

Peracetic Acid

Crops

Identification of Petitioned Substance

Chemical Names:

Peracetic acid; Ethaneperoxoic acid (IUPAC name); Acetic peroxide; Monoperacetic acid; Peroxoacetic acid; Acetyl hydroperoxide

CAS Numbers:

79-21-0
89370-71-8 (historic)

Other Names:

Peroxyacetic acid; PAA

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).

Trade Names:

BioSafe, BioSide™, Replete-O, Oxi Tech, Oxicure, Peroxy Punch, Tsunami

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 crop production. Peracetic acid is currently allowed for use in organic crop production at 7 CFR 205.601(a)(6) to disinfect equipment, seed, and asexually propagated planting material. It is also permitted in hydrogen peroxide formulations used as algicides, disinfectants and cleaners at a concentration of no more than 6% as indicated on the pesticide product label. Peracetic acid is also currently allowed in organic crop production at 7 CFR 205.601(i)(8) to control fire blight bacteria. It is permitted in hydrogen peroxide formulations used for plant disease control at a concentration of no more than 6% as indicated on the pesticide product label.

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

48 presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Specific grades are obtained by controlling
 49 the concentrations and amounts of hydrogen peroxide and acetic acid during the manufacturing process.
 50 Adding an acid or increasing the temperature during the manufacturing process can accelerate the
 51 establishment of the final equilibrium concentration (grade). Commercial grades are available in peracetic
 52 acid concentrations ranging from about 0.3 to 40 % by weight. Solutions with relatively low content of
 53 acetic acid and hydrogen peroxide can be produced by distillation of the equilibrium solutions. Based on
 54 the manufacturing process for sanitizing solutions of peracetic acid described above, it is evident that a
 55 pure peracetic acid solution is not produced or isolated when commercial peracetic acid solutions are
 56 manufactured.

57
 58 A peracetic acid solution also can be generated *in situ* by dissolving an activator (tetra-acetyl
 59 ethylenediamine) and a persalt (sodium perborate or sodium percarbonate) in water (OECD 2008), or on
 60 site (within 1 minute) by adding sodium hydroxide to triacetin and hydrogen peroxide (Harvey and
 61 Howarth 2013).

64 **Properties of the Substance:**

65 Pure anhydrous peracetic acid is a colorless liquid with a strong, pungent acid odor. It is an organic
 66 substance which is completely miscible with water (water solubility of 1000 g/L at 20 °C) and is also
 67 soluble in ether, sulfuric acid and ethanol. It is a strong oxidizing agent – stronger than chlorine or chlorine
 68 dioxide (Carrasco and Urrestarazu 2010). It is highly unstable and decomposes to its original constituents
 69 under various conditions of temperature, concentration and pH. Peracetic acid decomposes violently at
 70 230°F (110°C). Peracetic acid diluted with 60% acetic acid, when heated to decomposition, emits acid
 71 smoke and irritating fumes.

72
 73 Pure peracetic acid is not commercially available because it is explosive. For this reason it is not technically
 74 possible to determine the melting point, boiling point and vapor pressure of pure peracetic acid
 75 experimentally. Estimates based on modeling have been reported as -42 °C for melting point, about 105 °C
 76 for boiling point and 32 hPa at 25 °C for vapor pressure. The properties of commercial peracetic acid
 77 solutions vary based on concentrations (ratios) of their components (peracetic acid, hydrogen peroxide,
 78 acetic acid and water) for different grades. The physical and chemical properties of commercial equilibrium
 79 grades of 5% - 35% PAA are generally consistent in composition. Their properties are shown in Table 1.

80
 81 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 ₂ O ₂ :HOAc:H ₂ O	5 : 22 : 10 : 63	15 : 20 : 15 : 50	35 : 7 : 40 : 18
Freezing/Melting point	-26 to -30 °C	-30 to -50 °C	-44 °C
Boiling point	99 to 105 °C	> 100 °C	> 105 °C
Density (g/cm ³) at 20 °C	1.12	1.15	1.13
Vapor pressure at 20 °C	21 to 21 hPa	25 hPa	17 hPa
Flash point (closed cup)	74 to 83 °C	68 to 81 °C	42 to 62 °C
Self-accelerating decomposition	> 55 to > 65 °C	> 50 °C	> 55 °C

82
 83 Peracetic acid has a molecular weight of 76.05. Its dissociation constant (pKa) is 8.2 at 20 °C and, therefore,
 84 the substance is mainly present in the environment as peracetic acid at a neutral pH (pH = 7), while
 85 peracetate (the salt of peracetic acid) would mainly be present if the pH is significantly higher than 8.2
 86 (OECD 2008). The pH of peracetic acid solutions is reported to range from < 1 to 1.8 (OECD 2008; U.S.
 87 National Library of Medicine 2012; NOAA 2015).

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90 Specific Uses of the Substance:

91 Peracetic acid has a number of different approved uses in organic crop production. One use is to disinfect
92 equipment. In this capacity, it acts as a bactericide and fungicide on hard surfaces. Peracetic acid may be
93 applied by spraying, fogging or immersing to kill bacteria, fungi and viruses (U.S. EPA 1993). Peracetic
94 acid functions under cold conditions (-4 °C) and is thus effective at reducing microbial levels on equipment
95 normally held below ambient temperature (Pfundtner 2011).

96
97 The other approved use of peracetic acid in organic crop production is for the disinfection of seed and
98 asexually propagated planting material. Similar to use on equipment, in this capacity it functions as a
99 microbial control on seed and planting stock to prevent the spread of plant pathogens and disease.

100
101 Peracetic acid can also remove biofilms. Biofilms are polysaccharides produced by microorganisms such as
102 *E. coli*, *Salmonella spp.*, *Listeria spp.*, *Campylobacter spp.* and others. These biofilms facilitate attachment to
103 almost any surface. Their build-up can serve as a host to other bacteria and can be a source of ongoing re-
104 contamination (Pfundtner 2011).

