



106 School Street, Suite 201 • Spring Mills, PA 16875 • (814) 422-0251 • pco@paorganic.org

June 24, 2014

Melissa Bailey, Ph.D., Director, Standards Division
National Organic Program, USDA-AMS-NOP
1400 Independence Ave., SW.
Room 2646 So., Ag Stop 0268
Washington, DC 20250-0268

Re: AMS-NOP-14-0012;NOP-14-03

Comments regarding the draft guidance for Substances Used in Post-Harvest Handling

Dear Ms. Bailey:

Pennsylvania Certified Organic (PCO) welcomes the opportunity to provide comments to the National Organic Program (NOP) regarding the recently published draft guidance document on substances used in post-harvest handling. PCO is an NOP-accredited certifying agent that certifies more than 700 operations, including around 165 crops operations, 385 livestock operations, 120 processor/handler operations and various combinations of these categories.

PCO applauds the NOP for addressing the issue of post-harvest handling in organic production. This step within the production flow of organic products is not clearly addressed within the regulations, which has led to differing implementation strategies by certifiers. This guidance document will greatly enhance the consistency of certification and further ensure the integrity of organic products. However, in order for this approach to be effective in maintaining the integrity of organic production and processing, this approach must be implemented carefully and accurately. To this end, we provide the following comments for consideration by the NOP.

Below is a list of the major points from our comments. More detailed comments follow thereafter.

- The definition of *post-harvest handling* is the most critical element of this guidance document, and the proposed definition within this draft guidance can be improved. We encourage the NOP to accept PCO's recommended revision, specifically to include the phrase "activities that preserve the essential form of the product" in the definition of *post-harvest handling*.

- Part 3.2 of the proposed policy regarding §205.605 materials that may be used for post-harvest handling needs clarification, particularly regarding the phrase “provided that there is no restriction limiting their use”. This policy statement needs to be further explained in a manner that would allow common substances such as diatomaceous earth and chlorine to be used in post-harvest handling.
- Part 3.6 of the proposed policy regarding the facility pest management practice standard at §205.271 should apply to facilities at type of operation. The draft guidance implies that this standard only applies to handlers, but crop and livestock operations also have facilities that must manage pests (e.g. greenhouses, livestock housing).
- This effect of post-harvest substances on the “100% organic” label claim should be addressed by the NOP in conjunction with the publication of the final version of this guidance document.

Sound & Sensible Approach

The approach presented in the NOP’s draft guidance is to identify *post-harvest handling* as a discrete stage of the system that is unique and distinct from production or processing. Furthermore, this stage of the system can happen at any type of operation, not just at the operation at which the product is produced or harvested.

This approach is quite different from current PCO practice, wherein a handler cannot use any substances beyond what is specifically provided for on §205.605 (or §205.601(l) for post-harvest handling). In other words, once a raw agricultural product is received by a handler, it is now an “ingredient” and all activities are considered “processing”. Also, PCO’s current policies on post-harvest handling only apply to crop products, whereas NOP’s guidance document refers to “raw agricultural commodities” which includes livestock products such as raw milk, meat, and eggs.

PCO is open to the NOP’s new approach because we can see the potential for advancing the sound and sensible initiative. This new approach will allow us to focus on the organic integrity of the commodity, instead of which certification categories the operations is certified for to determine which input materials they can use on a commodity. For example, if a handler can apply carbon dioxide (listed on §205.605) to grain in storage, then there is no reason (in terms of organic integrity of the product) that a crop operator can’t also apply carbon dioxide (not listed on §205.601) to grain in storage. This is *sensible*. And providing a guidance document that incorporates public comment is *sound*.

Draft Policy – Parts 3.1 – 3.5

NOP Draft Guidance	PCO Comments
3.1. Synthetic substances that are listed in §205.601 of the National List specifically for post-harvest use may be used for handling raw	PCO agrees that a material that is annotated specifically for post-harvest use should be allowed for use in post-harvest activities by any operation (crops, livestock, and/or handling)

agricultural commodities, either on farms or in handling facilities. (E.g., lignin sulfonate, or sodium silicate.)

regardless of where the material is listed on the National List.

