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Docket # AMS-NOP-21-0087

Re. HS: Cetylpyridinium Chloride

These comments to the National Organic Standards Board (NOSB) on its Spring 2022 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers, and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

The NOSB must perform a comprehensive review of sanitizers, disinfectants, and cleansers.

Specific cleaning and sanitation materials remain on the agendas of the Crops, Handling, and Livestock Subcommittees. We continue to urge that, to the extent possible, all decisions involving sunsets and petitions for cleaning and sanitation materials be made in the context of this broader review.

The comments below address our conception of what a comprehensive review of cleaning and sanitizing materials would look like. The MS has, in the past, outlined many of the issues we believe should be covered, but we believe that they need to be addressed within a framework that first identifies the needs for cleaning and sanitizing materials.

These particular issues are especially timely in light of the COVID-19 (coronavirus) pandemic. There is a tendency during a period of crisis to elevate the use of toxic materials that are no more effective than safer materials. Regarding sanitizers, soap breaks down the COVID-19's fat membrane—and the infectious material falls apart—as long as you rub the soap on your hands for at least 20 seconds. Alcohol wipes with 60% alcohol do the same thing. These chemicals break down the virus by a similar process, by breaking down the lipid covering of the

virus.¹ Regarding disinfectants, which also sanitize, natural-based substances tend to be safer, while still effective at eliminating the virus on surfaces. We urge people to look for products with the following active ingredients (* indicates listed by EPA's Design for the Environment Program (DfE)²): Citric acid*; Ethanol*; Isopropanol*; L-lactic acid*; Hydrogen peroxide*; Sodium bisulfate*; and Thymol.

Overview: What is meant by a “comprehensive review of cleaning and sanitizing materials”?

We envision a comprehensive review of sanitizers as a review **starting with the needs of organic producers and handlers for cleaning and sanitizing materials** that identifies the materials itemized for those purposes on the National List, as well as alternatives. This is where we differ with the process outlined by the Materials Subcommittee (MS). Although the MS stated, “One of the aspects the NOSB reviews when assessing a material for inclusion on the National List is essentiality to organic production,” it does not use essentiality to structure its comprehensive review.

A preliminary step is defining “sanitizer,” “disinfectant,” and “cleanser.” In previous comments, we offered definitions used by the Centers for Disease Control and Prevention (CDC). If there are definitions more appropriate for the context of organic regulations, then they should be adopted. This step would establish the framework for NOSB review of cleaners, sanitizers, and disinfectants.

Such a review should start with the questions:

1. For what purposes are cleaning and sanitizing materials needed?
2. Are specific (e.g., chlorine-based) cleaning and sanitizing materials required by law?

The purposes in question 1 should be itemized in sufficient detail for a reviewer to determine what alternatives could be available and the degree of freedom from microorganisms that is required.

For ordinary preparation of fresh fruits and vegetables for sale, removal of microorganisms may be counterproductive. Fresh fruits and vegetables have natural communities of microorganisms living on them, which often protect them from colonization by plant or human pathogens. This may vary by specific fruits and vegetables.

A food processing facility, on the other hand, has greater needs for cleansers and antimicrobials, some of which may be required by law. In such facilities, the integrity of the plant product is destroyed, so the natural community cannot fight off invaders. In such

¹ Pall Thordarson, 2020. The science of soap – here's how it kills the coronavirus. <https://www.theguardian.com/commentisfree/2020/mar/12/science-soap-kills-coronavirus-alcohol-based-disinfectants>. See also: <https://www.youtube.com/watch?v=K2pMViml2bw&feature=youtu.be>.

² <https://www.epa.gov/pesticide-labels/design-environment-logo-antimicrobial-pesticide-products>.

facilities, however, there are places where cleansers are required and places where disinfection (not necessarily chemical disinfection) is needed.

