Peracetic Acid

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Peracetic acid; Ethaneperoxoic acid (IUPAC name); Acetic peroxide; Monoperacetic acid; Peroxoacetic acid; Acetyl hydroperoxide.

Other Name:
Peroxyacetic acid; PAA

Trade Names:
BioSide, Blitz, CitroBio, FreshFx, Inspexx, NicroBlast, Oxicure, Oxylleaf, Perasafe, Peracsan, Peraclean, Per-Ox, SaniDate, Stor-Ox, Tsunami, Vigor-Ox, Estosteril; Desoxone 1; Dialax; Caswell no. 644, Caswell no. 644.

CAS Numbers:
79-21-0
89370-71-8 (historic)

Other Codes:
EC Number 201-186-8; ICSC Number 1031; NIOSH Registry Number SD8750000; UN/ID Number 3105; No INS number or E number since peracetic acid is a sanitizer (not an intentional food additive).

Summary of Petitioned Use

Peracetic acid (PAA) is currently allowed under the National Organic Program (NOP) regulations for use in organic crop production, organic livestock production, and in organic food handling. This report addresses the use of peracetic acid in organic processing and handling, including post-harvest handling of organically produced plant and animal foods. Peracetic acid is currently allowed for use in organic handling in wash water and rinse water, including during post-harvest handling, to disinfect organically produced agricultural products according to FDA limitations, and to sanitize food contact surfaces, including dairy-processing equipment and food-processing equipment and utensils.

Characterization of Petitioned Substance

Composition of the Substance:

Chemically, the term "peracetic acid" describes two substances. "Pure" peracetic acid, described in the Merck Index (Budavari 1996), has the chemical formula $C_2H_4O_3$ (alternatively written CH_3CO_3H). Anhydrous peracetic acid explodes violently upon heating. In contrast, solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid and hydrogen peroxide. This equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid." Adding a mineral acid catalyst accelerates the reaction.

Peracetic acid is an unstable oxidizing agent, which is why it is such an effective sanitizer. Most commercial peracetic acid solutions contain a synthetic stabilizer and chelating agent such as HEDP (1-hydroxyethylidene-1, 1-diphosphonic acid) or dipicolinic acid (2,6-dicarboxypyridine) to slow the rate of oxidation or decomposition. These and other additives are discussed in *Combinations of the Substance*.

Source or Origin of the Substance:

Pure anhydrous peracetic acid is prepared from acetaldehyde and oxygen in the presence of cobalt acetate, or by the auto-oxidation of acetaldehyde (Budavari 1996). Solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, frequently in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Specific grades are obtained by controlling the concentrations and amounts of hydrogen peroxide and acetic acid during the manufacturing process. Adding an acid or increasing the temperature during the manufacturing process can accelerate the establishment of the final equilibrium concentration (grade). Commercial grades are available in peracetic acid concentrations ranging from about 0.3 to 40 % by weight. Solutions with relatively low content of acetic acid and hydrogen peroxide can be produced by distillation of the equilibrium solutions. Based on the manufacturing process for sanitizing solutions of peracetic acid described above, it is evident that a pure peracetic acid solution is not produced or isolated when commercial peracetic acid solutions are manufactured.

A peracetic acid solution also can be generated *in situ* by dissolving an activator (tetra-acetyl ethylenediamine) and a persalt (sodium perborate or sodium percarbonate) in water (OECD 2008), or on site (within 1 minute) by adding sodium hydroxide to triacetin and hydrogen peroxide (Harvey and Howarth 2013).

Properties of the Substance:

Pure anhydrous peracetic acid is a colorless liquid with a strong, pungent acrid odor. It is an organic substance which is completely miscible with water (water solubility of 1000 g/L at 20 °C) and is also soluble in ether, sulfuric acid and ethanol. It is a strong oxidizing agent – stronger than chlorine or chlorine dioxide (Carrasco and Urrestarazu 2010). It is highly unstable and decomposes to its original constituents under various conditions of temperature, concentration and pH. Peracetic acid decomposes violently at 230ºF (110ºC). Peracetic acid diluted with 60% acetic acid, when heated to decomposition, emits acrid smoke and irritating fumes.

Pure peracetic acid is not commercially available because it is explosive. For this reason it is not technically possible to determine the melting point, boiling point and vapor pressure of pure peracetic acid experimentally. Estimates based on modeling have been reported as -42 °C for melting point, about 105 °C for boiling point and 32 hPa at 25 °C for vapor pressure. The properties of commercial peracetic acid solutions vary based on concentrations (ratios) of their components (peracetic acid, hydrogen peroxide, acetic acid and water) for different grades. The physical and chemical properties of commercial equilibrium grades of 5% - 35% PAA are generally consistent in composition. Their properties are shown in Table 1.

Table 1. Physical and Chemical Properties of Three Equilibrium Grades of PAA (adapted from JACC 2001).

Property	Value		
	5% PAA	15% PAA	35% PAA
Ratio of components: PAA:H_2O_2:HOAc:H_2O	5 : 22 : 10 : 63	15 : 20 : 15 : 50	35 : 7 : 40 : 18
Freezing/Melting point	-26 to -30 ºC	-30 to -50 ºC	-44 ºC
Boiling point	99 to 105 ºC	> 100 ºC	> 105 ºC
Density (g/cm^3) at 20 ºC	1.12	1.15	1.13
Vapor pressure at 20 ºC	21 to 21 hPa	25 hPa	17 hPa
Flash point (closed cup)	74 to 83 ºC	68 to 81 ºC	42 to 62 ºC
Self-accelerating decomposition	> 55 to > 65 ºC	> 50 ºC	> 55 ºC

Peracetic acid has a molecular weight of 76.05. Its dissociation constant (pKa) is 8.2 at 20 °C and, therefore, the substance is mainly present in the environment as peracetic acid at a neutral pH (pH = 7), while peracetate (the salt of peracetic acid) would mainly be present if the pH is significantly higher than 8.2 (OECD 2008). The pH of peracetic acid solutions is reported to range from < 1 to 1.8 (OECD 2008; U.S. National Library of Medicine 2012; NOAA 2015).

Specific Uses of the Substance:
The primary use of peracetic acid is as a bactericide and fungicide, especially in food processing. The current NOP regulations permit the use of peracetic acid as a disinfectant in wash water and rinse water for raw and processed fruits and vegetables and meat and eggs (direct food contact) according to FDA limitations, and as a sanitizer on food contact surfaces.

Peracetic acid can be utilized over a wide temperature spectrum (0 to 40ºC), in clean-in-place (CIP) processes, and in carbon dioxide-saturated environments. It can also be used with hard water. In addition, protein residues do not affect its efficiency. No microbial resistance to peracetic acid has been reported. It is efficient over a wide spectrum of pH values, from 3.0 to 7.5 (Kunigk and Almeida 2001).

Regulatory Status and Approved Legal Uses of the Substance:
Peracetic acid is currently permitted in the NOP regulations for organic crop production, organic livestock production, and organic handling, with the annotations noted below. Sections 7 CFR 205.601(m) and 205.603(e) are also cited below because peracetic acid solutions contain certain inert ingredients that are essential for efficacy.

