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Module H8 Materials Used

This Module 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.]

Operation Name:	
Date:	

Section I: Nonorganic Materials, Ingredients, and Processing Aids

A. Nonorganic Materials and Processing Aids Disclosure	
1. Does this operation use any nonorganic ingredients in any product for which certification is sought? Examples: flavors, colors, salt, yeast, carbon dioxide, etc.	☐ Yes. **Complete Table A below.** ☐ No.
2. While being handled or processed by this operation, are any nonorganic materials, substances, or processing aids used which have direct contact with organic items? Examples: sanitizers and cleaners in contact with organic items, processing/packaging aids, filtering aids, flotation agents, anti-foam agents, acids, etc.	☐ Yes. **Complete Table A below.** ☐ No.
3. Does this operation add any substance to water that has direct contact with organic items? Examples: water additives, wash water additives, rinse agents, etc.	☐ Yes. **Complete Table A below.** ☐ No.
4. Are any modified atmospheres (such as ethylene gas, CO2 gas) or atmospheric gases used in storage areas where organic items are stored?	☐ Yes. **Complete Table A below.** ☐ No.
5. Does this operation understand that products seeking a "100% Organic" label claim cannot use nonorganic ingredients or processing aids?	☐ Yes.

Table A: Nonorganic Materials and Processing Aids (§ 205.105, 205.201(a)(2), and 205.301(f)).

Instructions:

(1) List all nonorganic ingredients.

(2) List all nonorganic materials, processing aids, or substances that directly contact organic items; that are added to water that directly contacts organic items; that are used

as atmospheric gases in organic storage areas; or which are added to organic items.

(3) Food/organic contact surface and equipment sanitizers and cleaners **should not** be listed in this table, as they will be the subject of another section of this module. Sanitizers and cleaners should only be listed below if they are applied directly to organic items or are added to water that has contact with organic items.

(4) Materials listed below are reviewed on a product-by-product basis (and not generically), so **be sure to list** the exact product name and the manufacturer as well as the function of the substance in your processing and handling.

(5) For each nonorganic material listed below used as an ingredient, please also submit one or more of the following affidavits (as applicable): Nonorganic Flavor Affidavit, Nonorganic Color Affidavit, Nonorganic Yeast Affidavit, Nonorganic Tocopherols Affidavit, Citric Acid Affidavit, or the general Nonorganic Material Affidavit.

(6) For each nonorganic material listed below not used as an ingredient, please **also** submit its SDS along with one of the following affidavits as applicable: Nonorganic Yeast Affidavit, Citric Acid Affidavit, or the general Nonorganic Material Affidavit.

(7) Any nonorganic material that is added to or comes into direct contact with organic items must be consistent with the use of that material as governed by the USDA NOP National List, including § 205.605 and/or 205.606 of the NOP regulations. [Note that agricultural ingredients and processing aids in "Made with Organic" products are not required to be organic.]

(8) For any nonorganic agricultural ingredients from § 205.606 (other than colors) in Table A, please also submit the Commercial Availability Affidavit.

(9) 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.

(10) Add additional rows as needed.

Product Name	**Manufacturer**	**Generic Material Name**	**Function**	**Americert Use Only** Restrictions on Use (Authority; Date Approved)
Ex: Birk Ox Sanitizer	*Birko Corp.*	*Peracetic Acid*	*Additive to produce rinse water.*	*Peracetic Acid (Processing). For use in wash and/or rinse water according to FDA limitation. (PCO 102923)*

B. Follow Up Questions	
1. **Nonorganic Color Affidavit**. Is this operation submitting the Nonorganic Color Affidavit for each nonorganic color listed in Table A?	☐ N/A, this operation does not use any nonorganic colors. ☐ Yes.
2. **Nonorganic Flavor Affidavit**. Is this operation submitting the Nonorganic Flavor Affidavit for each nonorganic flavor listed in Table A?	☐ N/A, this operation does not use any nonorganic flavors. ☐ Yes.
3. **Nonorganic Yeast Affidavit**. Is this operation submitting the Nonorganic Yeast Affidavit for each nonorganic yeast listed in Table A?	☐ N/A, this operation does not use any nonorganic yeast. ☐ Yes.
4. **Nonorganic Tocopherol Affidavit**. Is this operation submitting the Nonorganic Tocopherol Affidavit for each nonorganic tocopherol listed in Table A?	☐ N/A, this operation does not use any nonorganic tocopherols. ☐ Yes.
5. **Citric Acid Affidavit**. Is this operation submitting the Citric Acid Affidavit for each citric acid listed in Table A?	☐ N/A, this operation does not use any citric acid. ☐ Yes.
6. **Commercial Availability Affidavit**. Is this operation submitting the Commercial Availability Affidavit for any nonorganic agricultural ingredients from § 205.606 (other than colors) listed in Table A?	☐ N/A, this operation does not use any nonorganic 205.606 listed materials. ☐ Yes.
7. **Salt.** For any salt listed in Table A, is this operation submitting proof that the salt is free of any synthetic additives such as anticaking agents or flow agents?	☐ N/A, this operation does not use salt. ☐ Yes, such proof is enclosed with this application.
8. **Nonorganic Material Affidavit**. For each other nonorganic material listed in Table A (other than those discussed in #1-6 above), is this operation submitting the Nonorganic Material Affidavit?	☐ No, all nonorganic materials listed are addressed in #1-6 above. ☐ Yes.