Example: Policy Memo 14-2 Chlorine Use in Egg Breaking Facilities
<https://www.ams.usda.gov/sites/default/files/media/NOP-PM-14-2-ChlorineUseinEggBreaking.pdf>

The FSIS regulations require that immediately prior to breaking, all shell eggs shall be spray rinsed with potable water containing an approved sanitizer of not less than 100 parts per million (ppm) nor more than 200 ppm of available chlorine, or its equivalent. The FSIS regulations further specify that the eggs must be sufficiently dry before breaking, but do not provide for a rinse with potable water.

When breaking eggs for processing, the NOP defers to the FSIS requirement. Certifiers should not take enforcement action against operations that use chlorine sanitizers without a rinse step. This policy does not apply to eggs sold to consumers in the shell. These shell eggs are not subject to this FSIS regulation, but may be subject to voluntary egg grading standards (7 CFR Part 56).

FSIS provides a waiver process for operators of egg processing plants to seek use of alternate procedures or new technologies on an individual plant basis. ***Manufacturers of organic egg products have the option of seeking a waiver to use other sanitizing materials or practices consistent with the USDA organic regulations.*** (Emphasis added.)

Chlorine materials are not required for this use.

According to NOP-PM-14-2, eggs to be broken must be sprayed with the equivalent of 100-200 ppm available chlorine, but manufacturers of organic product may seek a waiver to use other materials or practices. This is an example of a use that should be evaluated in view of “equivalent” alternatives.

The second step in the review would be the identification of National List materials available for the purposes identified in step 1.

This step is non-trivial because it involves identifying the specific needs associated with each cleaning and sanitizing material on the National List (NL). As we have maintained elsewhere, the structure and content of the NL provides inadequate guidance for the use of these materials. The different types of materials encompassed by the broad term “cleaning and sanitizing materials”—cleansers, disinfectants, and sanitizers—must be defined. The uses of materials that fall under these categories must be clarified. Inadequacies of the NL, in terms of allowing for the use of suitable materials covering all needs (we note the absence of suitable cleansers), should be identified in this step.

The third step involves evaluating the materials on the NL for these purposes in accordance with OFPA criteria.

Evaluation according to OFPA criteria involves evaluating environmental and health impacts of the materials. It also involves an investigation of alternatives. In some cases, this investigation may reveal available alternatives in the form of changed practices or less hazardous materials on the NL (or that do not require listing on the NL.) In other cases, it may suggest less hazardous synthetic materials that are not on the NL, which may need to be petitioned.

The final step of the comprehensive review is synthesizing the information acquired through steps 1-3 and making recommendations for changes in the NL.

Recommendations may include annotations restricting the use of some materials on the NL and petitioning materials to meet needs that are not adequately addressed. They may also include petitioning materials that are less hazardous than the materials currently on the NL.

Conclusions Regarding Framework

- OFPA requires that all cleansers, sanitizers, and disinfectants used in organic production be itemized on the National List by specific use or application. This provides a framework for examining cleaning and sanitizing materials.
- NOP guidance and the practice of certifiers and inspectors have been inconsistent and often violate OFPA.
- The inadequacy of the National List with regard to cleansers has led to an acceptance of the practice of using any available cleanser (sometimes antimicrobial) with intervening steps considered by the producer/processor, certifier, and/or inspector to be “sufficient” to prevent contamination of organic product.
- Bringing practice into compliance with OFPA requires that the National List be evaluated for sufficiency and that cleansers be added to the National List.
- The inconsistencies among OFPA and regulations, guidance documents, and practice support the need for a comprehensive review of cleaning and sanitizing materials that will lead to a clarified National List that meets OFPA criteria and the needs of organic producers.

Issues to be Examined Within the Framework

As stated above in outlining steps of the review, the third step involves evaluating materials. It is this step that the MS discussion draft addresses. Here we address a number of issues to be examined within the framework outlined above.

How should sanitizers, disinfectants, and cleansers appear on the National List?

