April 14, 2016

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-15-0085

RE: Handling Subcommittee – Ancillary Substances Procedure (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's Proposal. The Handling Subcommittee is requesting feedback on: 1) a definition for ancillary substances; 2) criteria for determining compliance; 3) a procedure for NOSB review of ancillary substances; and 4) an example affidavit template that could be used by Accredited Certifying Agents (ACAs) or Material Review Organizations (MROs).

Summary of OTA's Position
The Organic Trade Association (OTA[1]) agrees with the need for all parts of this proposal. To strengthen and improve the overall clarity of the proposed compliance criteria, we are suggesting a few revisions.

Definition and Procedure: We support the proposed definition of "Ancillary Substance" as written and the proposed "Procedure for NOSB Review of Ancillary Substances" with one very minor revision that references additional criteria that would disallow ancillary substances (see below).

Compliance Criteria and Template: OTA is very supportive of spelling out criteria for compliance, and we generally support the criteria included in this document. However, it is unclear if the Criteria for Compliance in this proposal are intended to replace the baseline criteria that were passed in the April 2013 recommendation, or if they will be combined. When we compare the baseline criteria to the criteria included in this proposal, there appear to be inconsistencies. For the sake of clarity, we believe it would be best to move one proposal forward that combines all of the criteria needed to make a compliance determination on an ancillary substance. We also have concerns about using the list of known or probable carcinogens compiled by the American Cancer Society (based on the lists maintained by the International Agency for Research on Cancer and the National Toxicity Program) as part of the criteria for compliance.

[1] OTA is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

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We support evaluating ancillary substances for potential human health impacts, but we do not believe the list of carcinogens was designed for this purpose. Not all substances on the list are carcinogenic through all routes of exposure. Referencing this list will need further examination.

Our comments, as detailed below, **combine** the criteria from the 2013 recommendation and this 2016 spring proposal. We have also provided minor but additional criteria that the Material Working Group (MWG) initially recommended when we started this process. With our suggested changes to the compliance criteria, we would support the example information to be included in a template as written.

Our more detailed comments are as follows:

A. Definition of Ancillary Substances

OTA supports the subcommittee's proposed definition of **ancillary substance** as written:

> **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 product that the non-organic substance is used in. Ancillary substances may be present in the final organic product but only at 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) (3i 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).

We believe this definition is critical and it should remain central to compliance determinations when reviewing and approving ancillary substances for their specific use in materials on the National List at §205.605 and §205.606.

B. Criteria for Compliance

OTA strongly suggest that the **Criteria for Compliance** be revised to include the baseline criteria passed in the Fall 2013 Recommendation along with additional criteria points that were suggested by the Materials Working Group (MWG) in 2012. The baseline criteria passed in the Fall 2013 recommendation and the suggestions from the MWG reflects National List criteria found in the Organic Foods Production Act (OFPA). See **Appendix A & B**.

OTA suggests the following criteria for compliance:

> "Ancillary Substances" are those that are authorized for use in materials on the National List at § 205.605 and § 205.606 according to the following criteria for compliance:
>
> - The substance meets the definition of an "Ancillary Substance"
> - The ancillary substance was reviewed by NOSB and is approved under one of the following for its particular use as a food additive (OFPA references are included):
>
> a. Mandatory federal requirements [7 U.S.C. §6519(f)], or

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b. FDA (GRAS) [7 U.S.C. § 6517(c) and 7 U.S.C 6519(f)], or
c. Any other federal regulatory agency with primary jurisdiction over that substance [7 U.S.C 6519(f)].

- Ancillary substances that are certified organic, on the National List at 7 CFR 205.605 – 606 or are agricultural are allowed.
- Ancillary Substances would be **disallowed** if:
    a. Prohibited by federal regulatory action [7 U.S.C. § 6517(d)], or
    b. *Produced using excluded methods [7 CFR 205.105(e) and 7 CFR 205.2], or
    c. Contain any heavy metals or toxic residues in excess of established tolerance levels set by FDA or EPA [7 U.S.C. § 6510(a)], or
    d. It provides a technical or functional effect in the final certified organic product and is required to be on the label and therefore does not meet FDA's definition of an 'incidental additive.'

*Note that this is a general prohibition and, while it is included here as compliance criteria, the evaluation lies with the certifier or MRO. Excluded methods are generally prohibited so it's understood that any material on the National List must not be produced using excluded methods. Verification of this prohibition is conducted at the certifier/MRO level.

The above compliance criteria should be used by NOSB, ACAs and/or MROs in creating a compliance affidavit and in the course of reviewing ancillary substances.

