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October 3, 2014

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: Peracetic Acid

These comments to the National Organic Standards Board (NOSB) on its Fall 2014 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 groups around the world.

Beyond Pesticides supports the relisting of peracetic acid for use in handling. Compared to alternatives, it is relatively harmless, effective, and compatible with organic handling practices.

1. Environmental and Health Impacts

Peracetic acid exists as a solution in an equilibrium of hydrogen peroxide and acetic acid. According to the 2009 sunset recommendation, "These reaction components of peracetic acid – hydrogen peroxide and acetic acid—have various production methods, including (for acetic acid) oxidation of acetaldehyde, hydrolysis of acetylene, or fermentation of plant sources. For hydrogen peroxide, the Riedl-Pfleiderer process uses a polycyclic aromatic hydrocarbon derived from coal tar along with oxygen and hydrogen gases to produce the material." Breakdown products are acetic acid (same acid found in vinegar at 5% level) and hydrogen peroxide that breads down to O_2 and H_2O.

The 2009 recommendation also states that peracetic acid is an irritant of the skin, eyes, mucous membranes, and respiratory tract, and it is on the EPA Extremely Hazardous Substance list.

2. Ancillary Substances

According to the 2000 Technical Advisory Panel review, "Stock commercial preparations usually contain a synthetic stabilizer such as 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition (Kurschner and Diken, 1997). According to FDA regulations, HEDP may be used with PAA at a level not to

exceed 4.8 ppm in water used to wash fresh fruits and vegetables (21 CFR 173.315(a)(5)). Sanitizing combinations approved by 21CFR 178.1010 to be used with PAA under (b)(38) include: hydrogen peroxide; acetic acid; sulfuric acid; and 2,6-pyridinedicarboxylic (dipicolinic) acid. Under (b)(45) they include: hydrogen peroxide; acetic acid; octanoic acid; peroxyoctanoic acid; sodium 1-octanesulfonate; and 1-hydroxyethylidene-1,1-diphosphonic acid." The HS should investigate these potential ancillary substances.

3. Essentiality

According to the TAP review, alternatives include: fresh, clean water; rapid cooling; and reducing the time between harvest and consumption. Physical methods such as heat and steam can also be used in some situations. Other alternatives on the National List include hydrogen peroxide, chlorine bleach, phosphoric acid, and sodium hydroxide. Peracetic acid is superior to hydrogen peroxide in antimicrobial activity.

4. Compatibility

Peracetic acid is relatively compatible with organic practices. The TAP review says,

> In comparison to other most-used sanitizers in the food industry, peracetic acid may be more compatible with organic handling than the use of halogen-based sanitizers and disinfectants such as chlorine bleach, iodine-phosphorous (iodophors), or quaternary ammonia products (quats). For example, chlorination can seriously damage aquatic life and form chlorinated hydrocarbons with carcinogenic and mutagenic properties (Arturo-Schaan et al., 1996). Quats have the longest residual activity (Block, 1991). PAA degrades rapidly, leaves little residue, and decomposes into relatively harmless naturally-occurring substances (Evans, 2000).

5. Conclusion

We agree with the TAP review's assessment of the relative compatibility of peracetic acid, especially compared with chlorine-based materials. Since physical methods may not always appear to be workable, peracetic acid appears to be the safest, most effective, and most compatible of the chemical approaches.

Despite our support for the relisting of this material, it is critical that the subcommittee and Board prepare a more robust review for public discussion at the first meeting on a Sunset 2016 material. Since the Fall 2014 meeting is scheduled to be the only public NOSB meeting during which the Handling Subcommittee and Board members can share its thinking and receive "timely" public input on the checklist and assessment of the material in accordance with OFPA criteria, the lack of prepared written analysis by the subcommittee for this meeting makes for an incomplete and truncated assessment process. Under the current process, information brought to the Board at the Spring 2015 meeting will be considered "untimely." While we recognize that the Board has embarked on a new two-stage process, the first stage, or first

meeting on sunset materials, must be a more robust review process if the Board's assessment of exempt prohibited materials, like this one, on the National List is to be viewed by the public, including users and consumers, as credible. The process requires this, if there is to be continuing and building public trust in the assessment process and the organic food label. We have attached a checklist in which we provide the Board with answers to questions, based on available technical reviews, that are required to be considered as a part of a sunset review that is in compliance with the Organic Foods Production Act (OFPA) and the implementing regulations.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

National Organic Standards Board
Handling Subcommittee
Petitioned Material Checklist
Peracetic Acid

[Date of Vote]

