

### AMERICERT INTERNATIONAL

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# **Guidance on Completing Handler Organic System Plan Modules: Module 8 Materials Used**

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Module H8 is to be completed by operations that use a substance in organic handling. Such substances include (but are not limited to) water, salt, nonorganic ingredients, nonorganic processing aids, nonorganic substances having direct contact with organic items, and substances added to water/ice/steam that is in direct contact with organic items. Such substances also include cleaners or sanitizers used on equipment. Operations must provide a list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable. (§205.201(a)(2)). [Pest control substances used in physical facilities are addressed in Module H7 Physical Facility.]

#### Section 1: Nonorganic Materials, Ingredients, and Processing Aids

Four general categories of items must be disclosed in Table A in Module H8:

- Any nonorganic ingredients used in products for which certification is sought must be disclosed. Examples include flavors, colors, salt, yeast, carbon dioxide, etc.
- Any nonorganic materials, substances, or processing used that have direct contact with organic items during handling or processing by this operation must also be disclosed. Examples include sanitizers and cleaners in contact with organic items, processing/packaging aids, filtering aids, flotation agents, anti-foam agents, acids, etc.
- Any substance used in water, where that water has direct contact with organic items, must be disclosed. Examples include water additives, wash water additives, rinse agents, etc.
- Any cleaner or sanitizer used directly on unpackaged organic items must be disclosed.
- Any modified atmospheres (such as ethylene gas, CO2 gas) or atmospheric gases used in storage areas where organic items are stored must be disclosed.

All such materials are reviewed on a product-by-product basis and not generically by active ingredient. Therefore, operations must be sure to list the exact product name and manufacturer as well as the function of the substance in this operation's processing and handling.

# A. General Aspects of the Use of Nonorganic Ingredients, Materials, and Processing Aids. Under the USDA NOP organic regulations, in some cases, some nonorganic ingredients can be used. However, this is limited to the following cases and circumstances:

- 1. Nonorganic ingredients can only be used in products seeking an "Organic" or "Made with Organic (Specific Food Groups or Ingredients)" label claim. They cannot be used in a product seeking a "100% Organic" label claim.
- 2. Nonorganic ingredients allowed for use are limited to those nonorganic ingredients listed in § 205.605 and 205.606 of the USDA NOP organic regulations.
- 3. The total organic content for an "Organic" label claim must be 95% organic by weight or volume.
- 4. The total organic content for a "Made with Organic (Specified Food Groups or Ingredients)" label claim must be 70% organic by weight or volume.
- 5. Any nonorganic ingredient must be documented as being non-GMO, non-irradiated, and produced without the use of biosolids or sewage sludge.



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- 6. Some nonorganic ingredients can only be used when an organic version is not commercially available.
- 7. A product may not include organic and nonorganic versions of the same ingredient.
- 8. Many nonorganic ingredients have specific annotations or restrictions on use. These can be found in § 205.605 or 205.606 of the regulations and must be complied with.

## B. The Use of Organic Versions if Available.

For many of the nonorganic ingredients listed in § 205.605 and 205.606 of the regulations, they can only be used when an organic version is not available. The ingredients this requirement applies to include all of the ingredients listed in § 205.606, as well as flavors and yeast (as listed in § 205.605). To use a nonorganic ingredient which is listed in § 205.606 or nonorganic flavors or yeast, operations must prove (through documentation) that an organic version is either not available or is not suitable for use.

An organic version is considered not available when an operation can prove one of the following:

- There is no organic source available for that ingredient. A search must be conducted by contacting at least three sources of organic ingredients of that type and being told that the ingredient is not available in organic form. This search must be documented.
- There are organic versions available but the quantity of ingredient needed is not available. This search and finding must be documented.
- The quality or form of the ingredient is not suitable. You may be required to conduct trials of available organic versions to prove that the available organic versions are not suitable.

For any nonorganic agricultural ingredients from § 205.606 (other than colors) listed in Module H8 Table A, operations must also submit the Commercial Availability Affidavit.

#### C. Other Annotations.

Many ingredients listed in § 205.605 or 205.606 also have additional requirements which must be met. These can be found in the listing for that ingredient in § 205.605 or 206.606. An example would the annotation for flavors, which carries an additional requirement that: "All flavors must be derived from organic or non-syntheticsources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative." Operations must document that any additional ingredient annotation listed in § 205.605 or 205.606 is met.

- D. Documentation Required. An operation must submit with its application documentation that the requirements described above for any nonorganic ingredients have been met. For each nonorganic material listed in Module H8 Table A that is to be used as an ingredient, operations must submit the following affidavits (as applicable):
  - Nonorganic Flavor Affidavit
  - Nonorganic Color Affidavit
  - Nonorganic Yeast Affidavit
  - Nonorganic Tocopherols Affidavit
  - Citric Acid Affidavit
  - Nonorganic Material Affidavit

For each nonorganic material listed in Module H8 Table A that is not used as ingredient, operations must submit the following affidavits (as applicable):

- Nonorganic Yeast Affidavit
- Citric Acid Affidavit
- Nonorganic Material Affidavit



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Written verification must also be submitted that the nonorganic ingredient (except for salt) or processing aid is produced without the use of excluded methods, sewage sludge, or ionizing radiation. Written verification is considered valid for three (3) years after signing.