105
106 Significant use of peracetic acid occurs in food processing, including organic food processing per 7 CFR
107 205.605(b). Its use as a surface disinfectant extends to application in livestock facilities and on livestock
108 equipment, in hospitals, and in veterinary hospitals. See the Peracetic Acid Technical Reports for Handling
109 and Livestock, respectively, for further information.

110
111 Peracetic acid has many other chemical uses in addition to use as a sanitizer/disinfectant/microbial
112 control. It serves as a reagent in the production of glycerol and caprolactam and for preparing epoxy
113 compounds. It is a catalyst or co-catalyst for the polymerization of polyester resins. It is also a bleaching
114 agent for textiles, paper, oil, wax and starch (California Air Resources Board 1997; National Center for
115 Biotechnology Information 2015; U.S. EPA 2010). More recently peracetic acid has been employed in
116 disinfecting municipal wastewater.

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119 Regulatory Status and Approved Legal Uses of the Substance:

120 Peracetic acid is currently permitted in the NOP regulations for organic crop production, organic livestock
121 production, and organic handling, with the annotations noted below. Sections 7 CFR 205.601(m) and 205.603(e)
122 are also cited below because peracetic acid solutions contain certain inert ingredients that are essential for
123 efficacy.

124

125 7 CFR 205.601 Synthetic substances allowed for use in organic crop production.

126 (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

127 (4) Hydrogen peroxide.

128 (6) Peracetic acid – for use in disinfecting equipment, seed, and asexually propagated planting
129 material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at
130 concentration of no more than 6% as indicated on the pesticide product label.

131 (i) As plant disease control.

132 (5) Hydrogen peroxide.

133 (8) Peracetic acid – for use to control fire blight bacteria. Also permitted in hydrogen peroxide
134 formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the
135 pesticide product label.

136 (m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) for
137 use with nonsynthetic substances or synthetic substances listed in this section and used as
138 an active pesticide ingredient in accordance with any limitations on the use of such
139 substances.

140 (1) EPA List 4 – Inerts of Minimal Concern

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142 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production.

143 (a) As disinfectants, sanitizer, and medical treatments as applicable.

144 (19) Peroxyacetic/peracetic acid (CAS #-79-21-0) – for sanitizing facility and processing
145 equipment.

146 (e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) for
147 use with nonsynthetic substances or synthetic substances listed in this section and used as an
148 active pesticide ingredient in accordance with any limitations on the use of such substances.

149 (1) EPA List 4 – Inerts of Minimal Concern

150
151 **7 CFR 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed**
152 **products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”**

153 (b) Synthetics allowed: Peracetic acid/Peroxyacetic acid (CAS # 79-21-0) – for use in wash and/or rinse
154 water according to FDA limitations. For use as a sanitizer on food contact surfaces.

155
156 Peracetic acid has a complex regulatory status because several federal agencies have their own specific areas of
157 statutory jurisdiction. Each agency creates its own set of regulations for sanitizer which can impact the
158 permissible uses of peracetic acid in organic crop production, organic livestock production, and organic
159 handling, including post-harvest handling.

160
161 The Organic Foods Production Act (OFPA) of 1990 at 7 USC 6519(c)(6) specifies that nothing in the OFPA
162 shall alter the authority of the secretary of agriculture under the Federal Meat Inspection Act or under the
163 Poultry Products Inspection Act, the authority of the Secretary of Health and Human Services under the
164 Federal Food, Drug and Cosmetic Act, or the authority of the Administrator of the Environmental
165 Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act. Consequently, four
166 federal agencies regulate peracetic acid used in handling organic foods after harvesting or slaughter
167 (Theuer and Walden 2011).

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

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

186
187 FDA is responsible for exercising the authority of the secretary of health and human services under the
188 Federal Food, Drug and Cosmetic Act. FDA regulates peracetic acid by enumerating the permissible
189 ingredients in PAA solutions. FDA regulations relating to the use of PAA for the two handling uses
190 allowed in 7 CFR 205.605(b) are codified in 21 CFR 173 and 178. Part 173 is titled “Secondary direct food
191 additives permitted in food for human consumption” and includes two sections that specifically mention
192 peroxyacetic acid: section 173.315 (“chemicals used in washing or to assist in the peeling of fruits and
193 vegetables”) and section 173.370 (“peroxyacids”). Part 178 is titled “Indirect food additives: adjuvants,
194 production aids, and sanitizers,” and includes one section specifically mentioning peroxyacetic acid:
195 section 178.1010 (sanitizing solutions). Section 178.1010 contains three paragraphs describing compositions
196 of peroxyacetic acid solutions.
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198 Five specific aqueous mixtures are described in 21 CFR 173 and 178, but there is redundancy in these
199 mixtures, so there are only three generic PAA solutions of concern (Theuer and Walden 2011). These are
200 described in detail below. In addition, FDA reviews petitions for new sanitizer compositions or new uses
201 for existing compositions and issues “Food Contact Substance Notifications” (FCNs) for food contact
202 substances that have been demonstrated to be safe for their intended uses. A database of these notifications
203 is maintained online¹. Entries in the FDA online database include the food contact substance, the
204 manufacturer of the substance, the intended use, the limitations on the conditions of use and its
205 specifications, and the effective date. Thirty FCNs relating to peracetic/peroxyacetic acid have been issued
206 in the past six years².

207
208 EPA administers the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Every pesticide product
209 distributed in the United States must be registered with EPA. EPA approves the label and thus the
210 permissible uses of every pesticide product. Peracetic acid is an antimicrobial substance and thus is a
211 “pesticide” as defined by FIFRA.

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213 EPA regulations for food disinfection and food contact surface sanitation relating to the use of peracetic
214 acid for the uses allowed in 7 CFR 205.605(b) are codified in 40 CFR 180. In accordance with the regulatory
215 practice of EPA, these regulations enumerate the permissible tolerance limits of active ingredients and inert
216 ingredients in PAA solutions. Section 40 CFR 180.910 provides the list of inert (or occasionally active)
217 ingredients used pre- and post-harvest in direct food contact, and the exemptions from the requirement of
218 a tolerance of these ingredients on the food. Section 40 CFR 180.940 lists similar information for active and
219 inert ingredients in antimicrobial formulations used to sanitize food contact surfaces. Section 40 CFR
220 180.950 lists common safe ingredients, such as glycerin (glycerol), that are exempt from a tolerance in any
221 use. Sections 40 CFR 180.1196 and 180.1197 establish the conditions for an exemption from the requirement
222 for a tolerance for peroxyacetic acid (peracetic acid) and hydrogen peroxide, respectively. For example, if
223 the diluted solution applied to fruit contains less than 100 ppm of peracetic acid, the residue of peracetic
224 acid on the fruit is exempt from a tolerance.