The MS Notes record that a member “asked about adding another section on the National List, just for sanitizers: e.g. 205.607.” We agree that sanitizers, disinfectants, and cleansers should be separately considered, but it is more appropriate to create subsections of §§205.601, 603, and 605(a)—as is the case for §205.601(a). §205.603(a) lumps sanitizers, disinfectants, and cleansers used on equipment in a category with medical treatments, and it would be clearer to separate them—even if the “medical treatment” involves cleaning or

disinfecting, which should be a separate subsection of that subsection. The uses in handling and processing are most in need of separation—separate subsections of §205.605(a) and §205.605(b) should further distinguish substances used in direct contact with food, those used on food contact surfaces, and those used on other surfaces in the handling/processing environment. Listing the materials in separate sections is more convenient for the NOSB, producers, and certifiers, but is not essential. However, it is essential that the uses be identified in some way on the National List.

Example: Which cleansers, sanitizers, and disinfectants can be used in post-harvest handling, and what are the restrictions on their use?

It has come to our attention that some certified operators believe they can use any cleanser, disinfectant, or sanitizer on the market regardless of whether or not it is on the National List, as long as there is a sufficient “intervening step” prior to processing—e.g., a fresh water rinse or a “purge” or “flush” with organic product (with the purge material either going into a conventional product or dumped) to remove “contaminants” from the surface.

This issue arises out of a failure to perform a comprehensive review of cleansers, sanitizers, and disinfectants and their appropriate and necessary uses. Because the differences among these classes have not been defined, their specific uses have not been delineated, and the National List has not been developed to meet specific needs by annotating sanitizers, disinfectants, and cleansers clearly with specific uses as required by OFPA, guidance has been developed that allows use of materials not on the National List or contrary to the restrictions in their listings.

NOP rules and guidance are confused on this issue.

The *Guide for Organic Crop Producers*³ supports the position stated above in part—with respect to cleansers, but not sanitizers and disinfectants—saying:

As organic producers harvest crops into containers, they should consider the potential for contamination and take appropriate steps to prevent it. Harvest and storage bins should be clean and free of residue left from conventional produce. ***Almost any type of soap or detergent can be used to clean containers, as long as the containers are thoroughly rinsed. A few sanitizers, such as quaternary ammonium compounds, are prohibited because they leave residues that are difficult to remove. If the harvest containers must be sanitized, several brands of chlorine and peroxyacetic acid sanitizers are allowed for organic use.*** The chlorine residues can be easily washed off with water. Peroxyacetic acids may not even need rinsing because they will decompose into water and oxygen and because washing with water after using peroxyacetic acid risks further contamination. (p.50, emphasis added.)

The *Guide for Organic Processors*⁴ says,

³ <https://www.ams.usda.gov/sites/default/files/media/GuideForOrganicCropProducers.pdf> p.50.

⁴ <https://www.ams.usda.gov/sites/default/files/media/Guide-OrganicProcessors.pdf> pp.34-35.

A cleanser is used to remove soil, food particles, or unwanted debris from surfaces. Soaps and detergents are cleansers. Typically, cleansers are fully rinsed from food-contact surfaces; therefore, they never make contact with the food. **Phosphoric acid is the only cleanser on the National List. Most other cleansers are allowed for use in organic production and handling; they do not need to be on the National List.** (Emphasis added.)

and

Sanitizers differ from cleansers in that their purpose is to kill microorganisms, not to remove soil or other debris. Sanitizers are applied after food-contact surfaces are cleaned. Sanitizers also may be applied to fresh produce to kill harmful surface microorganisms or added to wash water for fruits, vegetables, eggs, poultry, and meat products. Section 205.605 of the National List explicitly mentions these allowed sanitizers:

- Acidified sodium chlorite
- Chlorine materials (including bleach)
- Hydrogen peroxide
- Ozone
- Peracetic acid/Peroxyacetic acid

Specific brand names of approved sanitizers can be found on the OMRI or WSDA lists, although other products also may comply with the USDA Organic Regulations. The lists also mention any particular restrictions or other allowed uses. **Some sanitizers leave residues on the equipment. In such cases, depending on the sanitizer you are using, the certifying agent may require you to have a plan to remove residues as well as a way to document that residues have been removed.** (Emphasis added.)

