March 30, 2015

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-15-0002

RE: Handling Subcommittee – Ancillary Substances Permitted in Microorganisms

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's Proposal on Microorganisms. The Handling Subcommittee is proposing to approve the ancillary substances listed in the chart included in the proposal (see Appendix A) along with a revision to the annotation to require organic sources for ancillary substances when available. The listing would read as follows:

> Microorganisms -- any food-grade bacteria, fungi, and other microorganism. Organic sources for ancillary substances must be used when available.

Summary

Motion #1: The Organic Trade Association (OTA[1]) supports the Handling Subcommittee's Proposal to approve the ancillary substances listed in the chart, although we are concerned about the static nature of the chart and the potential this closed list may have on the use of preferred alternatives that may be more compatible with organic principles. How will this list be maintained and how can it best accommodate innovation?

Motion #2: We're also supportive of the intent behind assigning organic preference to ancillary substances, but we believe there are practical obstacles and enforcement challenges in doing so. Those challenges aside, the wording in the proposed annotation is not clear. We recommend that the Handling Subcommittee clarify its intent. Do you mean to require that the "source" of the ancillary substance be organic when available, or, the ancillary substance itself? For example, maltodextrin is derived from corn. Is the intent for the corn to be organic, or for the maltodextrin to be organic? We believe the intent is for the maltodextrin to be organic if available. This intent should be clarified to NOP.

[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 mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

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We're also concerned about the statement "…must be used when available." We're assuming the intent is to require organic ancillary substances when they are commercially available, as defined in the organic regulations.

> **Commercially available.** The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

We recommend that the proposal clearly communicate the following:

> Microorganisms -- any food-grade bacteria, fungi, and other microorganism. Organic ~~sources for~~ ancillary substances must be used when commercially available.

Additional comments on the review and approval process: In addition to our general support for both motions, we offer comments and suggestions on the procedure that will be followed as this proposal moves forward to NOP. Our comments address: 1) the way in which the allowed ancillary substances will be made available to the public; and 2) the need for a USDA formalized affidavit/declaration that can be used by certifiers and all stakeholders in the supply chain to consistently communicate and collect the necessary information needed to assess compliance of ancillary substances.

We offer the following more detailed comments:

Creating a system that will allow for innovation and change

OTA supports NOSB review of "other ingredients." The uniformity and integrity of material review decisions are of paramount importance to the entire organic supply chain. We continue to advocate for a policy that will facilitate efficient review, and allow consistent compliance decisions at both the NOSB level (Generic Material review) and at the Accredited Certifying Agent (ACA) and Material Review Organization (MRO) level (Brand Name material review).

OTA supports the Handling Subcommittee's Proposal to approve the ancillary substances listed in the chart. However we are concerned about the static nature of the chart, and the potential this closed list may have on the use of a preferred alternative that may be more compatible with organic principles. It is unrealistic to assume that the Technical Review in combination with public comment will capture the entire universe of ancillary substances that may be used in a National List substance such as microorganisms. While we expect the list is fairly complete, we can be certain that some have been missed. To allow only the ancillary substances that are included in the chart may eliminate the ability to use other ancillary substances that may be preferred both by the certified operator and organic stakeholders at large. How will this list be maintained and how can it best accommodate innovation?

We also continue to state our position that a closed list of allowed ancillary substances submitted as part of a NOSB recommendation will be incredibly difficult to manage and extremely cumbersome for industry, certifiers and other regulators to navigate. The NOSB recommendation and checklist should be used for background information only. Restrictions and/or prohibitions would best be communicated in NOP Guidance or Policy. See our comments below.

Assigning organic preference to ancillary substances

OTA is supportive of the goal behind assigning organic preference to "other ingredients." However,

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we believe there may be obstacles and enforcement challenges in doing so. OTA remains committed to the increased use and development of organic ingredients and to the steps we take to accomplish that goal. Our focus is making sure we're spending our time and valuable resources directing energy to the places that will most effectively make this happen.