225
226 FSIS administers the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).
227 Under the FMIA and the PPIA, FSIS is responsible for determining the suitability of FDA-approved
228 substances in meat and poultry products. Pursuant to the memorandum of understanding signed in
229 January 2000, FDA and FSIS work together to evaluate petitions requesting the approval of new substances
230 or new uses of previously approved substances for use in or on meat and poultry products. FSIS inspectors
231 enforce FSIS policy by implementing “FSIS Directives.” FSIS Directive 7120.1 permits two peracetic acid
232 solutions for direct food contact with red meat and poultry. These two solutions are among the same
233 solutions allowed by FDA; however the allowance varies depending on use (USDA Food Safety and
234 Inspection Service 2015).

235
236 **Peracetic Acid Solutions Allowed by FDA and/or EPA and/or FSIS** (For the purpose of this report, each
237 PAA Solution is given a number which refers to one of the solutions listed below. More details on these
238 solutions are described in *Combinations of the Substance*.)

239
240 PAA Solution #1 – An aqueous solution of peracetic acid prepared by reacting the substances acetic
241 acid and hydrogen peroxide. The solution is stabilized with 1-hydroxyethylidene-1,1-diphosphonic
242 acid (HEDP).

243
244 PAA Solution #1A – An aqueous solution of peracetic acid prepared by reacting the substances acetic
245 acid, sulfuric acid and hydrogen peroxide. The solution is stabilized with HEDP.

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247 PAA Solution #2 – An aqueous solution of peracetic acid and peroxyoctanoic acid prepared by reacting
248 the substances acetic acid, octanoic acid and hydrogen peroxide. The solution is stabilized with HEDP.

¹ www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm

² As of 1 November 2015.

249 The food contact surface sanitizer version additionally contains the surface-active agent sodium 1-
 250 octanesulfonate.

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

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

261
 262 The following tables describe which solutions are permitted for which uses by the responsible agencies.

263 **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

³Pdf 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.

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

<u>PAA Solution</u>	<u>Agency</u>	<u>Status</u>	<u>References and Comments</u>
#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
#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

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

<u>PAA Solution</u>	<u>Agency</u>	<u>Status</u>	<u>References and Comments</u>
#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

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

<u>PAA Solution</u>	<u>Agency</u>	<u>Status</u>	<u>References and Comments</u>
#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

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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 (Pfundtner 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.

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The action of peracetic acid when employed in plant disease control is the same as that when used as a sanitizer: destruction of the microbial or fungal pathogen via cellular oxidation.

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

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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

310
311
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324

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

325 antimicrobial formulations (food contact surface sanitizing solutions). It is not permitted for direct food
326 contact at 21 CFR 173.370.

327
328 Glacial acetic acid is essentially pure acetic acid, with a specification of 99.5% to 100.5% by weight of acetic
329 acid (Wagner 2014). It has no direct antibacterial effects and thus is defined by EPA as an “inert
330 ingredient.”

331
332 Triacetin (CAS No. 102-76-1), referred to as “glycerol triacetate” by EPA at 40 CFR 180.910, is a synthetic
333 triglyceride (“fat”) created by reacting glycerin (glycerol) with acetic acid. Triacetin is soluble in 14 parts of
334 water and has been used as an antifungal agent (Budavari 1996).

335
336 Sulfuric acid (CAS No. 7664-93-9), a mineral acid used to reduce pH, is frequently included in peracetic
337 acid formulations to catalyze the formation of peracetic acid from acetic acid and hydrogen peroxide.
338 Sulfuric acid is classified by EPA as a List 4 inert. It is added during the manufacturing process to
339 accelerate the establishment of the final equilibrium concentration. Sulfuric acid is a GRAS food ingredient
340 listed at 21 CFR 184.1095.

341
342 Peracetic acid preparations usually contain a synthetic stabilizer such as HEDP (1-hydroxyethylidene-1,1-
343 diphosphonic acid) or dipicolinic acid (2,6-dicarboxy-pyridine) to slow the rate of oxidation or
344 decomposition of peracetic acid (Kurschner and Diken 1997). These stabilizers are chelating agents that
345 bind with metal ions and reduce their activity in solution. Synthetic stabilizers can be avoided if the
346 peracetic acid solution is produced on site as described for PAA solution #4 in Evaluation Question 2.
347 HEDP (CAS No. 2809-21-4) historically was classified by EPA as a List 4 inert. It is also exempt from the
348 requirement of a tolerance when used as a stabilizer/chelator in antimicrobial pesticide formulations at not
349 more than 1 percent (40 CFR 180.910).

350
351 Dipicolinic acid (DPA) (CAS No. 499-83-2) was classified by EPA as a List 3 inert in the past.

352
353 Octanoic acid (CAS No. 124-07-2), also known as caprylic acid, is an eight-carbon GRAS carboxylic acid (21
354 CFR 184.1025). It is a medium-chain fatty acid that occurs normally in various food fats, especially coconut
355 oil, babassu oil and palm kernel oil. It is commercially prepared by oxidation of n-octanol or by
356 fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

357
358 Octanoic acid historically was on EPA List 4 as an inert ingredient but it may also be an active ingredient in
359 certain formulations. In 2009, EPA published its determination (74 FR 30080) that “Caprylic (octanoic) acid
360 is an antimicrobial pesticide that is used as a food contact surface sanitizer in commercial food handling
361 establishments. It is also used as a disinfectant in health care facilities and as an algacide in greenhouses
362 and interiorscapes on ornamentals. In addition, caprylic (octanoic) acid is characterized by low toxicity, is
363 biodegradable, and is found extensively in nature.”

