

October 6, 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-15-0037

RE: Handling Subcommittee - Ancillary Substances Permitted in Microorganisms/Dairy Cultures, Pectin and Yeast

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's proposals on ancillary substances allowed in microorganisms (including dairy cultures), pectin and yeast. The Handling Subcommittee is proposing to approve the charts provided in each proposal (**see Appendix A**).

Summary

The Organic Trade Association (OTA¹) continues to support NOSB review of "ancillary substances" (formerly known as "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) levels (Brand Name material review).

As stated in our previous comments on this topic, we continue to be concerned about the confusing nature of this topic and the potential for inconsistent implementation at the industry and certifier level.

In order to improve the overall process, OTA urges NOSB and NOP to consider the following:

- A 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 charts should be used for background information and to subsequently inform proposed guidance from NOP. This will allow an additional comment period for those who may not be following the NOSB process, and it will create a formal pathway for

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.

submitting comments to NOP on the status of ancillary substances as we move forward.

- The topic of ancillary substances is very confusing, and the term is not a recognized term used within the food industry. OTA requests that NOSB develop a recommendation to NOP for the use of a template with standardized language and definitions that may be used by ACAs and certified operators to collect the information needed to determine compliance according to the ancillary substance policy.

We offer the following more detailed comments:

From NOSB to NOP to the Public

We continue to state our position that a list of allowed ancillary substances submitted as part of a NOSB recommendation will be incredibly difficult to manage and extremely cumbersome for industry, certifiers, MROs and other regulators to navigate. The NOSB recommendation and corresponding charts should be used for background information only, and inform subsequent guidance issued by NOP. This approach would support the message sent from NOP to NOSB via a memo on February 3, 2014. **See Appendix B.**

In that memo entitled “Trial Process for Ancillary Substance Review,” NOP restated its response to NOSB’s April 2013 recommendation in support of reviewing ancillary substances according to OFPA requirements. NOP 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 suggest the following process be followed:

- 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, formally adopted and explicitly communicated through NOP Guidance. Specifically, allowed/prohibited ancillary substances should be communicated via NOP’s Permitted Substance List (PSL) for Crops, Livestock and Handling).

This approach will assist organic producers and handlers by providing an additional comment period that would alert stakeholders who missed the NOSB process and potentially capture any functional classes or ancillary substances that have been missed. If functional classes or ancillary substances have been missed, NOP can direct this review to NOSB. This approach will ultimately assist organic producers, handlers, certifiers and ingredient suppliers by housing the final decision in a formal location (either in the organic regulations or in NOP guidance), and will provide a formal comment pathway year-a-round since the public may comment on guidance at any time. This approach is fully transparent and easily accessible to all stakeholders involved.

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 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 C.** OTA offers our assistance in the creation of such a standardized template.

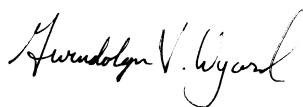
Conclusion

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, pectin and yeast.

While we are generally in support of the proposal, we believe further work is needed to clarify and improve the overall implementation and verification process.

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,

A handwritten signature in black ink, reading "Gwendolyn V. Wyard".

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

cc: Laura Batcha
Executive Director / CEO
Organic Trade Association

Appendix A

Ancillary Substances Permitted for use in 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, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose
Carriers and fillers, synthetic	Micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate, potassium phosphate, potassium sulfate, tricalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	Maltodextrin
Cytoprotectants used to freeze-dry dairy cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol, polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

Ancillary Substances Permitted for use in Pectin

Functional Class	Substance Name
Stabilizers/standardizing agents	Sugars (including dextrose)
Buffering agents	Trisodium citrate and other salts

Ancillary Substances Permitted for use in Yeast

Functional Class	Substance Name
Antioxidants	butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), propyl gallate (PG).
Preservatives	ascorbic acid
Emulsifiers	soybean oil, cottonseed oil, sorbitan monostearate, sorbitan tristearate, sorbitan monolaurate, sorbitan monooleate, sorbitan monopalmitate.
Defoaming agents	many in TR1
Substrate that may remain in final product	food waste, microorganisms, molasses, starch

Appendix B: [NOSB Chairperson: Trial Process for Ancillary Substance Review](#) (February 3, 2014)

Appendix C: Example Document: Natural Flavor Declaration

**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):

<input type="checkbox"/>	Compounded flavor	<input type="checkbox"/>	Extracts	<input type="checkbox"/>	Isolate
<input type="checkbox"/>	Compounded WONF	<input type="checkbox"/>	Essential oil	<input type="checkbox"/>	Oleoresin
<input type="checkbox"/>	Distillate	<input type="checkbox"/>	Essential oil Isolate	<input type="checkbox"/>	Other (please specify):

Natural Flavor Product**A. Flavor constituents**

- 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
- 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 diglycerides, 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 person¹:

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: _____ **Title¹:** _____

Signature: _____ **Date:** _____

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