

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: April 27, 2016

Subject: Ancillary Substances Procedure Proposal

NOSB Chair: Tracy Favre

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement: X

Other: Program Manual and PPM

Statement of the Recommendation:

The NOSB recommends a review process for ancillary substances, supported by the definition, criteria for compliance, and procedure as outlined.

Rationale Supporting Recommendation

The ancillary substances policy passed by the NOSB in 2014 did not completely address procedures needed by the Board in order to review ancillary substances, nor did the policy provide adequate guidance to ACAs. Therefore, this recommendation creates a clear set of steps that the NOSB will use to review ancillary substances, and provide optional template items that ACAs may use in determining compliance. The Board's intention is to establish sound and sensible processes for review of substances, while maintaining transparency.

The NOSB will seek guidance from the NOP about adding these procedures to the NOSB policy and procedures manual as well as the NOP Program Handbook.

NOSB Vote:

Listing Motion: Motion to adopt the proposal on ancillary substance review procedures.

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion Passed

**National Organic Standards Board
Handling Subcommittee
Ancillary Substances Procedure - Proposal
February 16, 2016**

Background

Ancillary substances have been discussed by the NOSB for several years now, with an overall policy being passed in 2014 and ancillaries being looked at in Technical Reports (TR) and NOSB reviews since then.

However, attempts to pass a separate ancillary substance proposal to accompany the review of specific National List entries have all been withdrawn by the board due to issues brought up by the public during the comment period. So far these have included ancillaries in microorganisms (brought forward 3 times), pectin, and yeast. Additional listings from the National List were recently renewed in the Sunset 2017 process that also have ancillary substances, including enzymes and nutrient vitamins and minerals. While ancillaries were covered in the TRs for these, it was decided not to bring forward proposals until the previous ones were approved and a standard format could be established.

Discussion

The main issues raised in public comment have been examined by the Handling Subcommittee (HS) and are as follows:

- Accredited Certifying Agents (ACA) would have to do a lot more paperwork to verify ancillary substances by functional class. Right now most specification sheets may list names of ancillaries but not specify the functional class each one is in.
- While the charts presented of the known ancillary substances are helpful, there is no clear procedure for ACAs to evaluate those that are not on the chart.
- Allowing other ancillaries that are not on the chart could result in some very problematic substances being allowed, specifically preservatives.
- A separate proposal and vote is not necessarily needed for those ancillaries that are allowed, but is needed for any that the NOSB wishes to prohibit.
- All ancillary substances should be reviewed separately and added to the National List. (This was rejected by the NOSB in the 2014 recommendation but it still keeps coming back in public comment).

In light of some of these issues, the HS has decided to propose an additional set of criteria and procedures for ACAs and suppliers of ingredients so that it is clear what tools everyone can use for compliance with the 2014 recommendation. If these are adopted and followed, there will not be a need for a separate ancillary substance proposal for each listing on the National List.

The proposal includes:

1. A definition of Ancillary Substance
2. Criteria used to review ancillary substances that can be used by both the NOSB in initial review and ACAs in subsequent verifications.
3. Procedures for the NOSB to follow for those materials that may have ancillary substances to be reviewed.
4. (optional) Example of a standardized template for ACAs to determine compliance.

Proposal

1. Definition

Ancillary Substance: Additives intentionally added to a non-organic substance on the National List that are not removed and have a technical or functional effect on the non-organic substance, not on the final organic product that the non-organic substance is used in. Ancillary substances may be present in the final organic product but only in insignificant amounts. Ancillary substances fall under the FDA definition and labeling regulations for “incidental additives,” which do not need to be declared on the label of the final food (including organic product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3) i to iii4). To illustrate: Enzymes are listed on 205.605(a). The enzymes might contain the following additives, which are considered by the organic industry as “ancillary ingredients”: calcium silicate (anticaking agent), calcium phosphate (carrier and/or filler), stearic acid (preservative), sorbitol (stabilizer), sodium citrate (pH control, buffer).

2. Criteria for Compliance

At least **one** must apply:

1. The ancillary ingredient was considered part of the manufacturing process that has already been reviewed by the NOSB.
2. The ancillary ingredient is certified organic, on the National List 205.605 or 205.606, or is agricultural (e.g., sugars as standardizing agents in pectin).
3. The ancillary ingredient is approved by FDA as GRAS for the particular use.
4. The ancillary ingredient is approved by FDA as a direct food additive or incidental additive for the particular use.
5. The ancillary ingredient is approved by FDA as a food contact substance for the particular use, as evidenced by a Food Contact Notification (FCN).

Additionally, the ancillary ingredient **cannot** be a known or probable carcinogen according to the International Agency for Research on Cancer (IARC) or the National Toxicity Program (NTP). A compiled list is published by the American Cancer Society at <http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformationaboutcarcinogens/known-and-probable-human-carcinogens>

Examples of ancillaries that are listed on the IARC and/or NTP list, and would therefore be prohibited, include formaldehyde and butylated hydroxyanisole (BHA)

3. Procedure for NOSB review of ancillaries

The first three of these procedures are already in place, but the last ones are different from the past approach.

- At the time of requesting a TR for a new or sunset substance, the NOSB will ask that information about identity and functional classes of ancillary substances be reviewed along with the other evaluation questions.
- For new substances, a chart of the ancillary substances by functional class will be incorporated in the checklist document or whatever review template is used.

- For sunset substances, a chart of the ancillary substances by functional class will be included in the first posting along with a request for new information about existing ancillaries and/or additional ancillary substances to be brought forward in public comment.
- The vote to approve a new substance will be considered to also approve the ancillaries that are associated with that substance unless the NOSB specifically states that one is not approved. Similarly, the vote to finalize the sunset review after the second posting will be considered to also approve ancillaries unless one is pulled out as not approved.
- Any ancillary substances that the NOSB wishes to prohibit (that are not already on the IARC and NTP lists) will have to come before the board in a separate proposal that can be voted on at the same meeting or a subsequent meeting of the board.

4. Example of Information for an Ancillary Substances Compliance Template.

For ancillary substances that are already on the list of those reviewed by the NOSB, another form may not be needed. But for new ancillary substances, and if ACAs wish to develop a compliance template, the following information should be included on the template:

1. Definition of ancillary ingredients (see 1 above)
2. A request for the name of the non-organic ingredient that the ancillary ingredient is in (e.g., pectin)
3. A request for the name of the ancillary ingredients in the product and CAS #'s (e.g., dextrose, CAS#: 50-99-7)
4. The Criteria for Compliance (see 2 above)
5. A request for the justification that ancillary ingredients meet the criteria (e.g., the FDA regulatory reference and confirmation that the ancillary is not a known or probable carcinogen according to the International Agency for Research on Cancer (IARC) or the National Toxicity Program (NTP)).
6. A request for a specification sheet with full ingredient disclosure for the non-organic ingredient (e.g., a specification sheet with full ingredient disclosure listing pectin and also the dextrose, which is used as a standardizing agent).
7. A request for the name, signature and date of the party signing the compliance declaration.
8. Language that speaks to the legal ramifications of falsifying information to ACAs.

Note: All requested information is required to be completed by the responsible party in order for the compliance declaration to be accepted by the ACA.

Motion to adopt the proposal as stated above for the definition, criteria for compliance, and procedure for the review of ancillary substances.

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0