364
365 In the presence of hydrogen peroxide, octanoic acid is reversibly converted to peroxyoctanoic acid (POOA),
366 CAS No. 33734-57-5. Octanoic acid and peroxyoctanoic acid have greater affinity for fatty tissues than
367 acetic acid and peracetic acid do, and thus peroxyoctanoic acid solutions are particularly useful for
368 disinfecting animal carcasses. A “peroxyacids” solution, referred to above as PAA solution #2, is
369 manufactured by mixing acetic acid, hydrogen peroxide, octanoic acid, and HEDP, following prescribed
370 relative proportions and order of addition at 13-27 °C. The mixture is allowed to equilibrate for about 7-13
371 days, whereby the acetic acid reacts in situ with hydrogen peroxide to form peroxyacetic acid, and the
372 octanoic acid reacts in situ with the hydrogen peroxide to form peroxyoctanoic acid. These sanitizing
373 mixtures are intended for washing of fruits, vegetables, meat, and poultry (Azanza 2004). The combination
374 of peroxyoctanoic acid and peracetic acid has a synergistic effect and greatly enhanced antimicrobial
375 activity when compared to peroxyoctanoic acid or peracetic acid alone, when used to control pathogens on
376 plants (Hei et al. 2001; Oakes, Stanley, and Keller 1993).

377
378

379	Status
380	
381	<u>Historic Use:</u>
382	Peracetic acid was first registered in the U.S. as a pesticide for use as a disinfectant, sanitizer and sterilant
383	in 1985.
384	
385	At its November 2000 meeting, the National Organic Standards Board (NOSB) reviewed the Technical
386	Evaluation Reports for use of peracetic acid and recommended inclusion of this sanitizer at 7 CFR 205.601
387	(crop production), 205.603 (livestock production), and 205.605 (handling). On October 31, 2003, NOP
388	published a final rule amending the National List to include peracetic acid at 7 CFR 205.601(a) for
389	disinfecting equipment, seed and asexually propagated planting material, and at 7 CFR 205.601(i) for use to
390	control fire blight bacteria (68 FR 61987).
391	
392	On September 11, 2006, NOP published a final rule amending 7 CFR 205.605(b) to include peracetic acid
393	with the current annotation: "Peracetic acid/Peroxyacetic acid (CAS No. 79-21-0) - for use in wash and/or
394	rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces" (71 FR 53299).
395	
396	On December 12, 2007, NOP published a final rule amending 7 CFR 205.603(a) to include
397	"Peroxyacetic/peracetic acid (CAS # -79-21-0) - for sanitizing facility and processing equipment" (72 FR
398	70479).
399	
400	A 2008 petition to the NOSB requested that 7 CFR 205.601 be modified to recognize that some hydrogen
401	peroxide sanitizers used in organic crop production, which had always contained some peracetic acid,
402	required relabeling to meet a new EPA requirement. This minor amount of peracetic acid was now
403	considered an active ingredient by EPA and thus must be labeled as such. In its November 2009
404	deliberations, the NOSB recommended that the peracetic acid annotation for crop production be amended
405	to add the following proviso: "Peracetic acid – Also permitted in hydrogen peroxide formulations as
406	allowed in §205.601(a) and (i) at concentration of no more than 6% as indicated on the pesticide product
407	label." The final rule incorporating this change into 7 CFR 205.601(a)(6) and (i)(8) was published (78 FR
408	31815) on May 28, 2013.
409	
410	
411	<u>Organic Foods Production Act, USDA Final Rule:</u>
412	Peracetic acid is not specifically listed in the Organic Foods Production Act of 1990. It is listed in several
413	parts of 7 CFR 205.601, 205.603, and 205.605(b) of the NOP regulations. Full regulatory text is included in
414	<i>Regulatory Status and Approved Legal Uses of the Substance.</i>
415	
416	
417	<u>International</u>
418	Canada
419	The Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) permits the
420	use of peracetic (peroxyacetic) acid at paragraph 4.3 (Crop Production Aids and Materials) with the
421	following annotation. "Permitted for: a) controlling fire blight bacteria; and b) disinfecting seed and
422	asexually propagated planting material." This allowance is consistent with the NOP regulations.
423	
424	CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing
425	of Organically Produced Foods (GL 32-1999)
426	The Codex Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing
427	of Organically Produced Foods (GL 32-1999) do not mention any permitted sanitizers. Peracetic acid also
428	does not appear on Annex 2 (Permitted Substances for the Production of Organic Foods) Table 2
429	(Substances for Plant Pest and Disease Control) in the guidelines.
430	
431	European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
432	Peracetic acid is not listed in Annex II – Pesticides – plant protection products referred to in Article 5(1).
433	Nonetheless, as of June 1, 2012, the European Union and the United States have an equivalence agreement

434 whereby organic products certified to the USDA or European Union (EU) organic standards may be sold
 435 and labeled as organic in both the U.S. and the EU.

436

437 **Japan Agricultural Standard (JAS) for Organic Production**

438 The Japanese Agricultural Standard, both for Organic Plants and for Organic Processed Foods, makes no
 439 mention of peracetic acid. However, the United States entered into an equivalency arrangement with Japan
 440 effective January 1, 2014. The scope of the arrangement is limited to plants and plant-based products which
 441 have final processing, packaging, or labeling within the boundaries of those two countries.

442

443 **IFOAM - Organics International (IFOAM)**

444 The IFOAM norms permit use of peracetic acid for cleaning equipment and disinfecting equipment with no
 445 final rinse (IFOAM Appendix 4, Table 2), for pest and disease control, and for disinfection of livestock
 446 housing and equipment (IFOAM Appendix 5).

447

448

449 Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

450

451 **Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the**
 452 **substance contain an active ingredient in any of the following categories: copper and sulfur**
 453 **compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated**
 454 **seed, vitamins and minerals; livestock parasiticides and medicines and production aids including**
 455 **netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is**
 456 **the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological**
 457 **concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert**
 458 **ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part**
 459 **180?**

460

461 (A) Peracetic acid is a production aid (7 USC 6517(c)(1)(B)(i)).

