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October 16th, 2009

The National Organic Standards Board
c/o Valerie Frances, Executive Director, NOSB
1400 Independence Avenue, SW
Room 4008 – South Building, Ag Stop 0268
Washington D.C. 20250-0200

RE: Docket Number AMS-TM-09-0060

- Classification of Materials

Comment Summary

Oregon Tilth finds several portions of the Joint Committee’s Recommendation to be generally favorable. With a few points of clarification added, as discussed in the detail or our comments, we request the recommendation as it relates to synthetic and nonsynthetic be accepted at this meeting. The recommendations pertaining to agricultural vs. nonagricultural, namely the definition of nonagricultural, remain problematic and should be withdrawn and readdressed at the next NOSB meeting.

Recommendation #1 – Guiding Principles

Oregon Tilth **SUPPORTS** the recommended principles that should guide the classification of materials, **EXCEPT** we are requesting further clarification on two points. **An acceptable recommendation needs to address:**

1. Whether chemical changes generated during processing methods specifically allowed in the OFPA and/or allowed National List materials, would render an otherwise agricultural product “synthetic”; and
2. Whether a synthetic solvent or processing aid used during the manufacturing of a nonorganic ingredient intended for use in an organic product, needs to be on the National List as indicated by § 205.270(c)(2).

Recommendation #2 – NOSB Practices

Oregon Tilth **SUPPORTS** the recommendation on NOSB practices, **EXCEPT** we have concerns about increasing the use of annotations. We agree that annotations may be useful and even necessary in some cases, but they generally create excessive regulatory burdens and they are very difficult if not impossible to enforce.

Recommendation #3 – Proposed Regulatory Language

Oregon Tilth **SUPPORTS** the recommendation to implement rule change to clarify the OFPA definition of ‘synthetic’. We support the proposed definitions for the following terms and their addition to the regulation:

1) Chemical Change; 2) Extract; 3) Formulate; 4) Manufacture; 5) Naturally Occurring Biological Process; and 6) Substance.

We **DO NOT SUPPORT** the proposed definition of **nonagricultural** because it makes reference to “an agricultural system”, which is not defined, **AND it contradicts the committee’s proposed 3rd Guiding Principle**.

Comment Detail

Synthetic vs. Nonsynthetic

Oregon Tilth **supports** the first two recommended guiding principles and **requests clarification** on the third:

1. The classification of a material is determined by both the source of the inputs and the process used to make the material.
2. The same material can be agricultural, nonsynthetic, or synthetic depending on source and process.
3. If a material is processed such that it is classified as synthetic, then the material is classified as synthetic regardless of its source.

We **REQUEST CLARIFICATION** in so far as the **third guiding principle would relate to a material from a source that is organic, or a material that is rendered synthetic by the normal effects of food processing**. A persistent problem that has been central to the discussion of agricultural and nonagricultural, is the fact that we are seeing substances listed under § 205.605 (both nonsynthetic and synthetic) showing up in the market place as “certified organic” ingredients. This is possible because several of the materials are derived from an agricultural source, or they are grown on agricultural substrate.

There are organic agricultural products that would be classified as “synthetic” if they were evaluated against the NOP definition of “synthetic”. The NOP definition of processing and the allowed materials on § 205.605 and § 205.606 can and will continue to bring about chemical changes when applied to raw agricultural material. The OFPA definition of ‘synthetic’ does not account for chemical changes brought about by physical or mechanical methods, or by allowed handling inputs. Keeping in line with the first two guiding principles, we are assuming that organic agriculturally sourced material that undergoes a chemical change, when processed in accordance with the regulations, would not be classified as “synthetic”.

The MWG document dated 4-20-09, on page 5, explicitly states that the term “manufacturing” is not intended to address the processing of agricultural products by a handling operation. The definitions apply only to substances used as non-organic inputs in crop, handling or livestock operations. This concept was extracted from the ‘August 16th, 2005 NOSB Clarification on the Definition of Synthetic’ and expressed by earlier Boards as well (see 6/14/93 Handling Committee Working Draft on the National List).

Oregon Tilth asks that the NOSB consider this an important point of clarification. The following question must be answered:

If something is synthetic under one condition (non-certified manufacturer of an input) can it also be organic if produced in a certified handling facility in accordance with the applicable sections of the regulation?

Oregon Tilth SUPPORTS the following points made on page 5 and page 6 of the document and we encourage the NOSB to incorporate such points into the guidance document and decision tree proposed under “Next Steps & Timing”.

A material would be classified as synthetic when:

- 1) The source of the material is not “from mineral, plant, or animal matter” (from the definition of nonsynthetic) and is not a “substance created by naturally occurring biological processes” (from the definition of synthetic) or;
- 2) The process used to manufacture the material is synthetic (per the definition of synthetic and clarifying definitions in our recommendation) or;
- 3) The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics. A significant level should be determined with reference to the applicable regulatory limits for the type of substance, in addition to the technical and functional effects produced by the residual level of the synthetic.