The organic sector is faced with a serious supply shortage of organic ingredients, especially grain, which is typically the source for most agricultural substrate used in ancillary substances. We're in a situation where we are struggling to transition the necessary acres needed to meet the organic demand for major crops being used to fulfill organic livestock feed requirements and the 95% -99% organic portion of organic products. Again, we are in agreement with the goal to use organic ancillary substances when they are **commercially available**. However, we believe from a practical perspective that our focus should be to first scale up the organic production of major and minor ingredients before moving on to "other ingredients" contained within approved non-agricultural non-organic minor ingredients. We're concerned that such a requirement is not in line with the goals of sound and sensible organic certification and we're not convinced that the exercise will actually result in increased organic acreage.

There is an enforcement challenge as well as a supply challenge when placing partial organic requirements on an otherwise allowed non-organic non-agricultural ingredient. The manufacturer of the non-organic ingredient is not certified and therefore will likely not be inspected by an ACA. The verification process will be carried out through the use of documentation and desk audits only, which raises enforcement issues. The manufacturer of the non-organic ingredient will be operating as an "exempt operation" that will simply be identifying an ingredient in the product as organic in an ingredient statement on a specification sheet. The certified organic operator, in turn, will not be able to represent that ingredient as "organic" on any of its certified products as per § 205.301[2] of the regulations. The certified operator will pay a premium price for a non-organic ingredient that is not certified organic and cannot be represented as organic in the certified end product. The intent remains good, but the feasibility and incentive are low.

Looking at this from both an enforcement and supply perspective, OTA continues to think it makes more sense to assign commercial availability to the ingredients or processing aids that appear on § 205.605, consistent with the requirement to use certified organic yeast when it is commercially available and consistent with our petition to require organic flavors when commercially available. This provides a much greater incentive for manufacturers to work towards a certified organic ingredient that can be marketed as such and it provides a clear means for certifiers to verify compliance.

Standardized Template/Affidavit for Ancillary Substances

The topic of ancillary substances continues to be an incredibly difficult subject to explain and an even more difficult topic to understand. The term "ancillary substance" is not a term recognized or used by food scientists, food manufactures or food regulators (other than USDA's NOP). Certified operators and their ingredient suppliers are struggling to understand what an ancillary substance is and how to identify

[2] **205.310(b) Agricultural products produced on an exempt or excluded operation:** An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as "organic" in a product processed by others.

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which ones are being used. Finding common language that can consistently be used for communicating the ancillary substance policy will be critical to future certification and enforcement.

To help this situation, we request that NOSB develop a recommendation to NOP for a template that contains standardized language to use in the creation of a non-organic ingredient affidavit/declaration. The affidavit would be used by ACAs and certified operators to collect and assess the information needed to determine compliance with the ancillary substance policy. The template could be adapted accordingly by ACAs to fit their information systems. In all cases, the resulting affidavit would include clear language that: 1) defines an "ancillary substance" with reference to the NOP policy; 2) provides examples according to the definition; 3) requests supporting documentation such as the specification sheet; 4) requires a signature and date; and 5) includes language that speaks to the legal ramifications of falsifying information to ACAs. This would facilitate consistent communications on the topic and provide guidance to industry. An example of an existing document is the Natural Flavor Declaration widely used by the flavor industry supplying flavors to certified organic operators. See Appendix B.

From NOSB to NOP to the Public

On February 3, 2014, NOP sent a memo to NOSB entitled "Trial Process for Ancillary Substance Review." **See Appendix C**. In that memo, NOP restated its response to NOSB's April 2013 recommendation in support of reviewing ancillary substances according to OFPA requirements. NOP also agreed that the review does not require these substances to be individually listed on the National List, and reiterated that NOP could communicate restrictions and prohibitions in an annotation for the generic substance or in published guidance regarding permitted substances for organic handling.