462 (B) Peracetic acid is not an inert ingredient.

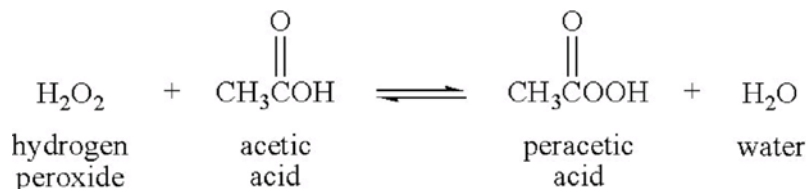
463

464

465 **Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the**
 466 **petitioned substance. Further, describe any chemical change that may occur during manufacture or**
 467 **formulation of the petitioned substance when this substance is extracted from naturally occurring plant,**
 468 **animal, or mineral sources (7 U.S.C. § 6502 (21)).**

469

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



473

474

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

476

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

480

481 Peracetic acid solutions are usually made with synthetic acetic acid. The major routes for synthetic acetic
 482 acid production are methanol carbonylation, acetaldehyde oxidation, butane/naphtha oxidation, and
 483 methyl acetate carbonylation. Comparatively small amounts are generated by butane liquid-phase

484 oxidation, direct ethanol oxidation, and synthesis gas. At present, methanol carbonylation using the Cativa
485 (iridium catalyst) or Monsanto (rhodium catalyst) process is the main route. These processes produce
486 glacial acetic acid, which is essentially pure acetic acid (Wagner 2014). Acetic acid is known as "vinegar
487 acid." Vinegar is an aqueous solution containing about 4-12% acetic acid (Le Berre et al. 2014), a
488 concentration too dilute to be practical in peracetic acid production.

489
490 Hydrogen peroxide (H₂O₂) is produced by autoxidation of an alkyl anthrahydroquinone. One way to
491 achieve this is via the 2-ethyl derivative, in a cyclic continuous process in which the quinone formed in the
492 oxidation step is reduced to the starting material by hydrogen in the presence of a supported palladium
493 catalyst. Another method is the electrolytic processes in which aqueous sulfuric acid or acidic ammonium
494 bisulfate is converted electrolytically to the peroxydisulfate, which is then hydrolyzed to form hydrogen
495 peroxide. It may also be carried out by autoxidation of isopropyl alcohol (Lewis 1997) and by
496 decomposition of barium peroxide with sulfuric acid or phosphoric acid.

497
498 PAA can reach concentrations of up to 40% in solution, with residual hydrogen peroxide from 5-25% and
499 acetic acid from 10-40% (Malchesky 2001). However, concentrations of 5-15% peracetic acid are more
500 typical in the food industry, and concentrations less than 6% are typical in crop pesticide solutions.
501 Residual hydrogen peroxide and acetic acid levels can be reduced through distillation of the equilibrium
502 solution. Stabilizers are generally added to chelate trace minerals and thereby retard PAA decomposition
503 (Malchesky 2001).

504
505 PAA solution #4, described in the *Regulatory* section, can be generated on site in either of two ways. When
506 a peracetic acid precursor (45 wt % triacetin and 55 wt % of 50% hydrogen peroxide) is reacted with
507 sodium hydroxide, triacetin is converted to peracetic acid at an 87% efficiency level and yields hydrogen
508 peroxide, glycerin and residual triacetin (13%) as inert ingredients. No stabilizers are required, allowing the
509 solution to be used immediately upon generation and at higher concentrations (Harvey and Howarth
510 2013). The same solution can be made alternatively by the electrolysis and oxygenation of a sodium sulfate
511 solution which generates sodium hydroxide and hydrogen peroxide. These are then combined with a
512 solution of sodium acetate and/or triacetin to form peracetic acid (Buschmann and Del Negro 2012).

513
514 Several other PAA manufacturing processes exist, but do not appear to be commercially available sources
515 based on the literature. One method is to produce peracetic acid by the oxidation of acetaldehyde
516 (Budavari 1996). In another method, hydrogen peroxide is mixed with a carboxylic acid in a reactor in the
517 presence of a sulfonic acid resin to form an aqueous PAA solution (Lokkesmoe and Oakes 1992). Still
518 another method involves the dissolution of an activator such as tetra-acetyl ethylenediamine (TAED) and a
519 persalt such as sodium percarbonate in water (Davies and Deary 1991).

520
521
522 **Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a**
523 **chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).**
524

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

531
532
533 **Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its**
534 **by-products in the environment (7 U.S.C. § 6518 (m) (2)).**
535

536 Peracetic acid is highly soluble in water (1000 g/L at 20°C) and is also a highly reactive oxidizer (OECD
537 2008). Based on its vapor pressure, PAA could be expected to exist primarily in the gas phase in the
538 atmosphere (California Air Resources Board 1997). However, due to its solubility, it readily dissolves in

539 clouds and is removed from the atmosphere through rain-out (U.S. National Library of Medicine 2012;
540 California Air Resources Board 1997). PAA occurs, therefore, almost exclusively (99.95%) as a liquid in the
541 environment.

542
543 In air the half-life of peracetic acid is 22 minutes. The abiotic degradation of peracetic acid increases with
544 temperature and higher pH. At a temperature of 25 °C and at pH of 4, 7 and 9, the degradation half-life
545 values were 48 hours, 48 hours and less than 3.6 hours, respectively (OECD 2008).

546
547 Peracetic acid exerts its oxidizing effect on contact with reducing materials (Massachusetts Department of
548 Environmental Protection 2010), breaking down to water and acetic acid (Pfundtner 2011). Peracetic acid is
549 also reported to have very low adsorption to soil (adsorption coefficient K_{oc} of 4) (PAN 2014b). Hydrogen
550 peroxide, its co-active ingredient, also oxidizes on contact, breaking down into oxygen and water. Peracetic
551 acid and hydrogen peroxide, therefore, degrade quickly and have low persistence in the environment and
552 on food (JECFA 2004). The Technical Report for hydrogen peroxide may be referenced for further
553 information on the persistence or concentration of hydrogen peroxide and its by-products in the
554 environment.