This provision should be broadened to also allow substances on §205.601 that don't have an annotation that specifically restricts the use of the substances to activities that are not considered post-harvest handling. Chlorine, peracetic acid, and hydrogen peroxide are typically used in post-harvest handling of raw agricultural commodities. As currently written, this draft policy would *not* allow these materials because they are not listed specifically for post-harvest use. According to the draft guidance, these materials could only be allowed if they were listed at §205.605 and comply with part 3.2 of this draft policy (which as 3.2 is currently written, would also not comply).

PCO suggests revising to read:

3.1. Synthetic substances that are listed in §205.601 of the National List may be used for post-harvest handling of raw agricultural commodities, either on farms or in handling facilities, provided there is not an annotation that specifically restricts the use of the substance to only activities that are not considered post-harvest handling.

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.)

The phrase, “provided that there is no restriction limiting their use” needs clarification. The examples do not provide insight to the intent of this phrase. Ethylene is restricted to specific post-harvest activities, so it is allowed only for that use. Nitrogen gas has no annotation, so it is allowed for any post-harvest use.

What about materials on §205.605 that have an annotation that limits their use but the limitation is only specific to *further processing* (e.g. “diatomaceous earth – as filtering aid only”)? It seems that NOP is intending to allow them. The example provided in Appendix A for diatomaceous earth says that diatomaceous earth is allowed for post-harvest handling even though it has an annotation on §205.605 that *restricts its use* to only as filtering aid (i.e. does not comply with this part of the draft policy). Also, chlorine is commonly used in post-harvest handling (washing, cleaning), but it has an annotation that *restricts its use* to sanitizing food contact surfaces. Clarification is needed from the NOP about what this part of the draft policy means, and what specific materials on §205.605 it would allow.

<p>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 handling of raw agricultural commodities, either on farms or in handling facilities.</p>	<p>PCO agrees.</p> <p>This provision, as written, would allow handlers to use non-organic nonsynthetic agricultural materials in post-harvest handling activities in direct contact with organic products. For example, a livestock feed handler could use non-organic oil in direct contact with livestock feed for pest control purposes. PCO currently requires organic certification for agricultural materials used in this way, but would revise our policy based on the final publication of this guidance document. Provided that the use of the substance is explicitly only for <i>post-harvest handling</i> (and not as a feed ingredient), there should not be a concern that non-organic agricultural ingredients are being used in direct contact with feed because only agricultural ingredients that are considered <i>feed</i> or <i>feed additives/supplements</i> must be organic.</p>
<p>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.</p>	<p>PCO agrees, although it is unclear what specifically certifiers are expected to verify and how to respond to violations of EPA or FDA requirements.</p>
<p>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.</p>	<p>PCO agrees that inert ingredients should be reviewed in pest control materials that are used in direct contact with organic products.</p>

Draft Policy – Part 3.6 (Facility Pest Management)

It would be ideal if this guidance document only addressed pest management materials substances that are used *in direct contact* with organic products during post-harvest handling. PCO would support a separate guidance or instruction document that applies to facility pest management in a broader sense. Nevertheless, we provide comments on the policy text presented in the draft guidance.