OTA agrees and we strongly support the following process:

- NOSB submits a recommendation to NOP for any future guidance, policy memos or rulemaking as necessary.
- NOSB allowances, restrictions and/or prohibitions are recommended to NOP, and formally adopted and explicitly communicated through a National List annotation and/or NOP Guidance or Policy.

This approach will assist organic producers and handlers by providing an additional comment period. It will ultimately house the final decision in a formal location (either in the organic regulations or in NOP guidance) that is fully transparent and easily accessible to organic stakeholders.

Conclusion

OTA supports NOSB's authority to set restrictions on National List substances and we thank the subcommittee for its work and published review of the ancillary substances used in microorganisms. While we are generally in support of the proposal, we believe the following revisions and suggestions will clarify and improve the overall process as we move forward:

- OTA would rather see commercial availability assigned to the § 205.605 listed ingredients that contain agricultural components and could potentially meet the organic standards. A requirement to use organic ancillary substances may not be practically feasible given supply and enforcement challenges. Should NOSB vote to approve this motion, we recommend that NOSB revise the recommendation to clearly communicate that "**Organic ancillary**

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substances" must be used when **commercially available**."

- OTA requests that NOSB develop a recommendation to NOP for the use of a template with standardized language that may be used by ACAs and certified operators to collect the information needed to determine compliance according to the ancillary substance policy.
- A closed list of allowed ancillary substances submitted as part of a NOSB recommendation will be extremely cumbersome for industry, certifiers and other regulators to find and navigate. The NOSB recommendation and checklist should be used **for background information only**. Restrictions and/or prohibitions must be codified in an annotation or specified in NOP Guidance or Policy.

Again, on behalf of our members across the supply chain and the country, OTA thanks NOSB 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

Microorganisms/Dairy Cultures

Functional Class	**Substance Name**
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or non-synthetic	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	Micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid
Stabilizers	Maltodextrin
Cyroprotectants used to freeze-dry dairy cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

Appendix B: Example Document: Natural Flavor Declaration

Appendix C: NOSB Chairperson: Trial Process for Ancillary Substance Review (February 3, 2014)

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NATURAL FLAVOR PRODUCT QUESTIONNAIRE - NATIONAL ORGANIC PROGRAM USE

The **USDA National Organic Program (NOP)** allows the use of certain natural (non-synthetic) substances, including flavors, in products labeled as "Organic" or "Made with Organic…(specified ingredients or food groups)" providing they comply with provisions established in the USDA NOP (*7 CFR Part 205*).

The NOP defines **Non-synthetic** (natural) in 7 CFR 205.2: a substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (*7 U.S.C. 6502(21)*). Under the terms of the Act, "**synthetic**" means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Non-synthetic Flavors authorized under the NOP, Section 205.605 (a)(9) must be from non-synthetic sources only and must not be produced using synthetic solvents, carrier systems or any artificial preservative. In addition, **Sections 205.105 (e)(f)(g)** respectively prohibit so-called "excluded" methods (GMOs), ionizing radiation or sewage sludge, defined in 205.2, from being applied to any ingredients or products under the NOP.

FDA Definition of Natural Flavors *FDA 21 CFR Part 101.22(a)(3)*: "… **natural flavor** or **natural flavoring** means the essential oil, oleoresin**,** essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice**,** fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include [*but not exclusively*] the natural essences or extractives obtained from plants listed in §§182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in §172.510 of this chapter."