We REQUEST CLARIFICATION on an additional statement made on page 6:

- Extraction with a synthetic not on the National List would not result in a material being classified as synthetic unless either the extraction resulted in chemical change or the synthetic remained in the final material at a significant level.

Oregon Tilth **AGREES** with this point as it relates to crop and livestock inputs, because it is supported by the OFPA definition of “synthetic”, and we recognize it to be consistent with material approval decisions made since the mid-90s by the NOSB, ACAs and material review organizations.

We are concerned however that section 205.270(c)(2) of the regulation may challenge such a point, as it relates to materials petitioned for § 205.605 and § 205.606. This section of the regulation prohibits handlers from using synthetic solvents or processing aids unless they are on the National List. The regulations goes on to say that the prohibition does not apply to non-organic ingredients used in “made with.....” products, implying that non-organic ingredients used in ‘organic’ products must not be handled using synthetic solvents or processing aids unless they are on the National List. The regulation here is ambiguous, and it’s not clear whether the prohibition applies to the certified handler, or the manufacturer of the non-organic ingredients.

Oregon Tilth has publicly requested clarification on this topic, from the NOP and the NOSB, for nearly three years, and we are submitting those comments once again (attached at the end of this document). We strongly insist the NOSB together with the NOP address this issue in the Guidance Document proposed on page 12 under “Next Steps and Timing.

Oregon Tilth **AGREES** with the recommendation to implement rule change to clarify the OFPA definition of ‘synthetic’, and we **SUPPORT** the proposed definitions for the following terms and their addition to the regulation:

- 1) Chemical Change; 2) Extract; 3) Formulate; 4) Manufacture; 5) Naturally Occurring Biological Process; and
- 6) Substance.

While we recognize that further guidance, including a decision tree, will be needed to facilitate better understanding of a very complex issue, we believe the addition of the proposed definitions will greatly increase the likelihood of consistent determinations.

Agricultural vs. Nonagricultural

We **SUPPORT** that “*or bacterial culture*” be deleted from the definition of nonagricultural and replaced with ‘atmospheric gas’. We recognize that cultured microorganisms are living organisms raised or managed by humans and have served as an integral part of the human food diet for

hundreds and hundreds of years. We support their potential classification as agricultural and the use of certified organic versions. The examples of ‘atmospheric gas’ and ‘mineral’ are good examples because neither are living biological organisms raised or produced by humans.

Oregon Tilth CANNOT SUPPORT, at this time, the deletion of the following phrase from the definition of nonagricultural:

“For the purposes of this part, a nonagricultural ingredient also includes any substances, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.”

It was this phrase that prompted Oregon Tilth to submit a request for clarification to the NOSB in October of 2004. The concept that an ingredient, product, or substance is no longer agricultural once it has been processed into an extract, isolate, or fraction is nearly impossible to evaluate, and is not consistent with many of the agricultural products currently on the market. Most processing activities render the finished products as unrecognizable from their original raw materials. Substances that are generally recognized as agricultural products, such as maltodextrin, cornstarch, rice syrup, and vegetable protein, could all be classified as non-agricultural according to this definition of ‘nonagricultural’.

While we agree that this phrase is problematic and needs to be addressed, removing it will result in a direct contradiction with the Joint Committee’s 3rd Guiding Principle.

If a material is derived from an agricultural source and undergoes a chemical change, according to the NOSB it is classified as synthetic. Once synthetic, the question of agricultural or nonagricultural is removed – and the material becomes nonagricultural. However, if the proposed definition of nonagricultural is accepted, it can’t be classified as such and placed on § 205.605 because according to the proposed definition, the material cannot originate from an agricultural system!

As ambiguous as the second part of the definition may be, the authors of the Rule were trying to communicate an idea that the current board and many organic community members can relate to. In the Oregon Tilth comments of October 2004, we tried to qualify the concept of “loss of identity”. We proposed that “loss of identity” be correlated with the definition of “synthetic”, but we provided exception to chemical changes that were brought about by physical or mechanical processing. We were trying to make room for the fact that the organic regulations allow for processes that result in chemical changes. We didn’t want a product to be classified as “non-agricultural” when organic versions were entirely plausible under the same process only using organic source material. Our approach was not to delete the second part of the definition, but to create a guidance document that further defined terms such as “identity” or “unrecognizable”.

Our take home message: if the NOSB intends to make a correlation between “synthetic” and “nonagricultural”, we strongly suggest revising the second part of the definition to clearly align with your intent. If the second part is deleted, then the NOSB needs to embrace the concept of, “once agricultural, always agricultural”.

