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Draft Guidance Substances Used in Post-Harvest Handling of Organic Products

1. **Purpose and Scope**

This draft guidance provides information to all USDA-accredited certifying agents (certifiers) and certified and exempt organic operations on substances that may be used in post-harvest handling of organic products. It clarifies: 1) what substances may be used; 2) the difference between post-harvest handling of raw agricultural crops and further processing; and 3) the provisions for facility pest management. This draft guidance also defines post-harvest substances.

See Appendix A for examples of post-harvest substances affected by this draft guidance, and Appendix B for questions and answers about using this draft guidance.

2. **Background**

The Organic Foods Production Act of 1990 (OFPA) requires substances used in organic production and handling to be itemized on the National List of Allowed and Prohibited Substances (National List) by specific use or application (see 7 U.S.C. § 6517). The National List, a subpart of the USDA organic regulations, is divided into the following sections:

- 7 CFR § 205.601 lists substances for use in crop production;
- 7 CFR § 205.603 lists substances for use in livestock production; and
- 7 CFR §§ 205.605 205.606 list substances for use in or on processed products.

The National List does not contain a separate section dedicated to substances for use in the post harvest handling of raw agricultural products.

Post-harvest handling includes actions such as washing, cleaning, sorting, packing, cooling, and storing raw agricultural products. These actions can be performed on farms or in handling facilities. Some post-harvest handling substances, such as the floating agents lignin sulfonate and sodium silicate, are included in § 205.601 of the National List for use in crop production; other post-harvest handling substances are included in § 205.605 of the National List for use in handling, such as ethylene, which may be used to ripen tropical fruits, and chlorine and peracetic acid, which may be used as antimicrobials. While synthetic substances allowed for use in organic crop production must be included in § 205.601 of the National List, there is no similar requirement for nonsynthetic (natural) substances allowed for use in organic crop production. Nonsynthetic substances are permitted for use in organic crop production unless they are specifically prohibited in § 205.602 of the National List.

The fact that substances approved for use in post-harvest handling appear in different sections of the National List, or are nonsynthetic and are therefore not included on the National List, has led

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to confusion about the point at which crop production for unprocessed commodities ends, when processing starts, and which substances may be used.

Since post-harvest handling of raw agricultural products is an action that can take place either on a farm or in a handling facility, this guidance clarifies that nonsynthetic substances allowed for use in crop production may be used post-harvest on raw agricultural commodities either on a farm or in a handling facility, provided that there is no limitation in § 205.602 of the National List that prevents or restricts their use. Similarly, substances allowed for use in handling in § 205.605 of the National List, with no specific use restrictions, may be used in post-harvest handling of raw agricultural products either on a farm or in a handling facility. Synthetic substances that are included in § 205.601 for use in crop production must be specifically annotated to permit post-harvest use in order to be used in the handling of processed products.

The USDA organic regulations provide for the use of certain substances in facility pest management, under certain circumstances, even though they are not on the National List. 7 CFR § 205.271 describes an order of preference for facility pest management. Producers or handlers must first apply management practices to prevent or control pests as described in § 205.271(a) and (b), including the use of lures and repellents containing nonsynthetic or synthetic substances that are consistent with the National List. If these practices are not adequate, then a nonsynthetic or synthetic substance "consistent with the National List" may be applied. (See 7 CFR § 205.271(c).)

The phrase "consistent with the National List" does not specify which section of the National List should be referenced in making this determination. Materials such as pheromones, sticky traps, boric acid, and Vitamin D₃ are listed in § 205.601 of the National List for use in crop production, and are therefore substances that would be "consistent with the National List" for facility pest control purposes.

For handling operations, if none of the practices listed in § 205.271 are effective, the handler may use substances that are not on the National List, provided that there is no contact with organic products or ingredients, the certifier and handler agree on the use of the substance, and its use complies with § 205.271(d).