For salt, operations must submit proof that the salt is free of any synthetic additives such as anticaking agents or flow agents.

#### Section 2: Water, Ice, and Boiler Additives

- A. <u>Water</u>.If water is used in organic handling (as an ingredient or to wash/rinse organic ingredients or products such as in wash or flume water), additional information is required.
- 1. If water is run through an ion exchange filter, the exchange ions/recharge solutions need to be listed in Module H8 Table A. Ion exchange filtration is allowed in organic production. The ion exchange filtration process has two main components: ion exchange resins and the exchange ions (added through a recharge solution). Per the NOP's 7/6/23 Memo, exchange ions/recharge solutions need to be listed on the National List, while the ion exchange resins do not need to be on the National List.
- 2. If water is sourced from a well, operations need to maintain documentation showing the water used meets Safe Drinking Water Act standards (such as absent for E. coli). Water used in organic handling must be potable and meet Safe Drinking Water Act (SDWA) standards. [Water from a municipality is deemed to comply since municipalities must comply with SDWA.]
- 3. If this operation adds any materials to the water (such as peracetic acid, hydrogen peroxide, chlorine, anti-scale additives, etc.), these must be disclosed in Module H8 Table A. Standard treatments (ex: reverse osmosis, UV light, carbon filtration, water softeners, pH adjustment) that do not use any inputs intended to remain in the water are water treatments allowed without review.
- 4. If chlorine is added to water in direct contact with organic ingredients or products, operations must implement measures to protect organic integrity as follows:
  - Chlorine materials are used at levels approved by the FDA or the EPA for such purpose (such as, used at label rates).
  - Residual chlorine levels in water at last point of contact with organic ingredients or products do not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (4 mg/L or 4 ppm expressed as chlorine or 0.8 mg/L or 0.8 ppm when expressed as chlorine dioxide).
  - Only an allowed form of chlorine is used: calcium hypochlorite, chlorine dioxide, sodium hypochlorite, or hypochlorous acid generated from electrolyzed water.
  - Records or SOPs are maintained for monitoring chlorine and are attached to the OSP submission.
- 5. If water is used as an ingredient in organic food and chlorine is added to the water, operations must have records showing the chlorine levels in the ingredient water do not exceed the SDWA limits.

### B. Steam and Ice.

If steam or ice have direct contact with organic items, organic contact surfaces, or interior of organic packaging or containers, additional information is needed in Module H8 as follows:

- A description of how steam or ice is used (such as in packaging head space, exterior of packaging, cooling, etc.)
- If substances are added to the water used to make that ice or steam, these substances must be disclosed in Module H8 Table A, and Module H8 must list the measures taken to protect organic integrity.



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Measures to protect organic integrity could include such things as follows:

- Additive used is allowed on National List and this operation follows all applicable restrictions.
- No direct contact with organic items.
- Use on food contact surfaces or interior of organic packaging is followed by a water rinse with water free
  of additives.
- Steam or ice additives are shut off 24 hours before organic use.
- Condensate tests conducted.
- The active ingredient of the additive is non-volatile.
- Boilers are properly maintained, and maintenance records are available for inspection.
- Additive is not injected into the steam header.

## Section 3: Cleaners and Sanitizers on Organic/Food Contact Surfaces (FCS), Equipment, Containers, and Utensils

Any cleaners and sanitizers used on equipment, utensils, containers, or organic/food contact surfaces must be disclosed in Module H8 Table B and its SDS provided with application. Operations must also have measures in place to ensure residues are removed from these surfaces and that any restrictions on use are met. Examples are as follows:

- <u>Detergents, Soaps, Cleaners</u>: Use is followed by a water rinse.
- Alcohol (Ethanol/Isopropanol): Use is followed by a water rinse.
- <u>Alcohol (Ethanol/Isopropanol</u>): Use is followed by an air dry, because proof on hand that the alcohol is non-synthetic.
- Citric Acid: Use is followed by a water rinse.
- <u>Citric Acid</u>: Use is followed by air dry, because proof on hand that the citric acid is produced by microbial fermentation of carbohydrate substrates and is non-GMO.
- Acetic Acid/Vinegar: Use is followed by water rinse.
- Acetic Acid/Vinegar: Use is followed by an air dry, because proof on hand that the vinegar is non-synthetic.
- Quaternary Ammonium (QUAT): Use on FCS is followed by rinse sufficient to remove all residues, as demonstrated through testing with test strip capable of proving 0 ppm residue.
- <u>Chlorine</u> (limited to calcium hypochlorite, chlorine dioxide, sodium hypochlorite, hypochlorous acidgenerated from electrolyzed water): Use is at label rates on FCS with no rinse necessary.
- <u>Peroxyacetic acid/peracetic acid, hydrogen peroxide, phosphoric acid, and ozone sanitizers</u>: Used on FCS; no rinse or air dry required.
- Residue testing is conducted for chlorine, pH, or quaternary ammonia.