NOP Draft Guidance	PCO Comments
<p>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</p>	<p>Specific sections of National List should not be pointed out because it implies that materials in a section not specifically listed here would not be allowed. The provision at §205.271(c) is not specific to only §205.601 or §205.605. The “National List” means every section in Subpart G. There</p>

<p>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.</p>	<p>is no reason to exclude §205.603 or any other section. §205.603 includes external pest control materials that should be eligible for use as facility pest management in accordance with §205.271(c). Furthermore, with the potential for more sections of the National List to be added, this guidance should remain flexible to adapt to future changes.</p> <p>PCO suggests revising to read:</p> <p style="padding-left: 40px;">3.6.1. According to 7 CFR § 205.271(c), producers and handlers may apply “a nonsynthetic or synthetic substances consistent with the National List”. <u>This includes nonsynthetic and synthetic substances across the entirety of Subpart G, provided that prohibitions and annotations are followed.</u></p> <p>If the substance will be used in direct food contact during a post-harvest activity, the substance must comply with this guidance document’s policies at 3.1-3.5.</p>
<p>3.6.2. Any EPA registered pesticide substance used in a facility pest application must be labeled for that use.</p>	<p>What about a pesticide that is not EPA-registered (i.e. exempt)? Would it have to be used according to labeled use, or could it be used off-label?</p> <p>PCO suggests revising to read:</p> <p style="padding-left: 40px;">3.6.2. Use of facility pest control materials must not violate label instructions.</p> <p>This suggested revised wording would require operators to follow label instructions in cases where the label includes a claim such as “using this product not in accordance with instruction is a violation of federal law.” It would also provide for off-label use of products when the label does not specify a required use.</p>
<p>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.</p>	<p>PCO disagrees with the requirement to review inert ingredients in facility pest management materials that <u>do not</u> come in contact with organic products. The operator must implement methods to prevent contamination of organic products from the pest control material. The review of inert ingredients in a material that does not contact organic products does not affect the organic integrity of the product.</p> <p>PCO suggests removing provision 3.6.3 from the draft</p>

	guidance document.
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.	<p>PCO agrees, but with one suggested revision: to add “Producer and” to the first sentence, so that it is clear that this provision applies to all operations including producers and handlers.</p> <p>PCO understands that the last sentence, “205.271(d) does not apply to substances used in crop or livestock production areas”, is not indenting to prohibit the use of substances in facilities at crop or livestock operations that do not pose a contamination risk to the organic production area.</p>

Definitions

Definitions are critical to understanding the context of the proposed policies. The success of this guidance document depends entirely on a clear definition of post-harvest handling, and the boundaries between it and production and processing.

PCO would support adding the approved versions of these definitions to §205.2 (Terms Defined) within the NOP regulations, since annotations on the National List refer to post-harvest handling.

The NOP should develop customized definitions that apply to the particular issues within organic production and processing, instead of relying on exact text from an FDA draft guidance. The NOP already defines post-harvest handling in the Crop Post-Harvest Handling Organic System Plan Template (available in the NOP’s Program Handbook) as “activities preserve the essential form of the product.” PCO and perhaps other certifiers already utilize this definition. The NOP should integrate this phrase into the definition of post-harvest handling so that consistency is maintained throughout the implementation of this guidance once it is finalized.

NOP Draft Guidance	PCO Comments
<i>Facility.</i> 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.	PCO agrees, provided that this definition is not meant to exclude mobile facilities that travel to multiple locations (within an single operation or between separate operations).
<i>Post-harvest substances.</i> Substances used in the handling of raw agricultural commodities either on	<p>PCO agrees with the first sentence.</p> <p>The second and third sentences describe <i>activities</i> not</p>

