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Ms. Michelle Arsenault, Special Assistant
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.,
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

**RE: Docket: AMS-NOP-15-0085
Handling Subcommittee – Ancillary Substances Procedure
Proposal**

Dear Ms. Arsenault:

Oregon Tilth would like to thank you, the Handling Subcommittee, and the entire NOSB for your work related to this proposal and the past work of the board on previous iterations and trials reviewing ancillary substances. We feel that the overall process as described in the proposal is sound and achievable for certifiers, MRO's, certified operations, and material operations. It provides transparency to certified operations so it is clear on what is permitted and what is prohibited in non-organic substances. While we do agree with the overall process, we do have some concerns about some of the criteria related to known or probable carcinogens. We agree with the intent, however we see some conflicting information related to potential/known carcinogens and what is currently allowed within the standard.

The standardized approach is much more dynamic for certifiers, the NOSB, MRO's, and certified operations. Additionally, the ability to provide criteria that is available to material manufacturers will help them understand the requirements they may be held to when their products are marketed for use in certified products.

Definition

The definition for ancillary substances is also greatly welcomed and in its current form in the proposal. It is understandable and as a bonus, it is inclusive of a relevant regulatory citation for incidental additives under FDA definitions. This reference is much more accessible to handlers and material manufacturers than "ancillary substances". It is a very new term, if not completely absent, from their vocabularies.

Compliance Criteria

We find that the criteria to determine the compliance of an ancillary substance is clear and relatively easy to verify based on the referenced standards, requirements, and available databases. While the ease to verify many of the criteria based on lists, referenced standards, there is one concern we do have that relates to the additional requirement for ancillary substances to not be a known or probable carcinogen. While we agree with the overall intent of the criterion of not allowing ingredients that are known or

potential carcinogens, there are some problematic and/or conflicting substances listed by the International Agency for Research on Cancer (IARC) or the National Toxicity Program (NTP), that are commonly used. For example, ethanol is often used as a carrier in various non-organic products. Meat is also listed and poses a problem with approving certain materials that may contain processed meat products.

The list provided by the American Cancer Society lacks some detail on certain specifics about the form, quantity, and method of ingestion or exposure that makes these substances carcinogenic or potentially carcinogenic, which adds a layer of uncertainty when it comes to evaluating substances with this proposal. Again, we agree with the intent of the requirement, but these criteria may need further clarifications to ensure clarity in the requirements.

Compliance Template

The use of a compliance template is not foreign to any certifier or any certified operation. Most non-organic ingredient suppliers also have familiarity with them, although some are not usually as willing to complete them. While we haven't integrated this type of criteria into our standard compliance affidavit for non-organic ingredients, we do request information on ancillary substances as part of our greater Materials Review Program. Updating our compliance affidavits to include this type of information would not be a laborious task and is attainable.

Conclusion

Overall, we agree with the proposal as a whole. With modification to clarify the IARC and NTP list of known and probably carcinogens to include the specifics about why a particular material is considered carcinogenic or potentially carcinogenic would help certifiers make clear and sound decisions related to the compliance of these materials.

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.