7 CFR 205.601 Synthetic substances allowed for use in organic crop production.
(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
(4) Hydrogen peroxide.
(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.
(i) As plant disease control.
(5) Hydrogen peroxide.
(8) Peracetic acid—for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.
(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1) EPA List 4 – Inerts of Minimal Concern

7 CFR 205.603 Synthetic substances allowed for use in organic livestock production.
(a) As disinfectants, sanitizer, and medical treatments as applicable.
(19) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.
(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1) EPA List 4 – Inerts of Minimal Concern

7 CFR 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."
(b) Synthetics allowed: 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.

Peracetic acid has a complex regulatory status because several federal agencies have their own specific areas of statutory jurisdiction. Each agency creates its own set of regulations for sanitizer use which can impact the permissible uses of peracetic acid in organic crop production, organic livestock production, and organic handling, including post-harvest handling.

The Organic Foods Production Act (OFPA) of 1990 at 7 USC 6519(c)(6) specifies that nothing in the OFPA shall alter the authority of the secretary of agriculture under the Federal Meat Inspection Act or under the Poultry Products Inspection Act, the authority of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act, or the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act. Consequently, four federal agencies regulate peracetic acid used in handling organic foods after harvesting or slaughter (Theuer and Walden 2011).

- The National Organic Program (NOP) of Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA)
- The Food Safety and Inspection Service (FSIS) of the USDA
- The Food and Drug Administration (FDA)
- The Environmental Protection Agency (EPA)

EPA, FDA, and FSIS have different approaches for implementing and codifying regulations, but the agencies closely coordinate their regulations to facilitate uniform compliance. AMS, FSIS, FDA, and EPA signed a memorandum of understanding (MOU 225-85-8400) in 1984 to promote more effective, efficient and coordinated federal regulatory activities concerning residues of drugs, pesticides and environmental contaminants that may adulterate food. Additional bilateral memorandums of understanding also ensure close harmony among the agencies' rules and regulations and define areas of responsibility. In 1971, EPA and FDA issued a memorandum of understanding (MOU 225-73-8010) that split the responsibility for pesticide materials used on agricultural products (other than meat). EPA is involved because peracetic acid is legally classified as a pesticide. This memorandum of understanding assigns the responsibility for processed fruit and vegetable products to FDA, and the responsibility for raw (unprocessed) fruit and vegetable products to EPA. FSIS is responsible for meat and poultry products. FSIS and FDA implemented a memorandum of understanding in January 2000.

FDA is responsible for exercising the authority of the secretary of health and human services under the Federal Food, Drug and Cosmetic Act. FDA regulates peracetic acid by enumerating the permissible ingredients in PAA solutions. FDA regulations relating to the use of PAA for the two handling uses allowed in 7 CFR 205.605(b) are codified in 21 CFR 173 and 178. Part 173 is titled "Secondary direct food additives permitted in food for human consumption" and includes two sections that specifically mention peroxyacetic acid: section 173.315 ("chemicals used in washing or to assist in the peeling of fruits and vegetables") and section 173.370 ("peroxyacids"). Part 178 is titled "Indirect food additives: adjuvants, production aids, and sanitizers," and includes one section specifically mentioning peroxyacetic acid: section 178.1010 (sanitizing solutions). Section 178.1010 contains three paragraphs describing compositions of peroxyacetic acid solutions.

Five specific aqueous mixtures are described in 21 CFR 173 and 178, but there is redundancy in these mixtures, so there are only three generic PAA solutions of concern (Theuer and Walden 2011). These are described in detail below. In addition, FDA reviews petitions for new sanitizer compositions or new uses for existing compositions and issues "Food Contact Substance Notifications" (FCNs) for food contact substances that have been demonstrated to be safe for their intended uses. A database of these notifications is maintained online[1]. Entries in the FDA online database include the food contact substance, the manufacturer of the substance, the intended use, the limitations on the conditions of use and its specifications, and the effective date. Thirty FCNs relating to peracetic/peroxyacetic acid have been issued in the past six years[2].

EPA administers the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Every pesticide product distributed in the United States must be registered with EPA. EPA approves the label and thus the permissible uses of every pesticide product. Peracetic acid is an antimicrobial substance and thus is a "pesticide" as defined by FIFRA.

[1] www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm
[2] As of 1 November 2015.

EPA regulations for food disinfection and food contact surface sanitation relating to the use of peracetic acid for the uses allowed in 7 CFR 205.605(b) are codified in 40 CFR 180. In accordance with the regulatory practice of EPA, these regulations enumerate the permissible tolerance limits of active ingredients and inert ingredients in PAA solutions. Section 40 CFR 180.910 provides the list of inert (or occasionally active) ingredients used pre- and post-harvest in direct food contact, and the exemptions from the requirement of a tolerance of these ingredients on the food. Section 40 CFR 180.940 lists similar information for active and inert ingredients in antimicrobial formulations used to sanitize food contact surfaces. Section 40 CFR 180.950 lists common safe ingredients, such as glycerin (glycerol), that are exempt from a tolerance in any use. Sections 40 CFR 180.1196 and 180.1197 establish the conditions for an exemption from the requirement for a tolerance for peroxyacetic acid (peracetic acid) and hydrogen peroxide, respectively. For example, if the diluted solution applied to fruit contains less than 100 ppm of peracetic acid, the residue of peracetic acid on the fruit is exempt from a tolerance.

FSIS administers the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). Under the FMIA and the PPIA, FSIS is responsible for determining the suitability of FDA-approved substances in meat and poultry products. Pursuant to the memorandum of understanding signed in January 2000, FDA and FSIS work together to evaluate petitions requesting the approval of new substances or new uses of previously approved substances for use in or on meat and poultry products. FSIS inspectors enforce FSIS policy by implementing "FSIS Directives." FSIS Directive 7120.1 permits two peracetic acid solutions for direct food contact with red meat and poultry. These two solutions are among the same solutions allowed by FDA; however the allowance varies depending on use (USDA Food Safety and Inspection Service 2015).

Peracetic Acid Solutions Allowed by FDA and/or EPA and/or FSIS (For the purpose of this report, each PAA Solution is given a number which refers to one of the solutions listed below. More details on these solutions are described in *Combinations of the Substance.*)

PAA Solution #1 – An aqueous solution of peracetic acid prepared by reacting the substances acetic acid and hydrogen peroxide. The solution is stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP).

PAA Solution #1A – An aqueous solution of peracetic acid prepared by reacting the substances acetic acid, sulfuric acid and hydrogen peroxide. The solution is stabilized with HEDP.

PAA Solution #2 – An aqueous solution of peracetic acid and peroxyoctanoic acid prepared by reacting the substances acetic acid, octanoic acid and hydrogen peroxide. The solution is stabilized with HEDP. The food contact surface sanitizer version additionally contains the surface-active agent sodium 1-octanesulfonate.