Section II: Water, Ice, Boiler Additives, and Radiation

A. Water	
1. For water used in organic handling, is it used as an ingredient or to wash/rinse organic ingredients or products (ex: wash or flume water)?	☐ No. **Skip to Part B.** ☐ Yes.
2. What is this operation's water source?	☐ Municipality or City. ☐ Well.
3. Is the water run through an ion exchange filter? Note: 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.	☐ No. ☐ Yes, please describe the process and include the exchange ions/recharge solutions in the materials listed in Table A above.
4. If water is sourced from a well, does this operation have documentation that the water used meets SDWA standards (such as absent for E. coli)?	☐ N/A, water is sourced from municipality. ☐ Yes.

Note: Water used in organic handling must be potable and meet Safe Drinking Water Act (SDWA) standards.	
5. Does this operation add any materials to the water? Examples: peracetic acid, hydrogen peroxide, chlorine, anti-scale additives, etc. Note: 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.	☐ No, no materials added to ingredient, wash, or flume water. ☐ Yes, and these materials are listed in Table A above.
6. If chlorine is added to water in direct contact with organic ingredients or products, please select the following **MANDATORY** measures this operation has implemented to protect organic integrity.	☐ N/A, chlorine is not added to water in direct contact with organic ingredients or products. ☐ 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 these are attached to this application.
7. If water is used as an ingredient in organic food and chlorine is added to the water, does this operation have records showing the chlorine levels in this water do not exceed the SDWA limits?	☐ N/A, water not used as an ingredient. ☐ N/A, water is used as an ingredient but chlorine is not added to it. ☐ Yes.
B. Steam and Ice	
1. Does steam or ice have direct contact with organic items, organic contact surfaces, or interior of organic packaging or containers?	☐ No. **Skip to Part C.** ☐ Yes.
2. How is steam or ice used? Examples: in packaging head space, exterior of packaging, cooling.	Describe:
3. Does this operation add any substance to the water used to make that ice or steam? Examples: anti-scale additives, boiler chemicals, etc.	☐ No, no materials added to water used to make steam or ice. ☐ N/A, materials are added to water used to make steam or ice but the steam or ice does not have direct contact with organic items, organic food contact surfaces, or interior of organic packaging (such as that used in jacketed systems). ☐ Yes, and these materials are listed in Table A above.
4. If this operation answered Yes to the previous question, how is organic integrity is protected?	☐ N/A, did not answer Yes to previous question. ☐ 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. ☐ Other:

C. Radiation

Are any organic items treated with ionizing radiation while at this facility? Note: UV light, microwaves, or X-rays (when used only to monitor for contaminants e.g. metal fragments, stones, etc.) are not considered ionizing radiation for the purposes of the organic regulation.	☐ Yes. ☐ No.

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

Cleaners and Sanitizers on Organic/Food Contact Surfaces (FCS), Equipment, Containers, and Utensils	
1. Does this operation use any substances or materials to clean or sanitize organic/food contact surfaces, equipment, containers, utensils, or surfaces that come into contact with organic items during receiving, handling, processing, transport, or storage, including grading or sampling equipment?	☐ No. **Skip to Section IV.** ☐ Yes. **Complete Table B and Question 2 below.**
2. How does this operation ensure cleaner and sanitizer residues are removed from organic contact surfaces and that any restrictions on use are met? **[SELECT ALL THAT APPLY]**	☐ Detergents, Soaps, Cleaners: Use is followed by a water rinse. ☐ Alcohol (Ethanol/Isopropanol): Use is followed by a water rinse. ☐ Alcohol (Ethanol/Isopropanol): 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. ☐ Citric Acid: 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. ☐ Chlorine (limited to calcium hypochlorite, chlorine dioxide, sodium hypochlorite, hypochlorous acid-generated from electrolyzed water): Use is at label rates on FCS with no rinse necessary. ☐ Peroxyacetic acid/peracetic acid, hydrogen peroxide, phosphoric acid, and ozone sanitizers: Used on FCS; no rinse or air dry required. ☐ Residue testing is conducted for chlorine, pH, or quaternary ammonia. ☐ Other:

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Table B: Sanitizers and Cleaners Used on Organic/Food Contact Surfaces (FCS), Equipment, Containers, and Utensils

Instructions:

(1) List all materials used to clean or sanitize equipment, surfaces, tools, utensils, or containers **that come into contact with** organic items. Submit SDS for each product listed.

(2) Materials used but that do not have contact with equipment, surfaces, tools, utensils, or containers contacting organic items (such as hand sanitizers, floor cleaners, foot baths, bathroom cleaners, drain cleaners, etc.) do not have to be listed.

(3) Add additional rows as needed.

Product (Manufacturer):	**Used?**	**Restrictions met?**	**How and Where Used**	**Americert Use Only** Restrictions on Use (Authority; Date Approved)
Ex: Dawn Dish Soap (Procter & Gamble)	*_X_ Yes*	*_X_ Yes*	*Used on utensils followed by water rinse.*	*Cleaners (Must Rinse). Must not be used in direct food contact. Equipment and food contact surfaces must be rinsed thoroughly with potable water after use. (PCO 102923)*
	☐ Yes	☐ Yes		
	☐ Yes	☐ Yes		
	☐ Yes	☐ Yes		
	☐ Yes	☐ Yes		
	☐ Yes	☐ Yes		
	☐ Yes	☐ Yes		

Section IV: Attestation

I attest this information is accurate and complete.	☐ Yes
Date Completed:	
Name of Person Completing Form:	