



United States
Department of
Agriculture

Agricultural
Marketing
Service

1400 Independence Avenue, S.W.
Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

February 3, 2014

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Miles McEvoy
Deputy Administrator
Agricultural Marketing Service
National Organic Program (NOP)

A handwritten signature in blue ink, appearing to read "Miles McEvoy", with a large, stylized flourish underneath.

SUBJECT: Trial Process for Ancillary Substance Review

On November 23, 2011, the National Organic Program (NOP) [requested](#) that the National Organic Standards Board (NOSB) clarify whether “other ingredients” are allowed in organic processed food products. The NOP stated that when used as a formulated product, some substances on the National List of Allowed and Prohibited Substances (National List) at 7 CFR 205.605 may contain additional “other ingredients” in various categories, including, but not limited to, carriers, stabilizers, and preservatives. These substances are intentionally added to a formulated product, but not considered part of the manufacturing process that is already reviewed by the NOSB. The NOP requested that NOSB develop a policy on “other ingredients” for substances listed on section 205.605 and that the NOSB consider the presence of any “other ingredients” as part of their review processes as substances on the National List come up for sunset review, or as new petitions are considered.

The NOSB began working on this topic in 2012 and utilizes the term “ancillary substances” in place of the term “other ingredients” to describe this group of substances. The term “ancillary substance” is a more descriptive term as these substances are not considered ingredients by the U.S. Food and Drug Administration.

At its April 2013 public meeting, the NOSB made a [recommendation](#) to review ancillary substances found in food handling substances in accordance with the Organic Foods Production Act (OFPA) criteria. The NOSB recommended that the review could be conducted as generic substances come up for sunset review or as new petitions are received.

On September 5, 2013, the NOP responded to the NOSB recommendation, supporting a review of these ancillary substances according to OFPA requirements. The NOP also agreed that the review does not require these substances to be individually listed on the National List, and reiterated that the NOP could communicate restrictions or prohibitions in an annotation for the generic substance or in published guidance regarding permitted substances for organic handling.



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Moving forward, the NOSB should review ancillary substances either 1) through its review of new petitions for section 205.605 of the National List, or 2) when a substance on section 205.605 of the National List is due for sunset review.

For new petitions, the NOSB is now receiving information on ancillary substances as part of technical reports to aid in its review. The NOSB should capture any recommended limitations or allowances for ancillary substances within its final recommendation on a given petition.

For substances that are due for sunset review, the NOSB should use the following procedure for its ancillary substance review:

- The NOSB Handling Subcommittee determines whether ancillary substances are present in a substance under sunset review. Information to aid in this determination may be available as part of a technical report or through public comment.
- If ancillary substances are not present:
 - The NOSB Handling Subcommittee indicates this in its preliminary sunset review which is posted for public comment prior to the next public meeting.
 - The NOSB uses this preliminary sunset review to inform its full sunset review at the next public meeting. The NOSB's findings are documented as part of its final NOSB sunset review.
- If ancillary substances are present:
 - The NOSB Handling Subcommittee evaluates whether the ancillary substances should be allowed in organic handling using the OFPA criteria (7 USC 6518(m)).
 - The NOSB Handling Subcommittee develops a separate ancillary substance proposal distinct from its sunset review to indicate whether the ancillaries should be allowed or restricted.
 - The NOSB Handling Subcommittee makes any proposal on ancillary substances available for public comment prior to the next public meeting.
 - The NOSB makes a recommendation on any proposals at the next public meeting.
 - The NOSB submits its recommendation to NOP for any future guidance, policy memos or rulemaking as necessary.

For substances that are due for sunset review, any ancillary substance proposals are limited to addressing ancillary substance issues only. Any annotation changes to change the use restriction for a substance already on the National List needs to be submitted as a petition. Ancillary substance proposals could be made concurrently with, or at meetings following, the final sunset review, depending on the need for more information. If made concurrently with a sunset review, the proposal must be posted in time for public comment at the same meeting. The NOP will work with NOSB to develop a template for these ancillary substance proposals to ensure completeness.



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Given that this is a new approach, the NOP requests that the NOSB proceed with its ancillary substance review using microorganisms, a substance due to sunset in 2016, as a trial run of the ancillary review procedure described above. The NOP will work with the NOSB to modify this procedure and adjust as necessary after the trial run.

We look forward to working with the NOSB on ancillary substances when handling materials are reviewed for inclusion or renewal on the National List.