PAA Solution #3 – An aqueous solution of peracetic acid prepared by reacting the substances acetic acid and hydrogen peroxide, optionally in the presence of sulfuric acid. The solution is stabilized with dipicolinic acid (DPA) and optionally HEDP.

PAA Solution #4 – An aqueous solution of peracetic acid prepared on site, either by adding sodium hydroxide to triacetin (glycerol triacetate) and hydrogen peroxide (Harvey and Howarth 2013), or by electrolysis and oxygenation of a sodium sulfate solution to produce sodium hydroxide and hydrogen peroxide, and then combining this with a solution of sulfuric acid and sodium acetate to produce peracetic acid (Buschmann and Del Negro 2012). No stabilizers are required.

The following tables describe which solutions are permitted for which uses by the responsible agencies.

Table 2: Post-Harvest Handling: Direct food contact – red meat and poultry.

PAA Solution	Agency	Status	References and Comments
#1	FSIS	permitted	Directive 7120.1

	FDA	permitted	FCN Nos. 323, 1144, 1236, 1247,1286, 1363, 1495, etc.
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#1A	FSIS	permitted	Directive 7120.1
	FDA	permitted	FCN Nos. 951, 1093, 1094, 1132, 1394, 1419, 1490, 1501, 1522, etc.
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#2	FSIS	permitted	Directive 7120.1
	FDA	permitted	21 CFR 173.370 ("Peroxyacids")
	EPA	permitted	Permitted in accordance with EPA registration, approved labeling, and FSIS approval
	NOP	see comment	Octanoic acid and peroxyoctanoic acid are not listed at 7 CFR 205.605(b). If either substance is labeled as an active ingredient, then the solution is not permitted.
#3	FSIS	permitted	Directive 7120.1 - Antimicrobial Update 10/21/15[3]
	FDA	permitted	FCN Nos. 1035, 1094, 1465, 1477, and 1522
	EPA	see comment	No tolerance exemptions for DPA but EPA has approved labels
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#4	FSIS	permitted[4]	No objection 15-ING-1043-N-A (FCN No. 1362) No objection 13-ING-0952-N-A (FCN No. 1384)
	FDA	permitted	FCN Nos. 1384 and 1362
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910, 180.950
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs

Table 3: Post-Harvest Handling: Direct food contact – fruits and vegetables.

PAA Solution	Agency	Status	References and Comments
#1	FDA	see comment	21 CFR 173.315(a)(5): for fruits and vegetables that are not raw agricultural commodities, subject to limitations
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations
#1A	FDA	permitted	FCN No. 1501
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910; Sulfuric acid is listed as GRAS at 21 CFR 184.1095
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs

[3] Pdf document available at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series/safe-suitable-ingredients-related-document. Accessed 19 November 2015.

[4] Food Safety and Inspection Service New Technology Information Table. Last Updates October 20, 2015; http://www.fsis.usda.gov/wps/wcm/connect/fsis-content/internet/main/topics/regulatory-compliance/new-technologies/new-technology-information-table. Accessed 21 November 2015.

#2	FDA	not permitted	21 CFR 173.370 permits use on meat and poultry only
	EPA	not permitted	No tolerance exemption for octanoic acid on growing crops or fruits and vegetables post-harvest at 40 CFR 180.910
	NOP	not permitted	7 CFR 205.605(b); Peroxyoctanoic acid is not listed in 7 CFR 205.605(b)
#3	FDA	permitted	FCN Nos. 1025 (not raw), 1426 (raw)
	EPA	see comment	No tolerance exemption for DPA in 40 CFR 180.910 but EPA has approved labels
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#4	FDA	permitted	FCN Nos. 1384 (both raw and not raw) and 1362 (not raw)
	EPA	see comment	Tolerance exemptions established in 40 CFR 180.910 and 180.950; May be permitted in accordance with EPA registrations (none have been registered as of November 1, 2015)
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs

Table 4: Sanitizer on food contact surfaces and equipment without an intervening event (e.g., no potable water rinse).

PAA Solution	Agency	Status	References and Comments
#1	FDA	permitted	21 CFR 178.1010(b)(30); Pasteurized Milk Ordinance
	EPA	permitted	40 CFR 180.940 and 180.910
	NOP	permitted	7 CFR 205.605(b)
#1A	FDA	permitted	21 CFR 178.1010(b) and 184.1095
	EPA	permitted	40 CFR 180.940 and 180.910
	NOP	permitted	7 CFR 205.605(b)
#2	FDA	permitted	21 CFR 178.1010(b)(45); Pasteurized Milk Ordinance
	EPA	permitted	40 CFR 180.940 and 180.910
	NOP	see comment	Peroxyoctanoic acid and octanoic acid are not listed in 7 CFR 205.605(b). If either substance is labeled as an active ingredient, then the solution is not permitted for use without an intervening event.
#3	FDA	permitted	21 CFR 178.1010(b)(38); Pasteurized Milk Ordinance
	EPA	permitted	40 CFR 180.940(b)
	NOP	permitted	7 CFR 205.605(b)
#4	FDA	see comment	Solutions are not specifically cited at 21 CFR 178.1010; May be permitted in accordance with FCNs (none have been approved as of November 1, 2015)
	EPA	see comment	40 CFR 180.910, 180.940, and 180.950; May be permitted in accordance with EPA registrations (none have been registered as of November 1, 2015)
	NOP	see comment	7 CFR 205.605(b); May be permitted in accordance with FDA-approved FCNs

Table 5: Crop Disease Control and Disinfection of Seed and Asexually Propagated Planting Material.

PAA Solution	Agency	Status	References and Comments
#1	EPA	permitted	Tolerances established at 40 CFR 180.910
	NOP	permitted	7 CFR 205.601(a)(4), (a)(6), (i)(5), (i)(8) and (m)(1)
#1A	EPA	permitted	Tolerances established at 40 CFR 180.910

	NOP	permitted	7 CFR 205.601(a)(4), (a)(6), (i)(5), (i)(8) and (m)(1)
#2	EPA	permitted	Tolerances established at 40 CFR 180.910
	NOP	see comment	Peroxyoctanoic acid and octanoic acid are not listed in 7 CFR 205.601. If either substance is labeled as an active ingredient, then the solution is not permitted.
#3	EPA	see comment	No tolerance exemption for DPA in 40 CFR 180.910 but EPA has approved labels
	NOP	not permitted	DPA is an EPA List 3 inert allowed solely as a component of passive pheromone dispensers [7 CFR 205.601(m)(2)]. Therefore, PAA Solution #3 is not permitted for the crop pesticide uses described in 7 CFR 205.601.
#4	EPA	see comment	40 CFR 180.910, 180.940, and 180.950; May be permitted in accordance with EPA registrations (none have been registered as of November 1, 2015)
	NOP	see comment	7 CFR 205.601(a)(4), (a)(6), (i)(5), (i)(8) and (m)(1) [all inerts on List 4]; May be permitted in accordance with EPA registrations

Action of the Substance:

Peracetic acid and other peroxy sanitizers disinfect via oxidation. Peracetic acid oxidizes the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores, making it an effective sanitizer against all microorganisms, including bacterial spores. The reason for the excellent and rapid antimicrobial effects of peracetic acid is its specific capability to penetrate the cell membrane. Once inside the cell, peracetic acid plays a role in denaturing proteins, disrupting cell wall permeability, and oxidizing sulfhydryl and sulfur bonds in enzymes and other proteins. PAA irreversibly disrupts enzyme systems, which destroys the microorganism. The end products of peracetic acid oxidation are acetic acid and water.