You must include all cleansers and sanitizers on your OSP [Organic System Plan], and they must be approved by your certifying agent before you use them. Review §205.605 to get familiar with the diversity of materials listed. (Emphasis added.)

The *Guide for Organic Livestock Producers*⁵ says the OSP must contain: Descriptions of procedures and materials used to maintain cleanliness of all containers, equipment, and storage areas in which organic feed or livestock products come into contact **as well as descriptions of how these materials are prevented from contaminating organic products.** (Emphasis added.)

and

Most OSPs have sections in which to include all types of ingredients and processing aids as well as all materials used for cleaning and/or sanitation. **Each material must be listed with its brand name and formulation (attach label information or Material Data Safety Sheets as appropriate), its manufacturer, the location and reason for its use in your operation, and the circumstances under which the material is allowed**

⁵ <https://www.ams.usda.gov/sites/default/files/media/Guide-OrganicLivestockProducers.pdf>.

(annotations or restrictions) for its intended use according to the National List.
(Emphasis added.)

The *Guide for Organic Livestock Producers* also reminds producers, Milk tankers that are used to haul milk from the dairy farm to the dairy processor must be either certified organic; noncertified but listed on the OSP for the dairy farm; or noncertified but listed on the dairy processor's OSP. ***Milk can lose its organic status if it is hauled in a tanker in which a sanitizer that is not allowed in organic production was used*** or if a noncertified tanker is used to haul the milk and neither the dairy farm nor the dairy processor includes milk tanker protocols in their OSP. (Emphasis added.)

NOP 5026 The Use of Chlorine Materials Rev 01 07 22 11 allows more contact of sanitizers and disinfectants with organic food.

<https://www.ams.usda.gov/sites/default/files/media/5026.pdf>

4. Policy

4.3 Handling operations (includes on-farm post-harvest handling):

1. For food handling facilities and equipment, chlorine materials may be used up to maximum-labeled rates for disinfecting and sanitizing food contact surfaces. ***Rinsing is not required unless mandated by the label use directions.***

2. ***Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purpose.***

a. ***Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use.***

b. ***Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA.*** (Emphasis added.)

We believe that the interpretation set forth in NOP 5026 is inconsistent with NOSB recommendations and the National List.

NOP 5023 Substances Used in Post-Harvest Handling of Organic Products

On the other hand, NOP 5023 Substances Used in Post-Harvest Handling of Organic Products,⁶ is more restrictive:

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).

⁶<http://www.ams.usda.gov/sites/default/files/media/NOP%205023%20Post%20Harvest%20Hdlg%20Rev01.pdf>.

Post-harvest handling includes actions such as washing, cleaning, sorting, packing, cooling, storing of raw agricultural products, and facility pest management. These actions can be performed on farms or in handling facilities. 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 substances). Nevertheless, post-harvest substances may be found in both sections 205.601 and 205.605.

Because substances allowed for use in post-harvest handling appear in different sections of the National List, or are nonsynthetic and are therefore not included on the crops section of the National List, confusion among organic stakeholders exists around: 1) the point at which crop production for unprocessed commodities ends and processing starts; and 2) the post-harvest substances allowed for use.

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 that prevent post-harvest use, 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.

3. Policy and Procedure

3.1 A substance may be used in post-harvest handling if it falls in one of the following categories:⁷

- ***Synthetic substances that are listed in §205.601 of the National List specifically for post-harvest use may be used for handling raw agricultural commodities, either on farms or in handling facilities. (E.g., lignin sulfonate or sodium silicate.)***
- ***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., carbon dioxide, nitrogen gas, and ozone.)***
- ***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. (Emphasis added.)***

⁷ 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.

