Environmental Assessment

1. Date October 16, 2017

2. Name of Applicant ———————

3. Address

Agent for Notifier:
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4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), and dipicolinic acid (DPA) in the production and preparation of whole or cut poultry and meat, fruits and vegetables, and processed/pre-formed meat and poultry. This notification requests an increase in the at-use levels of one of the components of the FCS, hydrogen peroxide, and to include the use of dipicolinic acid at existing regulated levels.

When used as intended, the components of the FCS mixture will not exceed:

(1) 2000 ppm peroxyacetic acid (PAA), 1474 ppm hydrogen peroxide (HP), 14 ppm 1-hydroxyethylidine- 1,1-diphosphonic acid (HEDP), and 0.88 ppm dipicolinic acid in spray, wash, rinse, dip, chiller water, low temperature (e.g., less than 40°F) immersion baths, or scald water for whole or cut poultry carcasses, parts, trim, and organs; and

(2) 1800 ppm PAA, 1215 ppm HP, 12 ppm HEDP, and 0.5 ppm DPA in process water or ice used for washing, rinsing, or cooling whole or cut meat, including carcasses, parts, trim, and organs; and

(3) 350 ppm PAA, 1000 ppm HP, 10 ppm HEDP, and 0.25 ppm DPA in water for washing or chilling fruits and vegetables in food processing facilities; and

(4) 230 ppm PAA, 186 ppm HP, 14 ppm HEDP, and 0.1 ppm DPA in water, brine, or ice used for washing, rinsing, or cooling processed and pre-formed poultry; and

(5) 495 ppm PAA, 335 ppm HP, 14 ppm HEDP, and 0.1 ppm DPA in water, brine, or ice used for washing, rinsing, or cooling processed and pre-formed meat.

b. Need for Action

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food during production.

The requested action to expand the currently approved uses of the FCS is needed to address current and future needs of food processors and governmental agencies to improve food safety. Use of the FCS provides more options for antimicrobial interventions. For example, the use of peroxyacetic acid at higher concentrations for relatively short periods of time, and in smaller total volumes, enhances the capacity of the food industry to improve processing techniques, such as providing more flexibility in terms of time, concentrations, application method (spray vs. immersion) to better control food pathogens.

c. Locations of Use/Disposal

The antimicrobial agent is intended for use in meat and poultry, and fruit and vegetable processing plants and packing facilities throughout the United States. After use, the FCS will be disposed of with processing plant wastewater according to National Pollutant Discharge Elimination System (NPDES) regulations. For processing plants that hold a NPDES permit (i.e., direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (i.e., indirect dischargers), the FCS-containing wastewater would travel through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments. As a conservative approach, we assume that waste water will be treated onsite before discharge to surface water pursuant to a NPDES permit. During the onsite treatment process, very minor quantities of the solution are lost to evaporation. We have also estimated maximum potential concentrations in soil from application of sludge from wastewater treatment facilities to soil.

i. Whole or Cut Meat and Poultry Processing

Meat and poultry processors are among those industries required by EPA to meet industry specific effluent pre-treatment standards.[1] Therefore, the waste process water containing the FCS is expected to be disposed of through the processing plant's onsite wastewater treatment facility before discharge to surface waters under National Pollution Discharge Elimination System (NPDES) permitting. In addition, when sewage sludge from POTW is treated and processed, it becomes biosolids which can be safely recycled and applied as fertilizer to sustainably improve and maintain productive soils and stimulate growth.[2]

In poultry processing facilities the antimicrobial will be applied to the surfaces of poultry carcasses, parts, organs, or trim by an immersion dip and/or a spray cabinet. Typically, the defeathered, eviscerated carcasses are sprayed before being chilled via submersion in baths. The carcass is carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be chilled by submersion in baths containing the antimicrobial agent. Chiller baths typically include a "main chiller" bath and a "finishing chiller" bath, both containing the FCS. After the diluted product is sprayed onto the poultry, or the poultry is unloaded out of an immersion dip, the bulk of the solution drains off of the product. The waste solution ultimately runs into drains and enters the poultry processing plant water treatment facility. All of this water is collected and treated by the facility prior to it being sent to surface waters, pursuant to the facility's NPDES permit. Very minor quantities are lost to evaporation.

