggs than a cow would naturally produce. *It would be advantageous for NOSB to request further information from industry professionals for additional context on the definitions used.*

OTCO's additional comments will focus on the process of IVF due to the fact that embryo transfer typically uses hormones that are currently not allowed in an organic production system, and that FiBL appears to consider embryo transfer and IVF to be interchangeable. We are addressing the information provided by FiBL as that was the only reference in the NOSB proposal for not approving what is being called "embryo rescue."

The FiBL comments stated that during IVF, there could be possible damage to the cell wall, but did not further describe the mutations that could occur. It is important to note that spontaneous mutations (caused from damage to the egg or sperm cell) can and do occur with traditional breeding techniques as well. FiBL did not describe specifically what abnormalities they believed could happen during the IVF process and if they are substantially more or different than what can occur naturally.

FiBL were concerned that allowing IVF means that selection is being determined by technology. Every operation uses selection to improve their genetics, whether that is by choosing a bull with desirable traits or obtaining semen and artificially inseminating their cows. There are many ways that technology is used to assess whether animals carry the desired traits that a farm is looking for. This concern expressed by FiBL does not include their definition of 'technology' and at what point human intervention to select for optimal genetic traits crosses the line into a prohibited technology.

FiBL also stated that the use of this process could cause gene pool narrowing as a reason for not allowing it. The National Organic Standards 205.238(a)(1) states that species and types of livestock should be selected with regard to suitability for site-specific conditions and resistance to prevalent disease and parasites. Historically, conventionally raised livestock have been bred purely for production, creating negative traits elsewhere in the animal. These very high production animals typically don't work well in an organic system where they need to have a better immune system, increased longevity and the capability to graze efficiently.

For example, due to the fact that organic producers do not rely on conventional treatments like antibiotics, it's important for them to develop a production system with a foundation that ensures a healthy immune system. It has been shown that animals will develop a better immunity over many years in an organic system but it is not a quick process. Some other traits that could be selected for a more robust animal include a strong, smaller frame for walking during grazing, and the ability to convert pasture to energy more efficiently. To this end, producers can use these technologies to incorporate genetics from animals that thrive in organic

systems. The use of in vitro fertilization allows for operations to more quickly expand and improve the herd's genetics, thereby improving animal health and welfare with greater efficiency.

Even though at this time the proposed prohibition would only adversely affect a few of our producers, Oregon Tilth chose to comment on this topic because we believe that it has the potential to affect the organic industry in the future. While the expense of the procedure currently poses a barrier to using these methods, they continue to become more economical with improvements in the process. Decisions like this should be made by carefully looking at all perspectives, and we recommend the NOSB remove embryo transfer from the proposed chart of excluded methods technologies.

While Oregon Tilth is not an expert on this topic, we would be happy to point you to industry professionals that can provide further information.

Next Steps for Improving Seed Purity – Discussion Document

Oregon Tilth appreciates the Subcommittee's careful consideration of public comment previously received on this topic and summarized in the discussion document. In particular, we are pleased to see the acknowledgment that thresholds and testing are tools to be used responsibly. We offer the following input on some of the suggestions outlined.

A. Enabling Data Collection

Oregon Tilth reiterates its earlier comments to the NOSB on the importance of data collection to measure the problem of GMO contamination as a prerequisite for determining the best course of action in managing the problem.

However, the data collection approach suggested is problematic for several reasons. The suggested approach begins by having Accredited Certifying Agents (ACAs) collect seed purity declarations for non-organic seed of high-risk crops. Declarations would preferably be provided on the seed tags of each bag. In the absence of seed tag purity declarations, it's suggested that the organic inspector collect a sample that could be sent for an inexpensive GMO strip test. Regarding the results of data collection, the discussion document explicitly states that there would be no thresholds, no adverse action (regardless of any detected levels found), and that test results would remain confidential (except for anonymous aggregated data).

While ACAs and their inspectors have access to records and the authority to collect samples, these activities are linked to the ACA's specific role of verifying compliance with organic standards. Without established thresholds and the possibility of adverse action based on test results, the role of ACAs and the purpose of records review and/or testing would be substantially re-defined. Additionally, it's problematic to remove an ACA's ability to take action when test results may trigger concerns regarding organic integrity. Finally, the NOP regulations require that results of all samples taken by ACAs be made publically available [205.670(f)], which contradicts the stated intention to maintain confidentiality of test results.

To be clear, Oregon Tilth understands the rationale for proposing a data collection approach that maintains confidentiality and removes risk of potential adverse action or penalties. This approach encourages active participation without fear of adverse consequences. However, we believe asking ACAs to serve the data collection role is inappropriate because it would adversely compromise our unique role within the organic certification and regulatory framework.

C. Strengthening the Organic Seed Requirement

The Organic Seed Alliance's State of Organic Seed report shows that overall use of organic seed has increased between 2009 and 2014 for vegetable crop acreage (14% increase), field crop acreage (5% increase) and cover crops (18% increase). NOP guidance from March 2013 helped establish consistency amongst ACAs in verification of organic seed requirements. However, while the NOP guidance established the floor via minimum requirements, it may have also established the ceiling, thereby diminishing prior attempts by ACAs to hold certified clients accountable for additional efforts beyond checking three reasonable sources to secure organic seed. This would explain for the State of Organic Seed report's finding of a perceived decrease in efforts by ACAs of continuous improvement in securing organic seed. When asked if certifiers were requiring more steps to request and secure organic seed, only 40% of respondents answered "yes" in 2014, compared to 61% in the 2009.

Oregon Tilth recommends enhancing the NOP Seed Guidance to begin with specifying a minimum of three reasonable seed sources and then establishing organic seed usage as a specific Organic System Plan goal. The guidance should require certifiers to work with farmers to track efforts and demonstrate reasonable, measurable increases in the use of organic seed over time.

Additionally, the NOP Seed Guidance should address handlers that source seed for contractual growing purposes. When a certified organic handler requires that a specific variety be planted and is responsible for sourcing the seed, then the certified handler should be held accountable to the same requirements as farmers for determining if the variety is commercially available as organic.

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.