555
556 Acetic acid, the by-product of PAA, is also highly soluble, has low adsorption to soil (adsorption coefficient
557 K_{oc} of 117), and degrades in water into carbon dioxide and water. Its aerobic soil-half life is reported as an
558 average of 0.05 days (PAN 2014a). Thus, it also has very low persistence in the environment. The residual
559 amounts of acetic acid on food sanitized with peracetic acid solutions are expected to be within levels
560 considered acceptable for antimicrobials (JECFA 2004).

561
562 Residual HEDP from peracetic acid solutions is generally estimated to remain on the surface of treated
563 food at low levels (in the ppb range) (JECFA 2004).

564
565

566 **Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its**
567 **breakdown products and any contaminants. Describe the persistence and areas of concentration in the**
568 **environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).**

569
570 Peracetic acid and hydrogen peroxide are both strong oxidizers, meaning that they remove electrons from
571 other chemical groups and are reduced in the process. This reaction can occur at the cell surface or with
572 intercellular matter. High levels of oxidation can damage cells by disrupting membrane layers, inhibiting
573 enzymes, impairing energy production, disrupting protein synthesis, and affecting oxygen scavengers,
574 thiol groups and nucleosides. Oxidation can ultimately cause cell death. It has been suggested that
575 oxidation by PAA increases cell wall permeability by disrupting sulfhydryl and sulfur bonds. One study
576 specifically found PAA to be a powerful oxidant of amino acids, to fragment proteins, and to affect enzyme
577 activity (Finnegan, et al. 2010).

578
579 EPA registered pesticide product labels for peracetic acid solutions state that they are toxic to birds, fish
580 and aquatic invertebrates, and instruct users to use caution when applying indoors because pets may be at
581 risk. These labels further instruct to not discharge effluent containing peracetic acid products into lakes,
582 streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of the
583 National Pollution Discharge System (NPDES) permit and the permitting authority has been notified in
584 writing prior to discharge.

585
586 Peracetic acid was readily biodegradable during a biodegradation test where its biocidal effect was
587 prevented (OECD 2008). It was reported that peracetic acid will be degraded in a sewage treatment plant if
588 the influent concentration is not extremely high (e.g., more than 100 ppm). If effluents generated during the
589 production or use of peracetic acid are treated by a waste water treatment plant, no emission of peracetic
590 acid to the aquatic environment is expected (OECD 2008). A different study found that urban wastewater
591 treated with peracetic acid (not going through a water treatment plant) would show acute toxic effects on
592 aquatic organisms (Crebelli et al. 2003). However, none of the uses permitted under NOP regulations

593 involve direct application of PAA to effluent, and residual PAA from agricultural and food sanitizing
594 applications is expected to be negligible due to its breakdown during oxidation.
595

596

597 **Evaluation Question #6: Describe any environmental contamination that could result from the**
598 **petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).**
599

600 Peracetic acid is considered to be an environmentally friendly substance, with very little potential to cause
601 contamination due to its rapid breakdown into benign substances already present in the environment.
602 It has, however, been reported that peracetic acid in the atmosphere can react with photochemically
603 produced hydroxyl radicals (reaction half-life of approximately 9 days) (U.S. National Library of Medicine
604 2012), with a suggested role in contributing to acid rain (Gaffney et al. 1987).
605

606 Both peracetic acid and hydrogen peroxide have been cited as potential contributors to acid rain. However,
607 while peracetic acid and hydrogen peroxide can be involved in chemical reactions in the atmosphere that
608 ultimately lead to acid rain, the literature does not cite them as being a significant contributor to or source
609 of acid rain (Calvert and Stockwell 1983).
610

611 Peracetic acid has been found in some instances to have beneficial effects related to environmental
612 contamination. One study reports peracetic acid to be effective in degrading toxic compounds
613 benzo(a)pyrene and α -methyl-naphthalene in lake sediments through oxidation of the parent compound
614 (N'Guessan, Levitt and Nyman 2004).
615

616

617 **Evaluation Question #7: Describe any known chemical interactions between the petitioned substance**
618 **and other substances used in organic crop or livestock production or handling. Describe any**
619 **environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).**
620

621 Peracetic acid can react violently with acetic acid anhydride, metal chloride solutions (e.g., calcium chloride
622 and potassium chloride), olefins (e.g., mineral oil) and organic matter (U.S. EPA 2010, National Center for
623 Biotechnology Information 2015), thus presenting potential health hazards if proper safety measures are
624 not employed. Manufacturers also recommend avoiding contact with strong bases, heavy metals, soft
625 metals (e.g., copper, brass, bronze, zinc and aluminum), leather, paper, wood and oxidizable organics
626 (EnviroTech 2014), as these will react with and accelerate the degradation of the peracetic acid. In practice,
627 PAA has been used as an oxidizing agent to decompose humic materials in soils in order to study their
628 composition (Schnitzer and Skinner 1974; Schnitzer and Hindle 1980). These reactions resulting in the
629 degradation of PAA are not expected to have a significant effect on the environment.
630

631 As discussed earlier, peracetic acid is used almost exclusively in combination with hydrogen peroxide,
632 acetic acid and stabilizers. The combination of peracetic acid and hydrogen peroxide has been reported to
633 have synergistic effects as a bactericide, with that synergy being maintained over contact time (Alasri, et al.
634 1992). EPA registered pesticide product labels for peracetic acid/hydrogen peroxide disease controls
635 instruct users to not mix or combine with other pesticide concentrations.
636

637

638 **Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical**
639 **interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt**
640 **index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).**
641

642 Peracetic acid has been studied as an oxidizing agent of organic materials in soil. Schnitzer and Hindle
643 (1980) looked at changes to the nitrogen profile of humic acid samples as a result of mild oxidation by
644 peracetic acid and found decreases in amino acid-N and carbon, and increases in ammonia-N, nitrite-N
645 and nitrate-N. As a bactericide, it can also impact soil microorganisms. However, nothing in the literature
646 reviewed for this report suggests that the impact on soil microbiota is a concern when using PAA as a

647 sanitizer, cleaner or in disease control applications. The reasons are likely due to the fact that the inhibitory
648 effects of PAA on microorganisms are intended and/or ephemeral.