3. **Policy**

- 3.1. Synthetic substances that are listed in § 205.601 of the National List specifically for postharvest use may be used for handling raw agricultural commodities, either on farms or in handling facilities. (E.g., lignin sulfonate, or sodium silicate.)
- **3.2.** Substances listed in § 205.605 of the National List may be used for post-harvest handling of raw agricultural commodities either on farms or in handling facilities, provided that there is no restriction limiting their use. (E.g., ethylene, or nitrogen gas.)
- 3.3. Natural (nonsynthetic) substances allowed for use in crop production that are not restricted or prohibited in § 205.602 of the National List may be used for post-harvest

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handling of raw agricultural commodities, either on farms or in handling facilities.

- 3.4. The use of any substance must comply with the U.S. Environmental Protection Agency (EPA) or U.S. Food and Drug Administration (FDA) requirements, as applicable.
- 3.5. All inert ingredients used in post-harvest pest control substances on raw agricultural commodities must be either nonsynthetic and not prohibited in § 205.602 of the National List, or allowed by § 205.601(m) of the National List.
- **3.6.** Facility pest management.
 - **3.6.1.** 7 CFR § 205.271(c) allows producers and handlers to use nonsynthetic or synthetic substances "consistent with the National List" in facility pest management. This means that nonsynthetic substances and synthetic substances listed in §§ 205.601 or 205.605 of the National List may be used for facility pest management provided that they are not restricted by annotations that prevent their use, or appear in § 205.602 of the National List as prohibited nonsynthetic substances.
 - **3.6.2.** Any EPA registered pesticide substance used in a facility pest application must be labeled for that use.
 - **3.6.3.** All inert and other ingredients in facility pest management products must be natural, included in § 205.601(m) of the National List, or included in § 205.605 of the National List. Producers and handlers must demonstrate compliance with § 205.271 in their Organic System Plans.
 - **3.6.4.** Handlers may use substances that are not on the National List for facility pest management, provided that there is no contact with organic products or ingredients, they are used in accordance with § 205.271(d), and the certifier agrees on the use and method of application of the substance. 7 CFR § 205.271(d) does not apply to substances used in crop or livestock production areas.

4. References

Organic Foods Production Act of 1990, as amended

7 U.S.C. § 6517 National List

USDA Organic Regulations (7 CFR Part 205)

7 CFR § 205.2 Terms Defined

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

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Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

7 CFR § 205.271 Facility pest management practice standard.

7 CFR §§ 205.601-605 of the National List of Allowed and Prohibited Substances.

Other Definitions (adapted from FDA Guidance for Industry: Antimicrobial Food Additives, July 1999):

Facility. A structure or site where production, handling, processing, packaging or storage of organic products occurs. A facility could include packing lines, wash lines, storage units, coolers, freezing plants, feed mills, milk houses, production structures such as housing for livestock, greenhouses and mushroom buildings, etc.

Post-harvest substances. Substances used in the handling of raw agricultural commodities either on farm or in handling facilities, that are not further processed. This includes substances used for flotation, washing, sanitizing, cooling, storing, and for facility pest management. "Further processing" includes chopping, peeling, cutting, waxing, coating, drying or combining with other ingredients.

Post-harvest handling. The act of handling raw agricultural commodities without further processing. This includes flotation, washing, sanitizing, cooling, packing, separation from foreign objects or plant parts (e.g., cleaning grain), removal of stems, leaves or husks, and storage and pest control practices.

Raw agricultural commodity. Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing (Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(r)). Substances used for coloring or coating must be permitted as per § 205.605 or § 205.606 of the National List.