Numerous sources cite the efficacy of PAA even in the presence of organic matter (Ruiz-Cruz, Acedo-Felix, et al. 2007). However, it also has been reported that the organic load of a solution can diminish PAA's effectiveness. As the pH of a solution approaches neutrality, PAA loses activity (Pfuntner 2011). One study on the action of PAA against microbial spores concluded that its sporicidal activity may be due to organic radicals created by PAA acting as reducing agents (electron donors) for spores normally in a highly oxidized state, as well as being oxidizing agents (electron acceptors) that cause damage to vegetative cells (Marquis et al. 1995). Peracetic acid has a higher oxidation potential than chlorine dioxide and bleach (sodium hypochlorite at pH greater than 10) and does not contribute chlorine.

Peracetic acid inactivates certain enzymes, such as peroxidase responsible for enzymatic browning of potatoes (Greenspan and Margulies 1950). This enzyme causes discoloration and deterioration of the vegetable. In the opinion of researchers in Florida working with the citrus industry, peracetic acid is believed to be better than chlorine and hydrogen peroxide for disinfecting fruit since it reduces fruit blemishes caused by the sanitizing treatment, and maintains fruit quality better than other sanitizers (Parra 2007).

Combinations of the Substance:

Peracetic acid solutions #1 – 3 discussed above are made by mixing the ingredients identified in Table 6. The resulting mixtures contain the "active ingredients" and "inert ingredients," as defined by EPA, identified in Table 7.

Table 6: Ingredients used to formulate PAA Solutions #1 – 3. The "+" symbol indicates that the ingredient is used in the formulation.

Ingredient	#1	#1A	#2	#3

Glacial acetic acid	+	+	+	+
Hydrogen peroxide	+	+	+	+
Octanoic acid			+	
Sodium 1-octanesulfonate			optional*	
Sulfuric acid		+		optional
HEDP	+	+	+	optional
Dipicolinic acid (DPA)				+

*only included in food contact surface sanitizer solutions; not included in solutions used in direct food contact

Table 7: Active or inert status of substances present in final PAA Solutions #1 – 3.

Substance Present in Final Solution	**#1**	**#1A**	**#2**	**#3**
Hydrogen peroxide	Active	Active	Active	Active
Peracetic acid	Active	Active	Active	Active
Octanoic acid			Active or Inert	
Peroxyoctanoic acid			Active	
Sodium 1-octane sulfonate			Inert	
Acetic acid	Inert	Inert	Inert	Inert
Sulfuric acid		Inert		Inert
HEDP	Inert	Inert	Inert	Inert
Dipicolinic acid (DPA)				Inert

PAA solution #4 can be generated on site in either of two ways. The first uses triacetin and hydrogen peroxide reacted with sodium hydroxide, and the end product contains hydrogen peroxide, glycerin and residual triacetin (13%). The alternative method using electrolysis yields the active ingredients peracetic acid and hydrogen peroxide; the inert ingredients are glycerin, residual triacetin, sodium sulfate, and sodium acetate, each of which is an EPA List 4A or List 4B inert.

Hydrogen peroxide is a synthetic substance. It is a Generally Recognized as Safe (GRAS) food ingredient (21 CFR 184.1366). Hydrogen peroxide itself is an antimicrobial used as a sanitizer. Sanitizing solutions of hydrogen peroxide are allowed in organic crop production at 7 CFR 205.601(a)(4) and (i)(5), in organic livestock production at 7 CFR 205.603(a)(13), and in organic handling at 7 CFR 205.605(b). See the Technical Report for hydrogen peroxide for additional information on this substance.

Sodium 1-octane sulfonate (CAS No. 5324-84-5) is a surface-active agent in food surface sanitizers. It is classified by EPA at 40 CFR 180.940 as an "inert ingredient" exempt from a tolerance for use in antimicrobial formulations (food contact surface sanitizing solutions). It is not permitted for direct food contact at 21 CFR 173.370.

Glacial acetic acid is essentially pure acetic acid, with a specification of 99.5% to 100.5% by weight of acetic acid (Wagner 2014). It has no direct antibacterial effects and thus is defined by EPA as an "inert ingredient."

Triacetin (CAS No. 102-76-1), referred to as "glycerol triacetate" by EPA at 40 CFR 180.910, is a synthetic triglyceride ("fat") created by reacting glycerin (glycerol) with acetic acid. Triacetin is soluble in 14 parts of water and has been used as an antifungal agent (Budavari 1996).

Sulfuric acid (CAS No. 7664-93-9), a mineral acid used to reduce pH, is frequently included in peracetic acid formulations to catalyze the formation of peracetic acid from acetic acid and hydrogen peroxide. Sulfuric acid is classified by EPA as a List 4 inert. It is added during the manufacturing process to accelerate the establishment of the final equilibrium concentration. Sulfuric acid is a GRAS food ingredient listed at 21 CFR 184.1095.

Peracetic acid preparations usually contain a synthetic stabilizer such as HEDP (1-hydroxyethylidene-1,1-diphosphonic acid) or dipicolinic acid (2,6-dicarboxy-pyridine) to slow the rate of oxidation or decomposition of peracetic acid (Kurschner and Diken 1997). These stabilizers are chelating agents that bind with metal ions and reduce their activity in solution. Synthetic stabilizers can be avoided if the peracetic acid solution is produced on site as described for PAA solution #4 in Evaluation Question 2. HEDP (CAS No. 2809-21-4) historically was classified by EPA as a List 4 inert. It is also exempt from the requirement of a tolerance when used as a stabilizer/chelator in antimicrobial pesticide formulations at not more than 1 percent (40 CFR 180.910).

Dipicolinic acid (DPA) (CAS No. 499-83-2) was classified by EPA as a List 3 inert in the past.

Octanoic acid (CAS No. 124-07-2), also known as caprylic acid, is an eight-carbon GRAS carboxylic acid (21 CFR 184.1025). It is a medium-chain fatty acid that occurs normally in various food fats, especially coconut oil, babassu oil and palm kernel oil. It is commercially prepared by oxidation of n-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

Octanoic acid historically was on EPA List 4 as an inert ingredient but it may also be an active ingredient in certain formulations. In 2009, EPA published its determination (74 FR 30080) that "Caprylic (octanoic) acid is an antimicrobial pesticide that is used as a food contact surface sanitizer in commercial food handling establishments. It is also used as a disinfectant in health care facilities and as an algaecide in greenhouses and interiorscapes on ornamentals. In addition, caprylic (octanoic) acid is characterized by low toxicity, is biodegradable, and is found extensively in nature."