Thus, NOP 5023 states that any synthetic substance used in post-harvest handling must be on the National List. In responding to comments on NOP 5023, NOP said,⁸

Two commenters requested that NOP make the interpretation that a lack of an annotation restricting post-harvest use implies that post-harvest use is permitted. Commenters state that without this interpretation, commonly used substances such as chlorine, hydrogen peroxide and peracetic acid could no longer be used. The NOP disagrees. We believe it is reasonable to extend use of nonsynthetic items used in crop production to the post-harvest handling of raw agricultural commodities. However, according to the Organic Food Production Act (7 U.S.C. 6517(d)(2)), the Secretary may not approve additional exemptions for synthetic substances unless recommended by the NOSB. Examples given by commenters, such as chlorine, peracetic acid, hydrogen peroxide are all already allowed under §205.605 and thus are allowed in post-harvest handling.

How should this question be resolved?

There are several issues:

1. What is consistent with OFPA?
2. Does the National List provide sufficient materials?
3. Should “cleansers” be treated differently from “disinfectants”?
4. What are other considerations?

1. What is consistent with OFPA?

The material must be on the National List.

As stated by NOP 5023, “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.”

§6504 of OFPA states, “To be sold or labeled as an organically produced agricultural product under this chapter, an agricultural product shall—(1) have been produced and handled without the use of synthetic chemicals, except as otherwise provided in this chapter;...”

§6517 says,

(a) In general

The Secretary shall establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under this chapter in order for such products to be sold or labeled as organically produced under this chapter.

(b) Content of list

⁸ NOP 5023-1 Response to Comments - Substances Used in Post-Harvest Handling
<https://www.ams.usda.gov/sites/default/files/media/NOP%205023-1%20Response%20to%20Comments%20%28final%29.pdf>.

The list established under subsection (a) shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2).

The “intervening step” of rinsing to remove residues is not sufficient for allowing the use of a sanitizer or cleanser.

Criteria for allowing synthetic materials to be used go beyond residues and contact of the material with organic food. §6517(c)(1) requires:

- (1) Exemption for prohibited substances in organic production and handling operations
The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if—
 - (A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—
 - (i) would not be harmful to human health or the environment;
 - (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and
 - (iii) is consistent with organic farming and handling;

§6518(m) lays out factors that the NOSB needs to consider in its evaluation:

In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider—

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
- (4) the effect of the substance on human health;
- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
- (6) the alternatives to using the substance in terms of practices or other available materials; and
- (7) its compatibility with a system of sustainable agriculture.

Thus, the lack of residues is not sufficient. Even cleansers like dishwashing detergent should be evaluated. Surfactants—the active ingredients in cleansers—include a number of problematic chemicals, such as nonylphenol ethoxylates (NPEs). The largest volume of use of NPEs has been as a surfactant in detergents, and EPA established water quality criteria for nonylphenol (NP) of 6.6 µg/L for acute exposures and 1.7 µg/L for chronic exposures. EPA’s Design for the Environment/Safer Choice program is actively promoting alternative surfactants in order to reduce discharges of NPEs and NP into surface water.

The term “nonylphenol ethoxylates” refers to a large group of chemicals that vary in chemical structure and toxicological effects. However, they all share common degradation products—nonylphenols and the short chain NPEs—that are more toxic and share common effects. Since the less toxic NPEs have short biodegradation half-lives, and their metabolites are longer lived, consideration of toxicology and ecotoxicology focuses mostly on NP and the short-chain NPEs (NP-1 and NP-2), which are persistent, bioaccumulative, and extremely toxic to aquatic organisms.⁹ NP and other alkylphenols are potent xenoestrogens, causing hormonal responses at concentrations as low as 1 femtomole to 10 picomoles per liter (10^{-15} to 10^{-11} moles per liter), exceeding the potency of estradiol.¹⁰

Therefore, both in terms of a strict reading of OFPA and common sense, it is appropriate to conclude that all cleansers and antimicrobials used in organic production and handling should be on the National List, regardless of the intervening steps.

2. Does the National List provide sufficient options for cleansers and antimicrobials?

While the National List includes several antimicrobial agents—chlorine compounds, alcohols, ozone, hydrogen peroxide, and peracetic acid—it includes only one cleanser—phosphoric acid. While options for antimicrobials used according to the restrictions in their annotations on the National List appear to be sufficient, it is fair to say that the National List provides insufficient options for cleansers.