649
650 Peracetic acid is reported to have some phytotoxic properties. Little is known about the toxicity of peracetic
651 acid to plants at levels expected in the environment (nanomolar to low micromolar concentrations in acidic
652 precipitation) (Gaffney et al. 1987). However, direct application in combination with hydrogen peroxide as
653 a disease control measure may cause some visible damage to treated plants. The label for one peracetic acid
654 product, BioSafe Disease Control, states that “treatments may result in lesions on plant tissue. BioSafe
655 Disease Control will oxidize parasitic organisms living in plant tissue that are not always visible to the
656 naked eye. Resulting oxidative effects may include spotting, or drying of the plant tissue where organisms
657 inhabited tissue.”

658
659 Hydrogen peroxide can also cause cellular damage to plants and, although its adverse effects in the
660 atmosphere have not been documented, scientists have noted the need to further study its impact on biota
661 (Gaffney et al. 1987). Atmospheric H₂O₂ (from both anthropogenic and non-anthropogenic sources) is
662 mostly removed from the atmosphere via dry deposition (Sakugawa, Kaplan and Shepard 1993).
663 According to one study, gas phase peracetic acid is less likely to be taken up by plants via dry deposition
664 than hydrogen peroxide (Wesely 1967).

665
666
667 **Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned**
668 **substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A)**
669 **(i)).**

670
671 While peracetic acid is a hazardous substance with acute toxicity due to its strong oxidizing action, its uses
672 as a sanitizer and in crop disease control are not likely to have significant adverse impacts on the
673 environment. As a reactive chemical, it does have immediate impacts, but those impacts are short lived and
674 not necessarily detrimental. There was no information in the literature reviewed for this report to suggest
675 cumulative or persistent harm to the environment resulting from the permitted use of peracetic acid in
676 organic agriculture and food processing.

677
678
679 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**
680 **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**
681 **(m) (4)).**

682
683 Concentrated solutions of peracetic acid are strongly irritating to the skin, eyes, mucous membranes, and
684 respiratory system (Budavari 1996). Skin contact can result in severe irritation and burns, as can eye
685 contact, leading to eye damage (New Jersey Department of Health and Senior Services 2004). When using
686 fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is
687 normally required (Budavari 1996). Ingestion can cause corrosion of the mucous membranes in the mouth,
688 throat and esophagus (California Air Resources Board 1997). The probable human oral lethal dose may
689 occur at a concentration of around 50-500 ppm (U.S. National Library of Medicine 2012), though EPA
690 found no data on human lethality due to peracetic acid exposure in the literature (U.S. EPA 2010).
691 Inhalation of PAA irritates the nose, throat and lungs, and causes coughing and/or shortness of breath. At
692 high levels of inhalation exposure, one can experience pulmonary edema or a build-up of fluid in the
693 lungs. High or repeated exposure may affect the liver or kidneys.

694
695 EPA considers concentrated solutions of peracetic acid to be in Toxicity Category I (highest toxicity
696 category) for acute irritation to eyes and skin, and in Toxicity Category III for acute oral effects (U.S. EPA
697 1993). Hydrogen peroxide is considered to be much less toxic than peracetic acid (National Research
698 Council 2010). Acetic acid is considered to be of low toxicity (PAN 2014a).

699
700 EPA has established Acute Exposure Guideline Levels (AEGs) for peracetic acid, shown in Table 8 below.
701 EPA reports that the effects of PAA exposure are more correlated with concentration than duration of

702 exposure. And, because PAA is soluble in water, it is expected to be effectively scrubbed in the upper
703 respiratory tract (U.S. EPA 2010).

704

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

	10 min	30 min	60 min	4 hr	8 hr
AEGL 1 ⁵	0.52 mg/m ³	0.52 mg/m ³	0.52 mg/m ³	0.52 mg/m ³	0.52 mg/m ³
AEGL 2 ⁶	1.6 mg/m ³	1.6 mg/m ³	1.6 mg/m ³	1.6 mg/m ³	1.6 mg/m ³
AEGL 3 ⁷	60 mg/m ³	30 mg/m ³	15 mg/m ³	6.3 mg/m ³	4.1 mg/m ³

706

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

712

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

719

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

725

726

727 **Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be**
728 **used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed**
729 **substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

730

731 Peracetic acid appears at 7 CFR 205.601 for a number of different uses which include disinfecting
732 equipment, seed and asexually propagated planting material, and in hydrogen peroxide formulations used
733 as algicides, disinfectants and sanitizers. It is also listed for fire blight control, and in hydrogen peroxide
734 formulations used for disease control.

735

736 Nonsynthetic alternatives to peracetic acid sanitizers include vinegar, natural alcohols, citric acid, lactic
737 acid and sodium bicarbonate.

738

⁵ 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.

⁶ 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.

⁷ 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.

739 Reports indicate that vinegar may not be able to consistently replicate the antimicrobial efficacy of peracetic
740 acid. One study reported that a 50% vinegar disinfectant had comparable effectiveness as an antimicrobial
741 agent to an 80 ppm peracetic acid solution (Nascimento et al. 2003). Another study reported that undiluted
742 vinegar showed antimicrobial activity against the Gram negative organisms *S. typhi* and *E. coli*; however, it
743 was not effective against the Gram positive *S. aureus* (Parnes 1997). Unlike peracetic acid, vinegar is
744 reported to have low efficacy in the presence of organic materials (Perry and Caveney 2011), but has been
745 shown to have greater efficacy as a disinfectant than both lemon juice (citric acid) and baking soda (sodium
746 bicarbonate) (Olson et al. 1994).