In the presence of hydrogen peroxide, octanoic acid is reversibly converted to peroxyoctanoic acid (POOA), CAS No. 33734-57-5. Octanoic acid and peroxyoctanoic acid have greater affinity for fatty tissues than acetic acid and peracetic acid do, and thus peroxyoctanoic acid solutions are particularly useful for disinfecting animal carcasses. A "peroxyacids" solution, referred to above as PAA solution #2, is manufactured by mixing acetic acid, hydrogen peroxide, octanoic acid, and HEDP, following prescribed relative proportions and order of addition at 13-27 °C. The mixture is allowed to equilibrate for about 7-13 days, whereby the acetic acid reacts in situ with hydrogen peroxide to form peroxyacetic acid, and the octanoic acid reacts in situ with the hydrogen peroxide to form peroxyoctanoic acid. These sanitizing mixtures are intended for washing of fruits, vegetables, meat, and poultry (Azanza 2004). The combination of peroxyoctanoic acid and peracetic acid has a synergistic effect and greatly enhanced antimicrobial activity when compared to peroxyoctanoic acid or peracetic acid alone, when used to control pathogens on plants (Hei et al. 2001; Oakes, Stanley, and Keller 1993).

Status

Historic Use:

Peracetic acid was first registered in the U.S. as a pesticide for use as a disinfectant, sanitizer and sterilant in 1985.

At its November 2000 meeting, the National Organic Standards Board (NOSB) reviewed the Technical Evaluation Reports for use of peracetic acid and recommended inclusion of this sanitizer at 7 CFR 205.601 (crop production), 205.603 (livestock production), and 205.605 (handling). On October 31, 2003, NOP published a final rule amending the National List to include peracetic acid at 7 CFR 205.601(a) for disinfecting equipment, seed and asexually propagated planting material, and at 7 CFR 205.601(i) for use to control fire blight bacteria (68 FR 61987).

On September 11, 2006, NOP published a final rule amending 7 CFR 205.605(b) to include peracetic acid with the current annotation: "Peracetic acid/Peroxyacetic acid (CAS No. 79-21-0) - for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces" (71 FR 53299).

On December 12, 2007, NOP published a final rule amending 7 CFR 205.603(a) to include "Peroxyacetic/peracetic acid (CAS # -79-21-0) – for sanitizing facility and processing equipment" (72 FR 70479).

A 2008 petition to the NOSB requested that 7 CFR 205.601 be modified to recognize that some hydrogen peroxide sanitizers used in organic crop production, which had always contained some peracetic acid, required relabeling to meet a new EPA requirement. This minor amount of peracetic acid was now considered an active ingredient by EPA and thus must be labeled as such. In its November 2009 deliberations, the NOSB recommended that the peracetic acid annotation for crop production be amended to add the following proviso: "Peracetic acid—Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) and (i) at concentration of no more than 6% as indicated on the pesticide product label." The final rule incorporating this change into 7 CFR 205.601(a)(6) and (i)(8) was published (78 FR 31815) on May 28, 2013.

Organic Foods Production Act, USDA Final Rule:

Peracetic acid is not specifically listed in the Organic Foods Production Act of 1990. It is listed in several parts of 7 CFR 205.601, 205.603, and 205.605(b) of the NOP regulations. Full regulatory text is included in *Regulatory Status and Approved Legal Uses of the Substance*.

International

Canada

The Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) permits the use of peracetic (peroxyacetic) acid at paragraph 7.3 as a food-grade cleaner, disinfectant and sanitizer permitted without a mandatory removal event, with the following annotation. "On food and plants: peracetic acid may be used in wash or rinse water. Peracetic acid may also be used on food contact surfaces." This allowance is consistent with the NOP regulations.

CODEX Alimentarius Commission

The Codex Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) do not mention any permitted sanitizers.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Peracetic acid is a permitted material for cleaning and disinfection of buildings and installations for animal production (EC No 889/2008 - Annex VII - Products for cleaning and disinfection referred to in Article 23). Peracetic acid and peroctanoic acid are permitted products for cleaning and disinfection of equipment and facilities in the presence as well as in the absence of aquaculture animals (EC No 889/2008 - Annex VII point 2.2). The EEC regulation makes no specific allowance for use of peracetic acid in organic food processing or for direct food contact. However, the European Union and the United States have an equivalency arrangement that became effective on June 1, 2012.

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard for organic production and processing makes no mention of peracetic acid. However, the United States and Japan have an equivalency that became effective January 1, 2014. The scope of the arrangement is limited to plants and plant-based products which have final processing, packaging, or labeling within the boundaries of those two countries. Alcoholic beverages, meat, dairy, and textiles are not included under this arrangement.[5]

IFOAM – Organics International (IFOAM)

[5] http://www.ams.usda.gov/nop/NOP/TradeIssues/JAS.html

The IFOAM norms permit use of peracetic acid for cleaning equipment and disinfecting equipment with no final rinse (IFOAM Appendix 4, Table 2), for pest and disease control, and for disinfection of livestock housing and equipment (IFOAM Appendix 5), but are silent with respect to direct food contact.[6]

Evaluation Questions for Substances to be used in Organic Handling

<u>Evaluation Question #1:</u> Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Peracetic acid solutions used for sanitation are equilibrium mixtures of peracetic acid, acetic acid and hydrogen peroxide. Solutions of peracetic acid are most commonly produced by reacting glacial acetic acid with a hydrogen peroxide solution, as shown in Figure 1.

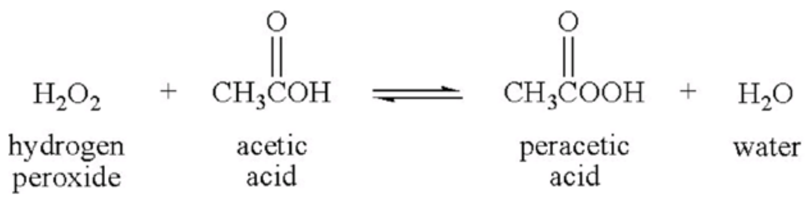

Figure 1. Production of peracetic acid (Buschmann and Del Negro 2012).

A mineral acid (e.g., sulfuric acid) may be added to catalyze the reaction, and increasing the temperature can accelerate the formation of PAA (National Center for Biotechnology Information 2015). If octanoic acid is included as a reactant, peroxyoctanoic acid also is created.

Peracetic acid solutions are usually made with synthetic acetic acid. The major routes for synthetic acetic acid production are methanol carbonylation, acetaldehyde oxidation, butane/naphtha oxidation, and methyl acetate carbonylation. Comparatively small amounts are generated by butane liquid-phase oxidation, direct ethanol oxidation, and synthesis gas. At present, methanol carbonylation using the Cativa (iridium catalyst) or Monsanto (rhodium catalyst) process is the main route. These processes produce glacial acetic acid, which is essentially pure acetic acid (Wagner 2014). Acetic acid is known as "vinegar acid." Vinegar is an aqueous solution containing about 4-12% acetic acid (Le Berre et al. 2014), a concentration too dilute to be practical in peracetic acid production.

