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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-15-0002
Handling Subcommittee – Ancillary Substances Permitted in Microorganisms**

Dear Ms. Arsenault:

Oregon Tilth would like to thank the Handling Subcommittee for their work on the Ancillary Substances Permitted in Microorganisms proposal. The subcommittee's work to address the issue of identifying and evaluating the ancillary substances present helps set the stage to evaluate future materials that are reviewed. We feel this process is critical for providing clear, enforceable standards for certifiers as well as well-defined transparency for ingredient manufacturers so they can be aware of any and all restrictions placed on specific ingredients they may employ.

For this review, and future ancillary substance reviews, we would like to ensure that these substances are reexamined comprehensively to address current ancillary substances known to be in use. Additionally, we would like to provide information from a certifier's perspective for the potential addition of commercial availability restrictions based on ancillary substance reviews as these changes become more numerous.

Microorganism Ancillary Substance Review

Specific concerns include the complete evaluation of all classes of substances and the current listing of selected substances. One example includes the proposal providing a listed class of cryoprotectants specific to freeze-drying, but no listing of cryoprotectants for use in typical freezing applications.

Reviews that are not comprehensive in scope could introduce several confusing scenarios. Microorganism preparations run deep risks for becoming non-compliant despite previous understandings of what would constitute permissible use of an item if it is left out due to oversight or inability to conduct a thorough survey of all applicable items for inclusion on the review list. In a case where the microorganism preparation is essential to a certified operation, it may prevent them from using that product and in a worst-case scenario they may need to give up their certification.

Ensuring Ancillary Substance Review is Comprehensive

The intent of these ancillary substance reviews is to provide a list of ancillary substances allowed for use in a material listed on the National List and prohibiting the use of substances not listed within these reviews. Because of this, it is important that a comprehensive review of ancillary substances is performed in order to avoid prohibition of a substance that may not have been accounted for during NOSB review. Leaving out a substance could prohibit the use of a currently allowed microorganism due to the lack of the specific carrier being listed within the proposal.

Oregon Tilth supports the continued work on a procedure for ancillary substance review utilizing TAP reviews to investigate ancillary substances in petitioned or sunset materials. We also recommend continuing to use certifiers, material manufacturers, and other organizations, such as the Organic Trade Association or Organic Materials Review Institute (OMRI) as information gathering avenues, to collect information on these substances to ensure a complete view of substances is obtained prior to final recommendations.

While it is unlikely that every possible situation is accounted for in these reviews, it is still important that participation from many groups is elicited.

Use of Organic Ancillary Substances When Available

Restrictions for commercial availability on materials found on §205.605 have been implemented in the last few years, specifically for Yeast and Silicon Dioxide. There is also a petition in process for at least one additional material found on §205.605 that intends to add a commercial availability restriction to the listing. The information on the ancillary substance review process, as well as this proposal, suggest that this type of restriction will be evaluated for any agricultural material identified through an ancillary substance review.

As a certifier, we work with many certified operations performing commercial availability searches and ensure these operations collect and maintain evidence of each search for review and inspection. Some of these searches can require a large volume of paperwork, time and effort be invested before approval can be given. As more materials on §205.605 have restrictions requiring commercial availability, this effort multiplies both on the level of documentation a certified operation must maintain as well as the information a certifier must review.

Each certifier addresses search requirements differently. We have refined the process for our certified operations, but the continued addition of these restrictions will have an impact on these operations and certifiers alike. An increase in commercial availability searches for materials found on the National List will likely require us to reevaluate our policies and procedures to accommodate the increased documentation load.

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.