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Appendix A

Examples of Post-Harvest Handling Substances Affected by this Guidance

- 1. Diatomaceous earth is a natural substance used in crop and livestock pest management. It is also listed for handling use in 7 CFR § 205.605(a) for use as a filter aid only. It is commonly used as a pest control substance in storage bins for grain or flour, and is regulated by EPA as a pesticide.
 - Allowed as a nonsynthetic substance permitted in crop production.
 - Allowed for post-harvest handling on raw agricultural products, including storage bins for grain or flour, since there are no restrictions in 7 CFR § 205.602.
 - Inert ingredients must either be on EPA List 4 pursuant to 7 CFR § 205.601(m), nonsynthetic, or approved synthetics in 7 CFR § 205.605.
 - Must be used in accordance with label directions.
- 2. Pyrethrum, *Bacillus thuringiensis*, or other botanical or biological pesticides.
 - Allowed as nonsynthetic substances for use in crop or livestock production, provided that the EPA label permits its use.
 - Allowed for post-harvest use on raw agricultural products provided that the label permits its use.
 - Inert ingredients must either be on EPA List 4, nonsynthetic, or approved synthetics in 7 CFR § 205.605.
- 3. Copper sulfate, narrow range oils, elemental sulfur, insecticidal soaps.
 - Allowed in 7 CFR § 205.601 as synthetic substances permitted for insect or disease control of crops.
 - Not allowed for post-harvest use in direct contact with organic products, since these substances are not on the National List for post-harvest use.
 - Could be used in compliance with 7 CFR § 205.271(d) for handling facility pest management, provided that there is no direct contact with organic products or ingredients, and the certifier approves the intended use and plan for application.
- 4. Clove oil, for sprout inhibition of potatoes, is considered a pesticide that is exempt from EPA registration requirements.
 - Allowed as a nonsynthetic substance permitted in crop production.
 - Allowed for post-harvest handling since there are no restrictions in 7 CFR § 205.602.
 - Inert ingredients must either be on EPA List 4, nonsynthetic, or approved synthetics in 7 CFR § 205.605.

¹ They must also meet all EPA requirements. EPA has updated the list of inert ingredients eligible for inclusion in Minimal Risk (exempt) pesticides at http://www.epa.gov/inerts/section25b_inerts.pdf.

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Allowed in direct contact with unprocessed organic potatoes, provided that the label permits this.

5. Ethylene gas.

- Allowed as a synthetic substance in 7 CFR § 205.605(b) for post-harvest use as a ripening agent for tropical fruit and for degreening of citrus. EPA regulates this use as a pesticide; therefore, inert ingredients must be on EPA List 4.
- Not allowed for other post-harvest uses since the listing in 7 CFR § 205.605 is limited to specific uses.
- 6. Sodium silicate and lignin sulfonate.
 - Allowed as synthetic substances in 7 CFR § 205.601 as post-harvest floating agents. These substances may be used in packing houses on farms, or in separate handling operations.
 - Formulations can include nonsynthetic substances or synthetics permitted without restriction for use in food in 7 CFR § 205.605.

7. Ethanol and isopropyl alcohol.

- Allowed as synthetic substances in 7 CFR § 205.601(a) as algicides, sanitizers and disinfectants for crop production.
- Not allowed in direct contact with food products for post-harvest use, since they are not listed for that use. (Note.—Organic ethanol is permitted for handling use).
- Could be used in compliance with 7 CFR § 205.271(d) for facility pest management, provided that there is no direct contact with organic products or ingredients.

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Appendix B

Questions and Answers Substances Used in Post-Harvest Handling of Organic Products



The substance is listed in 7 CFR § 205.601 (crops), with an annotation for post-harvest use.

✓ YES

> The substance is listed in 7 CFR § 205.605 (handling), without restrictions or limits that prevent this use.

✓ YES

The substance is nonsynthetic, and is not prohibited or restricted in 7 CFR § 205.602.

✓ YES

➤ The substance is synthetic, and is listed in 7 CFR § 205.601 for crop use, without annotation for post-harvest use:

X NO

2. Can I use this substance for <u>facility pest control?</u> ^{2,3}

➤ The substance is listed in 7 CFR § 205.601 for pest control:

✓ YES

The substance is listed in 7 CFR § 205.605 without restriction:

✓ YES

➤ The substance is nonsynthetic, and is not listed in 7 CFR § 205.602:

✓ YES

The substance is synthetic, not on the National List:

May only be used by handlers when the substance is not in contact with organic products or ingredients, and with the certifier's approval, pursuant to 7 CFR § 205.271(d).

² All pesticides must have an EPA registration or exemption from registration for use in facility pest control.

³ Pursuant to 7 CFR §§ 205.271(a)-(b), management practices must be demonstrated before the substance may be used.