747
748 Alcohol is classified as an intermediate-level disinfectant for healthcare equipment. Like peracetic acid, it is
749 fast acting. It is effective against *S. aureus*, *Salmonella*, *Streptococcus* and *Leptospira*. It leaves no residuals
750 which is positive in terms of environmental impact, but limits the duration of its efficacy. Alcohols are also
751 inactivated by organic material, whereas peracetic acid remains effective even in the presence of heavy
752 organic loads (Perry and Caveney 2011).

753
754 There are also a number of synthetic substances allowed in the NOP regulations for use as disinfectants or
755 sanitizers. These are: synthetic alcohols (ethanol and isopropanol), chlorine materials (including calcium
756 hypochlorite, chlorine dioxide and sodium hypochlorite, electrolyzed water⁸), hydrogen peroxide, ozone,
757 and sodium carbonate peroxyhydrate.

758
759 Another permitted use of peracetic acid is in the control of fire blight. Fire blight is a plant disease caused
760 by *Erwinia amylovora* and poses a serious threat to organic pome fruit production, as it can damage entire
761 orchards. Currently, there are few if any reports of organic fruit producers using peracetic acid, alone or in
762 combination, to control fire blight disease in the field (Schaefer-Joel 2015). Further research is needed to
763 explore its potential role in fire blight control programs.

764
765 Historically, the antibiotics streptomycin and tetracycline were the primary tools used for fire blight control
766 in organic apples and pears. However, the allowed uses of these materials in organic products expired on
767 October 21, 2014. In 2011, NOP had requested, and USDA awarded, federal funding to support the
768 development of viable alternatives. Although peracetic acid was at that time allowed for fire blight control,
769 it was not acknowledged as a viable alternative to tetracycline and streptomycin. Much research has been
770 done to identify other controls for the disease that are both effective and compatible with organic
771 regulations. Serratine-P, a phage tail-like bacteriocin produced by *Serratia plymiticum*, has been suggested
772 as one such biological control (Schoofs et al. 2002). A company called AmebaGone is currently developing
773 technology based on strains of amoebae that consume *E. amylovora* (AmebaGone 2015). One study found
774 promising effectiveness for fire blight control in apple orchards with the application of lime sulfur and fish
775 oil to thin the fruit, followed by the use of biological controls such as *Aureobasidium pullulans* and *Pantoea*
776 *agglomerans* (Johnson and Temple 2012). Another study found that the application of a copper bactericide
777 and horticultural oil to Bartlett pear trees prior to full bloom stage effectively delayed increases in the
778 pathogen's population to when the number of susceptible flowers greatly decreases (Elkins et al. 2015).
779 More recently, Johnson and Temple (2015) evaluated additional products used alone or in combination to
780 control fire blight bacteria. The products included active ingredients such as fermented *Bacillus subtilis* and
781 again *Aureobasidium pullulans*, this time applied with a companion buffer and followed by additional
782 treatment with one of the following: the *Bacillus subtilis* fermentation, a copper soap, a soluble copper-
783 ammonium complex, a hydrogen peroxide (27%) peracetic acid (2%) product, or an *E. amylovora*-specific
784 phage cocktail. Of these, the *A. pullulans* treatment followed by the copper-ammonium complex showed
785 the greatest efficacy. *A. pullulans* followed by the hydrogen peroxide/peracetic acid product was also
786 effective at reducing the incidence of blighted flower clusters, though to a much lower extent (Johnson and
787 Temple 2015). A webinar by some of these authors was recorded on March, 17, 2015, describing a program
788 for controlling fire blight using several of these alternatives at specific stages during the fruit production
789 cycle (Johnson, Elkins and Smith 2015).

790

⁸ NOP Policy Memo 15-4

791 In use as a seed treatment, peracetic acid has been employed to control bacterial fruit blotch in watermelon
792 seeds and has been found effective at reducing the bacterial pathogen, *Acidovorax avenae* subsp. *citrulli*,
793 responsible for the disease. One study reports the alternative use of biological control agents *Pseudomonas*
794 *fluorescens* and *Acidovorax avenae* subsp. *avenae* to treat seeds for the same disease control. The treatment
795 showed a 96.5% reduction in disease transmission (Fessehaie and Walcott 2005).

796
797

798 **Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned**
799 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

800

801 Disinfection of equipment, seed, and asexually propagated planting material is a critical step in preventing
802 cross contamination of crops with bacterial and other pathogens that may be present. Thus, other practices
803 should be viewed as complementary to disinfection, as the use of this tool does not preclude the use of
804 others. Additional practices which can help minimize the spread of pathogenic plant disease include using
805 disease resistant varieties, crop rotations, and appropriate management of soil nutrients and water
806 application. Enhancing the diversity of soil microbial populations through the application of organic
807 matter, for example, can provide competition to effectively suppress pathogen populations. One study
808 found that the application of manures and other plant and animal by-products improved control of soil-
809 borne diseases via the generation of ammonia and/or nitrous acid during the amendments' breakdown by
810 microbes (Lazarovits, Tenuta and Conn 2001). Concentrations of these compounds were found to be lethal
811 to pathogens under certain conditions of the soil environment. The study found that while application of
812 the materials reduced pathogen populations, soil microbial diversity increased, suggesting that not all
813 microorganisms have the same susceptibility to nitrogen toxicity. Biological control of plant pathogens
814 using beneficial microorganisms is another alternative method for disease control.

815

816 In terms of plant disease control, three key factors related to the occurrence of plant disease outbreaks
817 should be considered: susceptibility of plants, the presence of a pathogen, and favorable environmental
818 conditions (Sherf and MacNab 1986). Plant disease control practices must, therefore, be tailored to the
819 specific needs of the operation, including the pathogen to be controlled and its life cycle, the time and
820 method of infection, the plant parts affected and methods of dissemination, as well as climatic and soil
821 conditions.

822

823 In the cases of fire blight and bacterial fruit blotch, it is reported that blossom protection in particular
824 (using materials described in Evaluation Question 11), can prevent the spread of infections by blocking one
825 of the pathogens' major modes of entry into the plant. For fire blight, certain climatic and other
826 environmental conditions can be monitored to predict incidences of disease outbreak, enabling operators to
827 time their use of control substances.

828

829

830

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831

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