Summary of Proposed Action:
On 205.605(b): Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?
1. Impact on Humans and Environment N/A	☐ Yes ☐ No ☐
2. Essential & Availability Criteria N/A	☐ Yes ☐ No ☐
3. Compatibility & Consistency N/A	☐ Yes ☐ No ☐
4. Commercial Supply is Fragile or Potentially Unavailable N/A as Organic (only for §205.606)	☐ Yes ☐ No ☐

Substance Fails Criteria Category: [ ] **Comments:**

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Move to classify [substance] as [synthetic, nonsynthetic, agricultural]
Motion by:
Seconded by:
Yes: # No: # Absent: # Abstain: # Recuse: #

Listing Motion: Move to list [substance] on section **205.6xx** of the National List [with the annotation]
Motion by:
Seconded by:
Yes: # No: # Absent: # Abstain: # Recuse: #

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Approved by Subcommittee Chair to Transmit to NOSB

Name , Subcommittee Chair **Date**

NOSB Evaluation Criteria for Substances Added To the National List
Handling

Category 1. Adverse impacts on humans or the environment? **Substance:**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]	?			Breakdown products are acetic acid (same acid found in vinegar at 5% level) and hydrogen peroxide that breads down to O_2 and H_2O. Disposal in municipal sewer system may have a positive effect due to oxidation capabilities (Arturo-Schaan et al., 1996). It is more persistant than chlorine-based disinfectants, but less so than quaternary ammonium compounds (Evans, 2000). It can have a longer residual activity than chlorine (Gruetzmacher and Bradley, 1999). TAP (handling) p. 3
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	?			Peracetic acid is not produced and distributed for use as a solitary compound. It is only encountered as a solution in two- way equilibrium with hydrogen peroxide and acetic acid. These reaction components of peracetic acid- hydrogen peroxide and acetic acid- have various production methods, including (for acetic acid) oxidation of acetaldehyde, hydrolysis of acetylene, or fermentation of plant sources. For hydrogen peroxide, the Riedl-Pfleiderer process uses a polycyclic aromatic hydrocarbon derived from coal tar along with oxygen and hydrogen gases to produce the material. Details of which manufacturing process is used for the components or the potential adverse environmental effects from these processes were not provided in the TAP or the petition. 2009 Crops Checklist
3. Are there any adverse impacts on biodiversity? (§205.200)		X		Breakdown products are acetic acid (same acid found in vinegar at 5% level) and hydrogen peroxide that breads down to O_2 and H_2O. Disposal in municipal sewer system may have a positive effect due to oxidation capabilities (Arturo-

				Schaan et al., 1996). It is more persistant than chlorine-based disinfectants, but less so than quaternary ammonium compounds (Evans, 2000). It can have a longer residual activity than chlorine (Gruetzmacher and Bradley, 1999). TAP (handling) p. 3
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]	X	X		"Peracetic acid usually occurs with hydrogen peroxide and acetic acid in an aqueous solution. Stock commercial preparations usually contain a synthetic stabilizer such as 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition (Kurschner and Diken, 1997). According to FDA regulations, HEDP may be used with PAA at a level not to exceed 4.8 ppm in water used to wash fresh fruits and vegetables (21 CFR 173.315(a)(5)). Sanitizing combinations approved by 21CFR 178.1010 to be used with PAA under (b)(38) include: hydrogen peroxide; acetic acid; sulfuric acid; and 2,6-pyridinedicarboxylic (dipicolinic) acid. Under (b)(45) they include: hydrogen peroxide; acetic acid; octanoic acid; peroxyoctanoic acid; sodium 1-octanesulfonate; and 1-hydroxyethylidene-1,1-diphosphonic acid." TAP 2000, p. 2.
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Readily biodegradable. 2009 Checklist
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]	?			"Peracetic acid usually occurs with hydrogen peroxide and acetic acid in an aqueous solution. Stock commercial preparations usually contain a synthetic stabilizer such as 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition (Kurschner and Diken,

				1997). According to FDA regulations, HEDP may be used with PAA at a level not to exceed 4.8 ppm in water used to wash fresh fruits and vegetables (21 CFR 173.315(a)(5)). Sanitizing combinations approved by 21CFR 178.1010 to be used with PAA under (b)(38) include: hydrogen peroxide; acetic acid; sulfuric acid; and 2,6-pyridinedicarboxylic (dipicolinic) acid. Under (b)(45) they include: hydrogen peroxide; acetic acid; octanoic acid; peroxyoctanoic acid; sodium 1-octanesulfonate; and 1-hydroxyethylidene-1,1-diphosphonic acid." TAP 2000, p. 2. Material is an irritant of the skin, eyes, mucous membranes, and respiratory tract. The material is on the EPA Extremely Hazardous Substance list.(EPA 2000) 2009 Checklist Ancillary substances have not been reviewed.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]		X		TAP, p. 3. Ancillary substances have not been reviewed.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]		X		But see #4 above.