<p>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.</p>	<p><i>substances</i> and do not belong in this definition. The second sentence of this definition (This includes...) should be removed because it duplicates what is provided in the definition of post-harvest handling. The third/last sentence of this definition (“Further processing” includes...) should be moved to the definition of post-harvest handling.</p> <p>PCO suggests adding a few examples to this definition to further clarify the type of materials that this definition is referring to. Examples could include insecticides used in grain storage, and cleaners used to wash produce.</p> <p>PCO suggests revising to read:</p> <p><i>Post-harvest substances.</i> Substances used in the <u>post-harvest</u> handling of raw agricultural commodities either on farm or in handling facilities. (e.g. <u>insecticides used in grain storage; sanitizers used to wash produce</u>)</p>
<p><i>Post-harvest handling.</i> 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.</p>	<p>PCO agrees with the first sentence.</p> <p>PCO suggests integrating the NOP’s existing definition of post-harvest handling as indicated in the Post-Harvest Handling Organic System Plan Template, “activities preserve the essential form of the product”. The list of specific activities that are included or not included as a post-harvest activity should not be an exhaustive list, but rather provide a list of examples that fit into the overarching criteria of what activities are included as a post-harvest activity.</p> <p>PCO also suggests adding the last sentence of the proposed definition of “post-harvest substances” (“Further processing” includes...) to this definition. This sentence is critical to defining the boundary between post-harvest handling and further processing.</p> <p>PCO suggests revising to read:</p> <p><i>Post-harvest handling.</i> The act of handling raw agricultural commodities without further processing. This includes <u>activities that preserve the essential form of the product, such as 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.</u> “Further</p>

	<p>processing” includes <u>activities that change the essential form of the product, such as chopping, peeling, cutting, waxing, coating, or combining with other ingredients.</u></p> <p>There are types of “drying” activities that preserve the essential form of the product, like drying grains or drying herbs, and should not be exclusively classified as further processing.</p>
<p><i>Raw agricultural commodity.</i> 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.</p>	<p>PCO suggests removing the last sentence of the proposed definition (Substances used for...). This is a regulatory requirement for the use of non-organic ingredients and is not appropriate for the definition of a raw agricultural commodity. Furthermore, applying a coating or adding coloring would be considered “further processing” as identified in the definition of post-harvest handling, because other ingredients are being added to the commodity.</p> <p>PCO suggests providing more examples of the types of commodities that are covered by the definition raw agricultural commodities (e.g. vegetables, greens, nuts, raw milk, meat, eggs). 40 CFR 180.1(d) provides further explanation that can be integrated into the definition: “Raw agricultural commodities include, among other things, fresh fruits, whether or not they have been washed and colored or otherwise treated in their unpeeled natural form; vegetables in their raw or natural state, whether or not they have been stripped of their outer leaves, waxed, prepared into fresh green salads, etc.; grains, nuts, eggs, raw milk, meats, and similar agricultural produce...”</p> <p>PCO suggests revising to read:</p> <p><i>Raw agricultural commodity.</i> Any food in its raw or natural state, including, <u>among other things, fresh fruits in their unpeeled natural form, vegetables in their raw or natural state (may be stripped of their outer leaves), grains, nuts, eggs, raw milk, meats, and similar agricultural produce.</u></p>

Appendix A

This appendix would need to be revised to align with PCO’s previous comments regarding the draft policies.

NOP Draft Guidance	PCO Comments
<p>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.</p> <ul style="list-style-type: none"> ● 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. 	<p>PCO agrees with the allowed uses of diatomaceous earth as pest control in storage bins of grain, but is concerned with how this aligns with part 3.2 of the draft policy. See above comments.</p> <p>Flour is not a raw agricultural commodity (it has been <i>further processed</i>) and should be removed from this example.</p>
<p>2. Pyrethrum, Bacillus thuringiensis, or other botanical or biological pesticides.</p> <ul style="list-style-type: none"> ● 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. 	<p>PCO agrees.</p>
<p>3. Copper sulfate, narrow range oils, elemental sulfur, insecticidal soaps.</p> <ul style="list-style-type: none"> ● 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. 	<p>The third bullet point is incorrect. Copper sulfate is a substance that is consistent with the National List, therefore their use as facility pest management would be in compliance with 205.271(c), not (d). A facility pest management plan should not be needed for an operator to use a material that is already on the National List. Prevention of contamination with organic products would still be required.</p>