3. Should “cleansers” be treated differently from “disinfectants”?

As stated above, the surfactants that are active ingredients in cleansers can have significant ecological effects. Therefore, they should not be treated differently in terms of review and inclusion on the National List. However, listing in separate subsections of the list from antimicrobial actives would help ensure that they are evaluated with respect to the appropriate universe of materials and that the NOSB could more easily evaluate the need for additional materials in each group. In addition, the implications for the near future—in bringing the National List and current practice in line with OFPA—are different for cleansers and antimicrobials.

4. Other considerations?

Given the lack of cleansers on the National List, it is not surprising that some guidance materials, certifiers, and inspectors support the view that anything can be used given sufficient intervening steps.

⁹ U.S. EPA. 2010. Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) Action Plan [RIN 2070-ZA09]. US Environmental Protection Agency, August 2010. https://www.epa.gov/sites/production/files/2015-09/documents/rin2070-za09_np-npes_action_plan_final_2010-08-09.pdf.

¹⁰ Kochukov, M. Y., Jeng, Y. J., & Watson, C. S. (2009). Alkylphenol Xenoestrogens with Varying Carbon Chain Lengths Differentially and Potently Activate Signaling and Functional Responses in GH₃/B₆/F₁₀ Somatomammotropes. *Environmental health perspectives*, 117(5), 723.

Organic producers and processors have no control over cleansers that may have been used on containers and equipment before being re-purposed for organic farming purposes.

Detergents labeled as “ecologically friendly” are widely available.

Many organic growers and processors probably use cleansers whose active ingredients have been given high ratings by EPA’s Safer Choice program.¹¹

Evaluation Criteria

We largely agree with the MS evaluation criteria in the Fall 2019 discussion document, with a few comments:

1. “Odors” are not harmful *per se*, so #4 should be “Presence of harmful gases.”
2. Resistance is an issue not only with the target organism, but also with other organisms that may be exposed to the material through use or in effluent, so one additional criterion should be “**Is the material used to treat human disease?**”

Regarding the categorization of materials, chlorine, bromine, and iodine are all halogens, and iodophors consist of iodine plus a surfactant, so A, B, and K could be summarized as halogen materials. Surfactants are listed separately.

In addition to the excerpts of OFPA and the regulations that are provided, sections 6517(b) and (c) of OFPA are also relevant:

Organic Foods Production Act (U.S.C. 6517)

(b) Content of list

The list established under subsection (a) shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2).

(c) Guidelines for prohibitions or exemptions

(1) Exemption for prohibited substances in organic production and handling operations

The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if—

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances—

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

(B) the substance—

(i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides

¹¹ <https://www.epa.gov/saferchoice/safer-ingredients>.

and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or
(ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern; and
(C) the specific exemption is developed using the procedures described in subsection (d).

Conclusion

The above comments address our conception of what a comprehensive review of cleaning and sanitizing materials would look like. The Materials Subcommittee has outlined many of the issues we believe should be covered, but we believe that they need to be addressed within a framework that first identifies the needs for cleaning and sanitizing materials in organic production and handling. With this background, we look at the petitioned use of cetylpyridium chloride.

Comments on the cetylpyridinium chloride petition.

Incompleteness of the petition.

Attachment 5, which includes the studies summarized by the petitioner, is omitted.

Cetylpyridinium chloride (CPC) and other quaternary ammonium compounds are toxic chemicals that do not belong in organic processing.

Cetylpyridinium chloride (CPC) is a quaternary ammonium compound (quat). Other quats used as sanitizers and disinfectants include benzalkonium chloride, benzethonium chloride, cetalkonium chloride, cetrimide, cetrimonium bromide, glycidyl trimethyl, ammonium chloride, and stearylalkonium chloride. The highly toxic herbicides paraquat and diquat are also quaternary ammonium compounds.¹²

Respiratory toxicity

Of particular interest with regard to use as disinfectants in the COVID-19 pandemic, quats increase the risk for asthma and allergic sensitization. Evidence from occupational exposures shows increased risk of rhinitis and asthma with exposure to quats. Quats are on the Association of Occupational and Environmental Clinics list of asthmagens and may be more potent than bleach. One quat, benzalkonium chloride, has also been associated with dermatitis.¹³ Quats appear to be sensitizers and irritants to the skin and mucous membranes. Particular quats are suspected to display an immunologic cross-reactivity between each other

¹² J.R. Roberts and J.R. Reigart, 2013. Recognition and Management of Pesticide Poisonings, sixth edition. Chapter 12. https://www.epa.gov/sites/default/files/documents/rmpp_6thed_ch12_paraquatdiquat.pdf.