NOSB Evaluation Criteria for Substances Added To the National List
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Category 2. Is the Substance Essential for Organic Production? **Substance:**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Peracetic acid is not produced and distributed for use as a solitary compound. It is only encountered as a solution in two- way equilibrium with hydrogen peroxide and acetic acid. These reaction components of peracetic acid- hydrogen peroxide and acetic acid- have various production methods, including (for acetic acid) oxidation of acetaldehyde, hydrolysis of acetylene, or fermentation of plant sources. For hydrogen peroxide, the Riedl-Pfleiderer process uses a polycyclic aromatic hydrocarbon derived from coal tar along with oxygen and hydrogen gases to produce the material. Details of which manufacturing process is used for the components or the potential adverse environmental effects from these processes were not provided in the TAP or the petition. 2009 Crops Checklist
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		X		See #2 above.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See #2 above.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		See #2 above.
6. Is there an organic substitute? [§205.600(b)(1)]		X		Alternatives include: fresh, clean water; rapid cooling; and reducing the time between harvest and consumption. Physical methods such as heat and steam can also be used in some situations. TAP, p. 3.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		See alternatives below.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		?		Other alternatives on the NL include hydrogen peroxide chlorine bleach, phosphoric acid, and sodium hydroxide. Peracetic acid is superior to hydrogen peroxide in antimicrobial activity (Evans, 2000). TAP, p. 3.

9. Are there any alternative substances? [§6518(m)(6)]	X			Alternatives include: fresh, clean water; rapid cooling; and reducing the time between harvest and consumption. Physical methods such as heat and steam can also be used in some situations. TAP, p. 3.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			Alternatives include: fresh, clean water; rapid cooling; and reducing the time between harvest and consumption. Physical methods such as heat and steam can also be used in some situations. TAP, p. 3.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		"Peracetic acid usually occurs with hydrogen peroxide and acetic acid in an aqueous solution. Stock commercial preparations usually contain a synthetic stabilizer such as 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition (Kurschner and Diken, 1997). According to FDA regulations, HEDP may be used with PAA at a level not to exceed 4.8 ppm in water used to wash fresh fruits and vegetables (21 CFR 173.315(a)(5)). Sanitizing combinations approved by 21CFR 178.1010 to be used with PAA under (b)(38) include: hydrogen peroxide; acetic acid; sulfuric acid; and 2,6-pyridinedicarboxylic (dipicolinic) acid. Under (b)(45) they include: hydrogen peroxide; acetic acid; octanoic acid; peroxyoctanoic acid; sodium 1-octanesulfonate; and 1-hydroxyethylidene-1,1-diphosphonic acid." TAP 2000, p. 2. These have not all been reviewed.

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Category 3. Is the substance compatible with organic handling practices? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X	X		In comparison to other most-used sanitizers in the food industry, peracetic acid may be more compatible with organic handling than the use of halogen-based sanitizers and disinfectants such as chlorine bleach, iodine-phosphorous (iodophors), or quaternary ammonia products (quats). For example, chlorination can seriously damage aquatic life and form chlorinated hydrocarbons with carcinogenic and mutagenic properties (Arturo-Schaan et al., 1996). Quats have the longest residual activity (Block, 1991). PAA degrades rapidly, leaves little residue, and decomposes into relatively harmless naturally-occurring substances (Evans, 2000). TAP, p. 3. However, the use of PAA to intentionally bleach food would not be compatible with organic principles. TAP, p. 6.
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]				Impacts of manufacture depends on processes used. Various methods of manufacturing involve the use of acetaldehyde. Breakdown products are acetic acid (same acid found in vinegar at 5% level) and hydrogen peroxide that breads down to O_2 and H_2O. Disposal in municipal sewer system may have a positive effect due to oxidation capabilities (Arturo-Schaan et al., 1996). It is more persistant than chlorine-based disinfectants, but less so than quaternary ammonium compounds (Evans, 2000). It can have a longer residual activity than chlorine (Gruetzmacher and Bradley, 1999). TAP, p. 3.
3. Is the substance compatible with a				See #1 above.

	system of sustainable agriculture? [§6518(m)(7)]				
4.	Are the ancillary substances reviewed compatible with organic handling?	?			Ancillary substances have not all been reviewed.
5.	Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			Limited studies have shown no significant loss of water soluble vitamins as a function of direct food contact (asserted, but not backed up by any reference journal studies). It may inhibit various dairy cultures, but this effect is short-lived (Langeveld and van Montfort-Quasig, 1996). TAP, p. 3.
6.	Is the primary use as a preservative? [§205.600(b)(4)]		X		
7.	Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		

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Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Substance:**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?				
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?				
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Other issues which may present a challenge to a consistent supply?				