The use of this questionnaire is to determine compliance of a natural flavor for use in an "organic" or "made with organic…" product under the terms of the NOP. **Oregon Tilth may request additional information as needed.**

Identification of Natural Flavor Product (code/Name): _____

Supplier Name, Address: _____

Type of flavor (select one or more as necessary):

	Compounded flavor		**Extracts**		**Isolate**
	Compounded WONF		**Essential oil**		**Oleoresin**
	Distillate		**Essential oil Isolate**		**Other (please specify):**

Natural Flavor Product

A. Flavor constituents

1. Do all of the flavor constituents in the natural flavor product named above meet the FDA definition of a natural flavor (see above)?
   ☐**Yes** ☐**No**

2. **Natural flavors** authorized for use in NOP "organic" or "made with organic" products, in addition, must not be produced using **synthetic extraction solvents**. Extraction may only use **nonsynthetic, non-petroleum based solvents (see below)***.
   - Is/are the natural flavor constituent(s) made using NOP-suitable extraction solvents*?
     ☐**Yes** ☐**No**
   - If the solvent used to extract the natural flavors is not listed as an example of one of the NOP-suitable extraction solvents* please disclose:_____

***Allowed natural extraction solvents include water, natural ethanol, super-critical carbon dioxide, authentic essential oil, and natural vegetable oils**. No hydrocarbon solvents, or chlorinated, or halogenated solvents may be used. Propane, hexane, and freon are examples of solvents that are prohibited.

B. Non-flavor constituents and other ingredients

1. **Natural flavors** authorized for use in NOP "organic" or "made with organic" products must not contain any **synthetic carrier systems** or any **artificial preservatives**. This extends to synthetic processing aids, emulsifiers or antioxidants; i.e. prohibited substances include but are not limited to, e.g., propylene glycol, polyglycerol esters of fatty acids, mono- and di-glycerides, benzoic acid, polysorbate 80, medium chain triglycerides, BHT, BHA, triacetin, etc. **Acceptable carriers, preservatives or other additives or foodstuffs MUST BE either organic, nonsynthetic, or on the National List at 205.605(b).**

   - Please list any carrier system(s) used in this Natural Flavor Product or attach an Ingredient Statement: ☐ N/A

   Carrier:_____ Source Material:_____

   - Please list any preservative(s), *or other additives or foodstuff* ingredients used in this Natural Flavor Product or attach an Ingredient Statement: ☐ N/A

   Preservative/Additive/Foodstuff:_____ Source Material:_____

2. **If any of the above are synthetic, are they listed on the NOP National List at § 205.605(b)?** ☐Yes ☐No ☐N/A

C. Genetically Modified Organism (GMO) products may not be used at any stage in the process of making natural flavor products for NOP goods. **Excluded methods** (= GMO use) – a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include but are not limited to recombinant DNA technology (including gene deletion, gene doubling, introduction of a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology); therefore, GMO-plant extracts may not be used nor may natural flavors be the product of GMO-yeast fermentation, for example.

- *This natural flavor product, including any solvents, carriers, preservatives or other or processing aids used or contained therein, was produced or handled using excluded (GMO) methods?*
  ☐**Yes** ☐**No**

D. Ionizing Radiation is prohibited for all uses involving food preservation, pest control and pathogen control in NOP products. Other radiation uses, including food inspection, are permitted providing such use meets applicable FDA regulations, which establish limitations applicable to all (organic and non-organic) food products.

- *Ionizing radiation as described in 21 CFR 179.26 was used in the processing of this natural flavor product?*
  ☐**Yes** ☐**No**

E. Sewage Sludge (as a crop fertilizer) is solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. It is not permitted in the manufacture of any ingredients used in NOP products.

- *This natural flavor product was derived from products using sewage sludge in their agricultural production:*
  ☐**Yes** ☐**No**

This questionnaire is only to be signed by a qualified technical person[1]:

Pursuant to 7CFR §205.605(a)(9) and §205.105(e)(f)(g), I, on behalf of the supplier, hereby attest that the information provided in this form is accurate and truthful to the best of my knowledge.

Identification of Natural Flavor Product (code/Name): _____

Company Name:_____ **Phone/e-mail:**_____

Printed Name:_____ **Title[1]**: _____

Signature:_____ **Date:**_____

[1] *Falsifying statements to ACA's or the Secretary under the NOP will be subject to possible fines.*