Hydrogen peroxide (H_2O_2) is produced by autoxidation of an alkyl anthrahydroquinone. One way to achieve this is via the 2-ethyl derivative, in a cyclic continuous process in which the quinone formed in the oxidation step is reduced to the starting material by hydrogen in the presence of a supported palladium catalyst. Another method is the electrolytic processes in which aqueous sulfuric acid or acidic ammonium bisulfate is converted electrolytically to the peroxydisulfate, which is then hydrolyzed to form hydrogen peroxide. It may also be carried out by autoxidation of isopropyl alcohol (Lewis 1997) and by decomposition of barium peroxide with sulfuric acid or phosphoric acid.

PAA can reach concentrations of up to 40% in solution, with residual hydrogen peroxide from 5-25% and acetic acid from 10-40% (Malchesky 2001). However, concentrations of 5-15% peracetic acid are more typical in the food industry, and concentrations less than 6% are typical in crop pesticide solutions. Residual hydrogen peroxide and acetic acid levels can be reduced through distillation of the equilibrium solution. Stabilizers are generally added to chelate trace minerals and thereby retard PAA decomposition (Malchesky 2001).

[6] http://www.ifoam.org/standard/norms/cover.html

PAA solution #4, described in the *Regulatory* section, can be generated on site in either of two ways. When a peracetic acid precursor (45 wt % triacetin and 55 wt % of 50% hydrogen peroxide) is reacted with sodium hydroxide, triacetin is converted to peracetic acid at an 87% efficiency level and yields hydrogen peroxide, glycerin and residual triacetin (13%) as inert ingredients. No stabilizers are required, allowing the solution to be used immediately upon generation and at higher concentrations (Harvey and Howarth 2013). The same solution can be made alternatively by the electrolysis and oxygenation of a sodium sulfate solution which generates sodium hydroxide and hydrogen peroxide. These are then combined with a solution of sodium acetate and/or triacetin to form peracetic acid (Buschmann and Del Negro 2012).

Several other PAA manufacturing processes exist, but do not appear to be commercially available sources based on the literature. One method is to produce peracetic acid by the oxidation of acetaldehyde (Budavari 1996). In another method, hydrogen peroxide is mixed with a carboxylic acid in a reactor in the presence of a sulfonic acid resin to form an aqueous PAA solution (Lokkesmoe and Oakes 1992). Still another method involves the dissolution of an activator such as tetra-acetyl ethylenediamine (TAED) and a persalt such as sodium percarbonate in water (Davies and Deary 1991).

<u>Evaluation Question #2:</u> Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

All of the commercial processes for making peracetic acid are chemical processes, as described in Evaluation Question 2. One source of naturally occurring peracetic acid reported in the literature is that which forms in the atmosphere through a series of photochemical reactions involving formaldehyde. However, this is not a commercial source. Another report describes the production of peracetic acid by the enzyme haloperoxidase produced by *Pseudomonas pyrrocinia* (Jacks et al. 2002). However, this also is not a commercial source.

<u>Evaluation Question #3:</u> If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

No nonsynthetic or natural sources of peracetic acid are commercially available.

<u>Evaluation Question #4:</u> Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

Peracetic acid is an antimicrobial used to increase the safety of food and protect the public from foodborne infections. The uses of peracetic acid in crop and livestock production and food handling are tightly controlled by three major Federal agencies: FDA, EPA and FSIS, as discussed in *Regulatory Status and Approved Legal Uses of the Substance,* and a sampling of the regulations and notifications promulgated by these agencies is cited therein.

<u>Evaluation Question #5:</u> Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

When the Food Protection Committee of the National Academy of Sciences/National Research Council established the classification of GRAS Substances by Technical Effect in 1972, they defined "preservatives" as "including antimicrobial agents, fungistats, mold and rope inhibitors, etc." FDA adopted this definition at 21 CFR 170(3)(o). Peracetic acid is an effective sanitizer that oxidizes the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores, making it effective against all microorganisms, including bacterial spores. Thus, peracetic acid fulfills the definition of a "preservative."

<u>Evaluation Question #6:</u> Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

Peracetic acid preserves flavor, color, texture, and nutritive value ("wholesomeness") by preventing quality losses due to microbial deterioration and some enzymatic deterioration. It prevents the loss of flavor, color, texture, and nutritive value; it does not recreate or restore these qualities. For example, peracetic acid reduces orange fruit blemishing and maintains fruit quality better than other sanitizers (Parra 2007).

<u>Evaluation Question #7</u>: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

As described in Evaluation Question 6, the use of peracetic acid can prevent the loss of nutritive value. However, any aqueous rinsing of cut fruits and vegetables is likely to reduce the content of water-soluble vitamins such as vitamin C. For example, rinsing fresh-cut vegetables with water caused a loss of total vitamin C of about 20% for white cabbage and carrots (Vandekinderen et al. 2007) and 35% for iceberg lettuce (Vandekinderen et al. 2009). Peracetic acid sanitizer at accepted levels had no further effect on the vitamin C in cut lettuce (Vandekinderen et al. 2009).

The residual concentration of peracetic acid and hydrogen peroxide on intact tomatoes, broccoli and potatoes washed in a solution containing 80 ppm peracetic acid and 59 ppm hydrogen peroxide, with moderate agitation, with 5 minutes of contact time at 70-75ºF (21-24ºC), were not significantly different before and after treatment ($p>0.01$). The vitamin C content of potatoes and broccoli and the β-carotene content of tomatoes and broccoli were not significantly affected by this treatment. However, the ascorbic acid (oxidized form of vitamin C) content of tomatoes fell about 37%, with an equivalent increase in the content of dehydroascorbic acid (the reduced form of vitamin C) (Azanza 2004).

<u>Evaluation Question #8:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

HEDP and dipicolinic acid (DPA) are added to peracetic acid solutions to chelate metals, especially iron, copper and manganese, because decomposition of peracetic acid and, thus, loss of sanitizing power is accelerated by these impurities. Internationally accepted toxic heavy metal limits, reported as lead, are not more than 0.5 ppm for glacial acetic acid, 4 ppm for hydrogen peroxide, 5 ppm for HEDP, and 2 ppm for octanoic acid. The maximum limit for arsenic in HEDP is 5 ppm (Azanza 2004). The Food Chemical Codex (FCC) heavy metal maxima are 0.5 ppm for lead in glacial acetic acid, 4 ppm for lead in hydrogen peroxide, and 3 ppm for arsenic and 5 ppm for lead in concentrated sulfuric acid. There are no FCC heavy metal limits set for octanoic acid, HEDP, or DPA (U. S. Pharmacopeia 2010).

<u>Evaluation Question #9:</u> Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Peracetic acid is highly soluble in water (1000 g/L at 20ºC) and is also a highly reactive oxidizer (OECD 2008). Based on its vapor pressure, PAA could be expected to exist primarily in the gas phase in the atmosphere (California Air Resources Board 1997b). However, due to its solubility, it readily dissolves in clouds and is removed from the atmosphere through rain-out (U.S. National Library of Medicine 2011; California Air Resources Board 1997a). PAA occurs, therefore, almost exclusively (99.95%) as a liquid in the environment.