¹³ Holm, S.M., Leonard, V., Durrani, T. and Miller, M.D., 2019. Do we know how best to disinfect child care sites in the United States? A review of available disinfectant efficacy data and health risks of the major disinfectant classes. American journal of infection control, 47(1), pp.82-91. [https://www.ajicjournal.org/article/S0196-6553\(18\)30731-4/fulltext#sec0018](https://www.ajicjournal.org/article/S0196-6553(18)30731-4/fulltext#sec0018).

and with other chemical compounds containing ammonium ion, such as muscle relaxants widely used in anesthesia.¹⁴

CPC has been studied specifically for its inhalation effects. Researchers found, “Following CPC exposure, via intratracheal instillation (ITI), leakage of lactate dehydrogenase, a biomarker of cell injury, was significantly increased in all exposure groups. . . . The bronchoalveolar lavage fluid (BALF) analysis showed a significant increase in proinflammatory cytokines interleukin (IL)-6, IL-1 β , and tumor necrosis factor (TNF)- α levels. ITI of CPC induced focal inflammation of the pulmonary parenchyma in rats' lungs. Our study demonstrated that TNF- α was the most commonly secreted proinflammatory cytokine during CPC exposure in both in vitro and in vivo models. Polymorphonuclear leukocytes in the BALF, which are indicators of pulmonary inflammation, significantly increased in a concentration-dependent manner in all in vivo studies including the ITI, acute, and subacute inhalation assays.”¹⁵

Another study found, “BAC and CPC [both quats] cause cell death via caspase-3-dependent apoptotic pathway in A549 cells and alter the alveolar surfactant activity.”¹⁶

Genotoxicity

Some quats are shown to be mutagenic and to damage animal DNA and DNA in human lymphocytes at much lower levels than are present in cleaning chemicals.¹⁷

Antimicrobial Resistance

Genes have been discovered that mediate resistance to quats. There has been an association of some of these genes with beta lactamase genes, raising concern about a relationship between disinfectant resistance and antibiotic resistance.¹⁸ Exposure of cells to CPC produced mutants with “2- to 16-fold more resistance than the wild-type cells to biocides and antibiotics, including cetylpyridinium chloride, benzalkonium chloride, chlorhexidine gluconate, fluoroquinolones, tetracycline, and chloramphenicol.” The authors warn, “It must be

¹⁴ Lim, XiaoZhi, 2020. Do we know enough about the safety of quat disinfectants? Chemical and Engineering News, vol. 98, issue 30. <https://cen.acs.org/safety/consumer-safety/know-enough-safetyquat-disinfectants/98/i30>.

¹⁵ Kim, H., Yoo, J., Lim, Y.M., Kim, E.J., Yoon, B.I., Kim, P., Yu, S.D., Eom, I.C. and Shim, I., 2021. Comprehensive pulmonary toxicity assessment of cetylpyridinium chloride using A549 cells and Sprague–Dawley rats. *Journal of Applied Toxicology*, 41(3), pp.470-482.

¹⁶ Kanno, S., Hirano, S., Kato, H., Fukuta, M., Mukai, T. and Aoki, Y., 2020. Benzalkonium chloride and cetylpyridinium chloride induce apoptosis in human lung epithelial cells and alter surface activity of pulmonary surfactant monolayers. *Chemico-biological interactions*, 317, p.108962.

