

**National Organic Standards Board
 Handling Subcommittee Proposal
 Ancillary Substances Permitted in Microorganisms and Dairy Cultures
 August 4, 2015**

Ancillary substances are intentionally added to a formulated generic handling substance on the National List. These substances do not have a technical or functional effect in the finished product, and are not considered part of the manufacturing process that has already been reviewed by the NOSB. While some of these substances are removed or consumed in their processing, many may remain in the final product in tiny amounts.

Many public commenters for the first posting were concerned about a process for amending the ancillary substances included in this review between sunset periods. The Handling Subcommittee believes that this captures all of the functional classes in use for microorganism and Dairy Cultures products. Additional ancillaries that fall within one of the functional classes below do not need to be reviewed further to be used. Any new functional class of ancillaries however will have to be petitioned.

1. Identity of Ancillary Substances Permitted for use in Microorganisms and Dairy Cultures

Functional class	Substance name
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	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
Cryoprotectants used to freeze-dry (& freeze) microorganisms and 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

2. Identify any ancillary substances, or categories of substances prohibited for use in Microorganisms:
 None Known

3. Describe need for the ancillary substances, review of materials, discussion, and subcommittee vote.

Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism and then fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. Additional preservatives or anti-caking agents are used with some species. Capsules forms may have additional cryoprotectants and excipients. (See criteria below for discussion points).

Evaluation Criteria (provide narrative responding to each question, repeat as necessary for additional ancillary substances or groups)

1. **Impact on Humans and Environment:** Is there any evidence the substance(s) may be harmful to human health or the environment?

"There is no literature to suggest that the manufacture or use of microbial preparations with ancillary substances is harmful to the environment or biodiversity." (2014 TR page 26). There is no literature to suggest that microbial preparations with ancillary substances have negative effects on human health. (2014 TR page 28)

2. **Essential & Availability:** Is the substance necessary to the handling of the product because of unavailability of wholly natural substitute products, or essential for the handling of an organic product?

All the substances in the chart above are necessary because they are what keep the microorganism alive, pure and able to perform its function. Formulations of the desired microorganism products are not available without some of these ancillary substances. The availability of organic carriers and substrates is sometimes possible and the NOSB encourages the use of organic ancillary substances whenever possible.

3. **Compatibility & Consistency:** Is the substance's use consistent and compatible with organic handling practices?

"There is no literature to suggest preservatives used in microbial preparations as ancillary substances exert any technical or functional preservative effect in the final fermented product. Typically, Good Manufacturing Practices (GMP) dictate that preservatives are added at a maximum level of 0.1% by weight of the finished product to exert the desired effect (FDA 2013b)." (2014 TR page 23)

Subcommittee Action & Vote:

Motion to approve the functional classes of ancillary substances in the chart above for use with Microorganisms and Dairy Cultures.

Motion by: Zea Sonnabend

Seconded by: Tom Chapman

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 4, 2015