In air the half-life of peracetic acid is 22 minutes. The abiotic degradation of peracetic acid increases with temperature and higher pH. At a temperature of 25 °C and at pH of 4, 7 and 9, the degradation half-life values were 48 hours, 48 hours and less than 3.6 hours, respectively (OECD 2008).

Peracetic acid exerts its oxidizing effect on contact with reducing materials (Massachusetts Department of Environmental Protection October 2010), breaking down to water and acetic acid (Pfuntner 2011). Peracetic acid is also reported to have very low adsorption to soil (adsorption coefficient K_{oc} of 4) (Pesticide Action Network North America 2014b). Hydrogen peroxide, its co-active ingredient, also oxidizes on contact, breaking down into water and oxygen. Peracetic acid and hydrogen peroxide, therefore, degrade quickly and have low persistence in the environment and on food (Azanza 2004). The Technical Report for hydrogen peroxide may be referenced for further information on the persistence or concentration of hydrogen peroxide and its by-products in the environment.

Peracetic acid has been found in some instances to have beneficial effects related to environmental contamination. One study reports peracetic acid to be effective in degrading toxic compounds benzo(*a*)pyrene and α-methylnaphthalene in lake sediments through oxidation of the parent compound (N'Guessan, Levitt, and Nyman 2004).

Peracetic acid was readily biodegradable during a biodegradation test when its biocidal effect was prevented. Peracetic acid will be degraded in a sewage treatment plant if the influent concentration is not extremely high (e.g., more than 100 ppm). If effluents generated during the production or use of peracetic acid are treated by a waste water treatment plant, no emission of peracetic acid to the aquatic environment is expected (OECD 2008).

Acetic acid, the byproduct of peracetic acid, is also highly soluble, has low adsorption to soil (adsorption coefficient K_{oc} of 117), and biodegrades in water into carbon dioxide and water. Its aerobic soil-half life is reported as an average of 0.05 days (Pesticide Action Network North America 2014a; Azanza 2004). Thus, it also has very low persistence in the environment. The residual amounts of acetic acid on food sanitized with peracetic acid solutions are expected to be within levels considered acceptable for antimicrobials (Azanza 2004).

EPA-registered pesticide product labels for peracetic acid solutions state that they are toxic to birds, fish and aquatic invertebrates, and instruct users to use caution when applying indoors because pets may be at risk. These labels further instruct not to discharge effluent containing peracetic acid products into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of the National Pollution Discharge System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. None of the uses permitted under NOP regulations involve direct application of PAA to effluent, and residual PAA from agricultural and food sanitizing applications is expected to be negligible due to its breakdown during oxidation.

<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Concentrated solutions of peracetic acid are strongly irritating to the skin, eyes, mucous membranes, and respiratory system (Budavari 1996). Skin contact can result in severe irritation and burns, as can eye contact, leading to eye damage (New Jersey Department of Health and Senior Services 2004). When using fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is normally required (Budavari 1996). Ingestion can cause corrosion of the mucous membranes in the mouth, throat and esophagus (California Air Resources Board 1997). The probable human oral lethal dose may occur at a concentration of around 50-500 ppm (U.S. National Library of Medicine 2012), though EPA found no data on human lethality due to peracetic acid exposure in the literature (U.S. EPA 2010). Inhalation of PAA irritates the nose, throat and lungs, and causes coughing and/or shortness of breath. At high levels of inhalation exposure, one can experience pulmonary edema or a build-up of fluid in the lungs. High or repeated exposure may affect the liver or kidneys.

EPA considers concentrated solutions of peracetic acid to be in Toxicity Category I (highest toxicity category) for acute irritation to eyes and skin, and in Toxicity Category III for acute oral effects (U.S. EPA 1993). Hydrogen peroxide is considered to be much less toxic than peracetic acid (National Research Council 2010). Acetic acid is considered to be of low toxicity (PAN 2014a).

EPA has established Acute Exposure Guideline Levels (AEGLs) for peracetic acid, shown in Table 8 below. EPA reports that the effects of PAA exposure are more correlated with concentration than duration of exposure. And, because PAA is soluble in water, it is expected to be effectively scrubbed in the upper respiratory tract (U.S. EPA 2010).

Table 8. Acute Exposure Guideline Levels (AEGLs) for Peracetic Acid.

	10 min	30 min	60 min	4 hr	8 hr
AEGL 1[7]	0.52 mg/m3	0.52 mg/m3	0.52 mg/m3	0.52 mg/m3	0.52 mg/m3
AEGL 2[8]	1.6 mg/m3	1.6 mg/m3	1.6 mg/m3	1.6 mg/m3	1.6 mg/m3
AEGL 3[9]	60 mg/m3	30 mg/m3	15 mg/m3	6.3 mg/m3	4.1 mg/m3

The EPA Registration Eligibility Decision (RED) document for peracetic acid states that peroxy compounds pose essentially no risk to human health through dietary exposure, and the risks described above are minimized to applicators and mixers through the use of protective equipment, as required by product labeling. According to the report, EPA considers the risks posed to humans by the use of peroxyacetic acid to be negligible (U.S. EPA 1993).

An *in vitro* dermal penetration assay at 37ºC using 0.8% peracetic acid (8000 ppm) (non-corrosive) indicated a low dermal uptake of peracetic acid through the intact skin of pigs. When the skin of rats was exposed to a corrosive concentration of radiocarbon-labeled peracetic acid, a considerable uptake of radiocarbon was found but it is unknown if it was present as peracetic acid, acetic acid, or carbon dioxide. It is expected that corrosive concentrations of peracetic acid would compromise the normal barrier function of the skin (OECD 2008).

Two reliable in vitro studies, using different analytical methods, showed a rapid degradation of peracetic acid in rat blood. When rat blood was diluted 1000 times, the half-life of peracetic acid was less than five minutes. In undiluted blood the half-life is expected to be several seconds or less. For this reason the distribution of peracetic acid is probably very limited and it is not expected to be systemically available after exposure to peracetic acid (OECD 2008).

[7] AEGL-1 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation or certain asymptomatic, non-sensory effects that are transient or reversible. For peracetic acid this is reported to be irritation to the upper respiratory tract.

[8] AEGL-2 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape. For peracetic acid, it is associated with slight to tolerable discomfort to nasal membranes and eyes for exposure durations up to 20 minutes.

[9] The AEGL-3 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death. These values for peracetic acid are adjusted from the highest concentrations at which no mortality was observed in exposed rats.

<u>Evaluation Question #11:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Peracetic acid is used for chemical sanitation of food surfaces and food contact surfaces. The objective of chemical sanitation is elimination of microbiological threats to human health in the foods we eat. The microbial load on foods is determined by practices from farm to fork, including on-farm worker sanitary practices (hand-washing, etc.), animal and poultry husbandry practices (crowding, Salmonella-free laying hens, etc.), animal and poultry slaughtering practices, rapid cooling, harvested produce storage and pest control, and the time interval between harvest and consumption or between harvesting and processing.