¹⁷ Holm, S.M., Leonard, V., Durrani, T. and Miller, M.D., 2019. Do we know how best to disinfect child care sites in the United States? A review of available disinfectant efficacy data and health risks of the major disinfectant classes. *American journal of infection control*, 47(1), pp.82-91. [https://www.ajicjournal.org/article/S0196-6553\(18\)30731-4/fulltext#sec0018](https://www.ajicjournal.org/article/S0196-6553(18)30731-4/fulltext#sec0018).

¹⁸ Holm, S.M., Leonard, V., Durrani, T. and Miller, M.D., 2019. Do we know how best to disinfect child care sites in the United States? A review of available disinfectant efficacy data and health risks of the major disinfectant classes. *American journal of infection control*, 47(1), pp.82-91. [https://www.ajicjournal.org/article/S0196-6553\(18\)30731-4/fulltext#sec0018](https://www.ajicjournal.org/article/S0196-6553(18)30731-4/fulltext#sec0018).

stressed that such a mutant is resistant not only to biocides but also to a broad spectrum of antibiotics.”¹⁹

Reproductive Toxicity

Mice whose cages were cleaned with QACs had very low fertility rates.²⁰ Exposure to a common quat disinfectant mixture significantly impairs reproductive health in mice.²¹ CPC was found to inhibit mitochondrial synthesis and

The ingredient polypropylene glycol must also be reviewed.

The Technical Review states:

When used as petitioned in food processing applications, cetylpyridinium chloride must be combined with propylene glycol at 1.5 times the concentration of cetylpyridinium chloride. Propylene glycol acts as a stabilizer and solubility enhancer for cetylpyridinium chloride. Additionally, the use of propylene glycol reduces the absorption of cetylpyridinium chloride into treated poultry products. The petition also states that all propylene glycol used in cetylpyridinium chloride formulations is produced from renewable resources, including vegetable oil and glycerin byproducts from biodiesel manufacturing.²²

First of all, the sourcing of propylene glycol or CPC from bioethanol or biodiesel by the petitioner is not relevant to consideration of the petition unless the annotation of the CPC listing includes a requirement for such sourcing.

Any material that is used in organic processing must be organic or on the National List for that use. Propylene glycol is on §603 for treatment of ketosis in ruminants, so propylene glycol must also be petitioned and recommended for use with CPC. In examining propylene glycol, its impacts must be considered both by itself and together with CPC.

CPC is not necessary.

The TR identifies a number of natural and listed synthetic alternatives that are currently available--ranging from water to organic acids to chlorine materials.²³

¹⁹ Maseda, H., Hashida, Y., Konaka, R., Shirai, A. and Kourai, H., 2009. Mutational upregulation of a resistance-nodulation-cell division-type multidrug efflux pump, SdeAB, upon exposure to a biocide, cetylpyridinium chloride, and antibiotic resistance in *Serratia marcescens*. *Antimicrobial agents and chemotherapy*, 53(12), pp.5230-5235. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2786342/>.

²⁰ Holm, S.M., Leonard, V., Durrani, T. and Miller, M.D., 2019. Do we know how best to disinfect child care sites in the United States? A review of available disinfectant efficacy data and health risks of the major disinfectant classes. *American journal of infection control*, 47(1), pp.82-91. [https://www.ajicjournal.org/article/S0196-6553\(18\)30731-4/fulltext#sec0018](https://www.ajicjournal.org/article/S0196-6553(18)30731-4/fulltext#sec0018).

²¹ Melin, V.E., Potinini, H., Hunt, P., Griswold, J., Siems, B., Werre, S.R. and Hrubec, T.C., 2014. Exposure to common quaternary ammonium disinfectants decreases fertility in mice. *Reproductive toxicology*, 50, pp.163-170.

²² Technical Evaluation Report for Cetylpyridinium Chloride (TR), 2021. Lines 207-213. Internal references omitted.

²³ TR Lines 440-559.

Conclusion

CPC is a hazardous chemical that does not belong in organic handling and processing. It is not necessary. Therefore, the petition should be rejected.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terry Shistar, Ph.D.
Board of Directors