<p>4. Clove oil, for sprout inhibition of potatoes, is considered a pesticide that is exempt from EPA registration requirements.</p> <ul style="list-style-type: none"> • 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. • Allowed in direct contact with unprocessed organic potatoes, provided that the label permits this. 	<p>PCO agrees, and we acknowledge that this example is not requiring the clove oil to be certified organic.</p>
<p>5. Ethylene gas.</p> <ul style="list-style-type: none"> • 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. 	<p>PCO agrees.</p>
<p>6. Sodium silicate and lignin sulfonate.</p> <ul style="list-style-type: none"> • 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. 	<p>The second bullet point appears to be adding additional verification requirements that are not present in the draft policy. The review requirements for ancillary ingredients are not relevant to this guidance. The second bullet point should be removed.</p>
<p>7. Ethanol and isopropyl alcohol.</p> <ul style="list-style-type: none"> • 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. 	<p>The third bullet point is incorrect. Ethanol and isopropanol are substances that are consistent with the National List, therefore their use as facility pest management would be in compliance with 205.271(c), not (d). A facility pest management plan should not be needed for an operator to use a material that is already on the National List. Prevention of contamination with organic products would still be required.</p>

Appendix B – Part 1 (Post-Harvest Handling Substances)

This appendix would need to be revised to align with PCO’s previous comments regarding the draft policies.

NOP Draft Guidance	PCO Comments
The substance is listed in 7 CFR §205.601 (crops), with an annotation for post-harvest use: YES	PCO agrees, but substances without restricting annotations should also be allowed (e.g. hydrogen peroxide). See above comments.
The substance is listed in 7 CFR §205.605 (handling), without restrictions or limits that prevent this use: YES	This provision needs clarity. See above comments.
The substance is nonsynthetic, and is not prohibited or restricted in 7 CFR §205.602: YES	This statement should also ask about §205.604.
The substance is synthetic, and is listed in 7 CFR §205.601 for crop use, <u>without annotation</u> for post-harvest use: NO	Substances on §205.601 should be allowed for post-harvest handling unless there is an annotation that specifically restricts the use of the substances to uses that are not considered post-harvest handling. See above comments.

Appendix B – Part 2 (Facility Pest Management Substances)

This appendix would need to be revised to align with PCO’s previous comments regarding the draft policies.

NOP Draft Guidance	PCO Comments
The substance is listed in 7 CFR §205.601 for pest control: YES	This statement should ask if the substance is listed anywhere on the National List.
The substance is listed in 7 CFR §205.605 without restriction: YES	See above.
The substance is nonsynthetic, and is not listed in 7 CFR §205.602: YES	This statement should also ask about §205.604.
The substance is synthetic, not on the National List: May only be used by <u>handlers</u> 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).	This is incorrect. Facility pest management substances may be used by any type of operation, not just handlers. Crop and livestock operations also have facilities that require facility pest management (e.g. storage, packing houses, greenhouses, livestock housing).

Affect on “100% Organic” Label Claim

This guidance document does not address an extremely important aspect of post-harvest handling: How does the use of a post-harvest handling substance affect the labeling category eligibility of the final processed product? If a substance is used in post-harvest handling of a raw agricultural commodity, is it excluded from the “100% organic” label category?

If post-harvest handling is meant to be a discrete stage of production that is separate and distinct from *further processing*, then one could conclude that the use of a substance during post-harvest production *would not* disqualify a product from the “100% organic” label category.

This issue calls back to the NOSB Spring 2012 Discussion Document called “Sanitizer and 100% Organic Products”. Food contact sanitizers are often used in post-harvest handling of raw agricultural commodities. The discussion document acknowledges the confusion and difficulty of assessing the affect of food contact sanitizers on the label category of the product.

The issue how input materials including sanitizers and post-harvest substances affect the “100% organic” label claim is still an extremely important area for clarification. PCO encourages the NOP to address this subject through guidance in a timely manner and in conjunction with the publication of the final version of the guidance on substances used in post-harvest handling.

PCO appreciates the opportunity to provide comments and thanks the NOP for its careful consideration.

Sincerely,



Johanna Mirinda
Policy Director