Alternative methods that handlers can use to reduce the microbial load on the food raw materials they receive are limited. Applying heat or steam or fermenting the food can be effective in some situations, but these practices are likely to drastically change the properties of the food.

Several alternative materials are allowed in organic handling for sanitizing food surfaces and food contact surfaces: chlorine materials, including calcium hypochlorite, chlorine dioxide, and sodium hypochlorite; hydrogen peroxide (present in all PAA solutions); ozone; and acidified sodium chlorite. Phosphoric acid is allowed for cleaning food-contact surfaces and equipment. Organic acids such as acetic acid (used to make PAA) and lactic acid also can be effective antimicrobials.

Compared to hydrogen peroxide and chlorine materials, peracetic acid has reported advantages. Researchers in Florida working with the citrus industry generally believe that peracetic acid is better than chlorine and hydrogen peroxide for disinfecting fruit while simultaneously reducing fruit blemishes caused by treatment and maintaining fruit quality, compared to these other sanitizer products (Parra 2007).

According to the 2000 Technical Evaluation Report on the use of peracetic acid in organic processing and handling, "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). Peracetic acid degrades rapidly, leaves little residue, and decomposes into relatively harmless naturally-occurring substances. Ruiz-Cruz and colleagues found that the efficacy of peracetic acid was not affected by the organic compounds present in wash water, whereas the efficacy of chlorine was reduced (Ruiz-Cruz, Acedo-Felix, et al. 2007).

An evaluation of sanitizing agents that have been of interest in recent years identified chlorine dioxide, ozone, organic acids, peracetic acid and hydrogen peroxide as the main options (Ölmez and Kretzschmar 2009; Evans 2000). Ozone and hydrogen peroxide share the advantage of peracetic acid of being chlorine-free. However, a question has been raised as to whether the permitted level of peracetic acid in fresh-cut fruit wash water (80 ppm) is sufficient to achieve the desired level of disinfection (Ölmez and Kretzschmar 2009).

Ozone, a GRAS substance allowed in organic handling at 7 CFR 205.605(b), is effective against many bacteria, molds and yeast even at low concentrations (1–5 ppm) and for short exposure times (1–5 minutes) (Kim, Yousef, and Khadre 2003). Ozone has an antimicrobial activity higher than that of chlorine (Khadre, Yousef, and Kim 2001), and acts more quickly than permissible levels of chlorine, which makes it more suitable for washing procedures with short contact times. Efforts to decontaminate bean sprouts and remove biofilm with ozone have not been successful (Kim 2003). Ozone is a strong oxidative agent that may cause physiological injury to the produce above certain levels. Above 5 ppm, ozonated water damaged the surface texture of lettuce leaves (Kim et al. 2006). Iceberg lettuce treated with 10 ppm ozonated water developed rapid onset of browning (Koseki and Isobe 2006). Ozone increases the corrosion potential of stainless steel. Ozone in the air has adverse effects on the lungs (Al-Hegelan et al. 2011).

Hydrogen peroxide exists in every peracetic acid solution and is listed at 7 CFR 205.605(b). Although hydrogen peroxide is GRAS, its use is restricted to only a few products - milk for cheese making, dried egg, starch, tripe, herring, tea, wine, corn syrup (to reduce the sulfite level), etc., and for use as an antimicrobial or bleaching agent (21 CFR 184.1366). Any residual hydrogen peroxide must be removed by appropriate physical and chemical methods during the processing of foods (Ölmez and Kretzschmar 2009). One of the main disadvantages of using hydrogen peroxide is that it causes extensive browning on some products (lettuce, mushrooms) unless applied in combination with an antibrowning agent (McWatters et al. 2002; Sapers et al. 2001). Hydrogen peroxide, at approximately 10,000-fold higher concentration, was less effective than ozone against Bacillus spores (Khadre and Yousef 2001).

A newer form of chlorine in the form of hypochlorous acid is acidic electrolyzed water (Kim et al. 2003), which has been proven effective in sanitizing lettuce, cucumbers and strawberries (Koseki et al. 2004; Koseki, Isobe, and Itoh 2004; Koseki et al. 2001). Acidified sodium chlorite also has been proven useful in a comparative study on fresh-cut carrots (Gonzalez et al. 2004). The carrots retained higher levels of sugars, carotene, and antioxidant capacity (Ruiz-Cruz, Islas-Osuna, et al. 2007).

Peracetic acid has advantages compared to sodium hypochlorite, the most common sanitizer. One important advantage is that it does not produce toxic residues when decomposed and, therefore, does not affect either the final product or the waste treatment process. Peracetic acid also contains no chlorine.

<u>Evaluation Question #12:</u> Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Peracetic acid is permitted for two purposes at 7 CFR 205.605(b): for use in wash and/or rinse water according to FDA limitations, and for use as a sanitizer on food contact surfaces. Food contact surfaces are present wherever food is processed or prepared. Microbial contamination of food leads to microbial contamination of the surfaces, which can cause human disease. Pathogenic bacteria that are of the most concern to food processors are *Listeria monocytogenes*, *E. coli* and *Salmonella*.

No natural or nonsynthetic substances can replicate safely the antimicrobial effects of synthetic sanitizers such as peracetic acid. One minute exposure to chlorine bleach diluted one teaspoon to one quart of water (6% sodium hypochlorite) at 25ºC (77ºF) or undiluted hydrogen peroxide solution (3% H_2O_2) at 55ºF (131ºF) for one minute effectively kills *Listeria*, *E. coli*, and *Salmonella*. Similar results are produced by one minute of exposure to 5% acetic acid at 55ºF (131ºF). White vinegar, which contains 4% to 7% acetic acid, used at room temperature for ten minutes, was effective against Salmonella but would not effectively eliminate *E. coli* or *Listeria* (Yang et al. 2009; Buffer et al. 2010).

A 5% acetic acid solution could produce a 3-log reduction in the population of *E. coli* O157:H7 in iceberg lettuce, but may impair the sensory quality by causing an unacceptable sour flavor (Chang and Fang 2007). A 5% acetic acid solution produced a more than 6-log reduction in the population of *Shigella sonnei* on parsley, but the high level of acetic acid resulted in a noticeable discoloration and a strong vinegar odor (Wu et al. 2000).

Using vinegar, a 5% to 9% acetic acid solution, as rinse water creates an acidic waste stream with more than 5% of organic solids and a pH of 3, and thus a high chemical oxygen demand (COD) and a high biological oxygen demand (BOD) (Ölmez and Kretzschmar 2009).

<u>Evaluation Information #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

As noted above, vinegar, which is available as an organic product, is an effective food contact surface sanitizer when heated to 55ºF (131ºF) and applied to a food contact surface for one minute. A solution with this temperature is hazardous to workers. Organic vinegar would be undesirable in post-harvest handling for direct food contact even at room temperature, because it is likely to affect the taste and color of vegetables and meat and the wastewater treatment would create a major environmental burden.

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