We **DO NOT SUPPORT** the use of “agricultural system” in the proposed definition unless it is defined:

A product, such as a mineral or atmospheric gas that does not originate from an **agricultural system**.

The Joint Committee used a definition proposed by the MWG (Definition B from the November 2008 presentation), however the MWG also included a definition for “agricultural system”. We therefore agree with minority opinion II that without a definition of “agricultural system”, nonagricultural has not been fully defined and the true issue of what qualifies to be certified organic has not been addressed. We support the MWG definition of ‘agricultural system’ and request that it be included as part of the definition, or added under § 205.2 – Terms Defined.

Agricultural System. A production system that includes living organisms that are managed by humans and intended for human or livestock consumption. For the purposes of this part, management includes intentional activities such as gathering, producing, raising, cultivating, or growing.

The above definition will support the Committee’s intent to consider some microorganisms as agricultural. It will also address one of the primary questions presented to the Board by the MWG:

Does an “agricultural product” necessarily require a combination of land, soil, and livestock or plant life, or is cultivation (or culture) of a living (nonGMO) organism by humans sufficient to support the possibility that the organism and its derivatives may be organically produced?

Byproducts of Naturally Occurring Processes:

The NOSB continues to refer to “problematic materials” as being “products of naturally occurring biological processes”. This doesn’t accurately reflect the problematic materials. The problematic materials that have held this discussion up for 5 years are primarily yeast and microorganisms. Additional problematic materials that have been central to the discussion are kelp, citric acid, dairy cultures, and enzymes. There is a need to differentiate between the “products of” naturally occurring processes, and the “little critters (aka microorganisms)” carrying out the process. It’s the “little critters” that have primarily been problematic, AND their products *if* they are isolated enzymes or metabolites that are used as minor ingredients or processing aids, rather than consumed as whole food or beverage.

The organic community is not asking the NOSB to address all of the products of naturally occurring biological processes. We do however know of one company that has for five years asked the Board to address yeast. We are optimistic that an excellent petition providing the NOSB all the information needed will be submitted, and the Board will move forward with a decision. If the issue of livestock feed continues to persist, **Oregon Tilth encourages the NOSB to FURTHER EXPLORE an amendment to § 205.237 to allow for the use of non-organic microorganisms and other aquatic feed products (kelp, fish meal) until they become commercially available.** As it stands, the use of non-organic kelp or non-organic fishmeal in livestock feed is analogous to the use of non-organic yeast. Is kelp agricultural? Jury is out on this one. Is fishmeal agricultural? Standards for organic fish are being developed. Are livestock producers using organic kelp and organic fishmeal? We know they are not using organic fishmeal, so how is it that yeast is so special?

In the interim of classifying yeast or other microorganisms as agricultural, the NOP should clarify that they ***can currently be certified*** based on the product composition requirements of § 205.301 (b or c) and the handling requirements of § 205.270. This is consistent with the allowance to certify “natural flavors” currently listed as nonagricultural. The NOP describes this situation as the “imperfect world” we live in. If

flavors can be listed as nonagricultural AND be certified as organic, yeast should also be granted this exception. This approach would also facilitate recognition for organic yeast produced under the EU regulations.

NOSB Practices

Oregon Tilth **SUPPORTS** the following recommendations with respect to NOSB practices:

- Voting on the classification of a petitioned material before voting on whether a petitioned material should be listed on the National List.
- Refocus on fully understanding the technical aspects of a petitioned material and all the variations of source and process available in the marketplace to manufacture the material.

We DO NOT SUPPORT a recommendation to increase the use of annotations. We agree that annotations may be useful and even necessary in some cases, but they are generally difficult to interpret, they create excessive regulatory burdens, they can quickly become outdated, and they are very difficult if not impossible to enforce. They are also a nightmare for certification agencies that are certifying to multiple standards. A clear definition of synthetic, nonsynthetic, agricultural and nonagricultural, along with additional guidance and criteria for material review should in most cases adequately address questions of source and process. We therefore urge the NOSB to use annotations as a last resort.

Once again, Oregon Tilth would like to thank the NOSB for their ongoing work and commitment to the organic industry. We offer our support.

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Oregon Tilth, Inc.

Oregon Tilth is a nonprofit research and education membership organization dedicated to biologically sound and socially equitable agriculture. Oregon Tilth offers educational events throughout the state of Oregon, and provides organic certification services to organic growers, processors, and handlers internationally. An NOP accredited certifier since 2002, Oregon Tilth currently certifies over 650 farms and ranches and over 600 handlers in more than 35 states affording us a broad perspective of current practices and challenges faced by organic producers and handlers. This perspective also extends to the anticipated successes and challenges that this discussion topic will affect upon them.