Known or Probable Carcinogens

The subcommittee is recommending that ancillary substances 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:

http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformationaboutcarcinogens/known-and-probable-human-carcinogens

Taking this approach seems appropriate at first glance, however upon further examination, we find alcoholic beverages, ethyl alcohol/ethanol and red meat on the list. This presents a challenge. Ethanol, for example, is available in organic form and both organic and non-organic forms are commonly used as carriers and solvents. When ethanol is used as an ancillary substance the amount remaining in a final certified organic product would be insignificant to none. It would also be drastically less than the amount of ethanol contained in the organic beer and wine we consume directly. Allowing the organic certification and consumption of ethanol on one hand while prohibiting it as an ancillary substances on the other, presents a conflict. It is recognized in the introductory text for the list that substances may only be carcinogenic if a person is exposed in a certain way and to a certain extent. Using the list without any context could be problematic. Referencing this list will need further examination.

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C. Procedure for NOSB Review of Ancillary Substances

OTA agrees with the proposed procedure with **one minor revision** in the last bullet that takes into account our suggested compliance criteria:

- Any ancillary substance that the NOSB wishes to prohibit (that are not already disallowed under the compliance criteria ~~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.

D. Ancillary Substance Compliance Template

OTA thanks the Handling Subcommittee for recommending language that should be included on a template. This is a key tool that will greatly assist ACAs and MROs in their process of determining compliance of ancillary substances. It will not only greatly improve everyone's ability to gather information in a consistent manner, it should improve the understanding of ancillary substances (by definition) throughout the organic sector. Our only suggested improvement is to ensure that the template specifically includes an agreement that the substance is being used in accordance with definition of an ancillary substance. This can be easily remedied by including the definition in the compliance criteria as we have done in section B of our comments.

Conclusion

OTA thanks the Handling Subcommittee for its perseverance on this very complex topic. We believe the changes we are requesting are important, and it is worth the time and effort to take this proposal back to the subcommittee for another round of revisions.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard
Senior Director of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendix A: Baseline Criteria from the MWG Paper to NOSB (supported by OTA)

Appendix B: Baseline Criteria from the Fall 2013 NOSB Recommendation

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Appendix A

Baseline Criteria from the April 11, 2013 Final NOSB Recommendation

We believe that baseline criteria should be used for the evaluation of ancillary substances, based on the existing requirements that are already imposed by OFPA and 7 CFR Part 205. As baseline we propose that all ancillary substances must be legal for use in food in the United States, (appears with a regulated status in the FDA database "Everything Added to Food in the United States" (EAFUS)), or be subject of a FDA "no objections" response in the GRAS Notification Inventory published by FDA. The NOSB is aware that some ingredients are legally used in food products that are deemed GRAS by manufacturers who do not disclose the safety information by submitting a notification to FDA, but finds that ingredients used in organic food, should at a minimum, be reviewed for safety by the FDA, with such information publicly disclosed.2

The **baseline criteria** are as follows:

Ancillary substances ("Other ingredients") are those that are authorized for use in materials on the National List at § 205.605 and § 205.606 according to the following criteria:

1. Any substance either approved as a food additive or listed or affirmed as GRAS in the FDA Database "Everything Added to Food in the United States (EAFUS)" [http://www.fda.gov/Food/FoodIngredientsPackaging/ucm115326.htm]
2. Any substance listed in the GRAS Notification Inventory published by FDA, with a letter of no objection. [see http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing]

AND any component or ingredient would be disallowed if:

3. Prohibited by federal regulatory action [7 U.S.C. § 6517(d)] or;
4. It is required by the FDA to be on an ingredient label of the product to which the substance is being added, and therefore does not meet FDA's definition of an 'incidental additive'.

Appendix B

Baseline Criteria submitted to NOSB by the Materials Working Group

MWG first established baseline criteria that should be used for the evaluation of "other ingredients," based on the existing requirements that are already imposed by OFPA and 7 CFR Part 205. The **baseline criteria** are as follows:

"Other ingredients" are those that are authorized for use in materials on the National List at § 205.605 and § 205.606 according to the following criteria:

1. The National List [7 CFR 205.605 – 606] or;
2. Mandatory federal requirements [7 U.S.C. §6519(f)] or;
3. FDA (GRAS) or otherwise [7 U.S.C. § 6517(c) and 7 U.S.C 6519(f)]; or
4. EPA [7 U.S.C. § 6517(c) and 7 U.S.C 6519(f)] or;
5. Any other federal regulatory agency with primary jurisdiction over that substance [7 U.S.C 6519(f)].

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AND any component or ingredient would be disallowed if:

6. Prohibited by federal regulatory action [7 U.S.C. § 6517(d)] or;
7. *Produced using excluded methods [7 CFR 205.105(e) and 7 CFR 205.2] or;
8. Contain any heavy metals or toxic residues in excess of established tolerance levels set by FDA or EPA [7 U.S.C. § 6510(a)] or;
9. It provides a technical or functional effect in the final certified organic product and therefore does not meet FDA's definition of an 'incidental additive'.

*Note that this is a general prohibition and, while it is included here as baseline criteria, the evaluation lies with the certifier or MRO. Excluded methods are generally prohibited so it's understood that any material on the National List must not be produced through excluded methods. Verification of this prohibition is conducted at the certifier/MRO level.

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