[1] 40 C.F.R. Part 432; additional information available at https://www.epa.gov/eg/meat-and-poultry-products-effluent-guidelines.
[2] https://www.epa.gov/biosolids/basic-information-about-biosolids.

In meat processing facilities the product is applied to the surface of meat carcasses or parts by spraying the carcasses that are suspended on a moving conveyor line or rail system. The system carries the carcass into a spray cabinet, in which spray nozzles are distributed in a manner that ensures even application of the dilute FCS solution onto the surface of the carcass. The carcass exits the other side of the spray cabinet and continues on the processing line. In some instances, meat parts are placed in a dip tank containing the FCS, diluted to an appropriate intervention treatment concentration, in order to ensure full contact with the intervention treatment. After the diluted product is applied to the carcass, the majority of the product drains off of the meat and ultimately runs into drains and enters the meat processing plant water treatment facility prior to it being sent to surface waters, as described above.. Very minor quantities are potentially lost to evaporation.

ii. Fruit and Vegetable Processing Facilities

Different methods may be used to wash different types of produce, including submersion, spray, or both.[3] Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in the fruit and vegetable processing water and the subsequent disposal of such water draining into the processing plant wastewater treatment facility. There may also be direct discharge to surface waters from use of the PAA product in fruit and vegetable processing facilities.

iii. Processed and Preformed Meat and Poultry

The FCS is intended for use as a treatment for washing, rinsing, and cooling water applied to processed and pre-formed meat and poultry products. The bulk of the solution drains off the product.

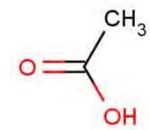
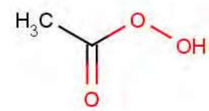
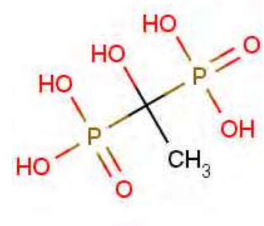
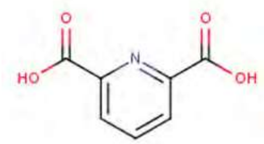
5. Identification of Substances that are Subject of the Proposed Action

The raw materials used in this product are hydrogen peroxide, acetic acid, HEDP, DPA and water. Peroxyacetic acid formation is the result of an equilibrium reaction between hydrogen peroxide and acetic acid. The FCS is supplied in concentrated form and is diluted at the processing plant for use to achieve the desired level of peroxyacetic acid that is needed to address the microbial load.

Table 1: Chemical Identity of Substances of the Proposed Action

Component	CAS No.	Molecular Weight	Structural Formula	Molecular Formula
Hydrogen peroxide	7722-84-1	34.01	HO-OH	H_2O_2

[3] U.S. Food and Drug Administration, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, Section VIII.C.2.b, available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm#ch4.

Acetic acid	64-19-7	60.05		$C_2H_4O_2$
Peroxyacetic acid	79-21-0	76.05		$C_2H_4O_3$
1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP)	2809-21-14	206.3		$C_2H_8O_7P_2$
Dipicolinic acid (DPA)	499-83-2	167.12		$C_7H6_6NO_4$
Water	7732-18-5	18.01	H-O-H	H_2O

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) the action threatening a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with the proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in

Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Introduction of dilute solutions of the product into the environment will take place primarily via release from wastewater treatment systems. Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water and spray applications onto food, and the subsequent disposal of such water and spray drainage into on-site treatment plants or POTWs. The total amount of product used at a typical facility will vary significantly, depending on the equipment used and the amount of food processed. The maximum at-use concentration of PAA, hydrogen peroxide, HEDP, and DPA for each application will be as follows:

Table 2: Summary of Intended Uses

Use	**PAA ppm**	**H_2O_2 ppm**	**HEDP ppm**	**DPA ppm**
Spray, wash, rinse, dip, chiller water, low temperature (e.g., less than 40°F) immersion baths, or scald water for whole or cut poultry carcasses, parts, trim, and organs	2000	1474	14	0.88
Process water or ice used for washing, rinsing, or cooling whole or cut meat, including carcasses, parts, trim, and organs	1800	1215	12	0.5
Water for washing or chilling fruits and vegetables in food processing facilities	350	1000	10	0.25
Water, brine, or ice used for washing, rinsing, or cooling processed and pre-formed poultry	230	186	14	0.1
Water, brine, or ice used for washing, rinsing, or cooling processed and pre-formed meat	495	335	14	0.1

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in complete degradation of PAA, hydrogen peroxide, and acetic acid. Specifically, the PAA will breakdown into oxygen, water and acetic acid, while hydrogen peroxide will break down into oxygen and water.[4] All three compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. The half-life of PAA in buffered solutions was 63 hours at pH 7 for a 748 ppm solution, and 48 hours at pH 7 for a 95 ppm solution.[5] The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm, and increased to 15.2 days and 20.1 days

[4] U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993), p. 18, available at https://archive.epa.gov/pesticides/reregistration/web/pdf/peroxy_compounds.pdf.
[5] European Centre for Toxicology and Toxicology of Chemicals (ECETOC), *Joint Assessment of Commodity Chemicals (JACC) No. 40 Peracetic Acid and its Equilibrium Solutions*, January 2001, Table 11, p. 29, available at http://www.ecetoc.org/jacc-reports.

when the concentration decreased to 250 ppm and 100 ppm, respectively.[6] In biodegradation studies of acetic acid using activated sludge, 99% degraded in 7 days under anaerobic conditions.[7] Acetic acid is not expected to concentrate in the wastewater discharged to the treatment facility/POTW. Therefore, these substances are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. As a result the remainder of this section will consider only the environmental introduction of HEDP and DPA.

i. Poultry Processing Facilities

When the FCS is used at the maximum level under the proposed action, HEDP and DPA would be present in water at a maximum level of 14 parts per million (ppm) and 0.88 ppm, respectively. Water is used in poultry processing for scalding (feather removal), bird washing before and after evisceration, chilling, cleaning and sanitizing of equipment and facilities, and for cooling of mechanical equipment such as compressors and pumps.[8] Many of these water uses will not utilize the FCS, resulting in significant dilution of HEDP and DPA into the total water effluent. Assuming, in the very worst-case, that all of the water used in a poultry processing plant is treated with the FCS, the level of HEDP and DPA in water entering the plant's wastewater treatment facility, the environmental introduction concentration (EIC), would be 14 ppm and 0.88 ppm, respectively.

ii. Meat Processing

The FCS may be used in contact with all types of meat, including pork, venison, and mutton/lamb. Its use in the processing of beef constitutes the largest sector of the meat processing industry in terms of market share, while the processing of pork is the sector that is expected to generate the largest amount of effluent.[9]

Although the total water usage may differ between beef and pork processing plants, when the FCS is used in either application the maximum at-use concentration of HEDP and DPA in the wash water is limited to 12 ppm and 0.5 ppm, respectively. Water is used in meat processing facilities for purposes other than carcass and meat washing (i.e. for cleaning, boiler water, cooling waters, etc.). This additional water use will dilute the concentration of HEDP and DPA in the total water effluent to lower levels. Indeed, these other uses are reported to account for approximately 60% of the total water used in a hog slaughterhouse.[10] Nevertheless, assuming, in

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[6] ECETOC, *JACC No. 22, Hydrogen Peroxide*, January, 1993, Table 6, p. 23, "Degradation in the River Soane of Hydrogen Peroxide," available at http://www.ecetoc.org/jacc-reports.

[7] American Chemistry Council, Acetic Acid and Salts Panel, *U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category*, June 28, 2001, Appendix 1, p. 1, https://iaspub.epa.gov/oppthpv/document_api.download?FILE=c13102tp.pdf.

[8] U.S. Environmental Protection Agency, *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 CFR 432)*, EPA-821R-04-011, September 8, 2004, p. 6-7, available at https://www.epa.gov/sites/production/files/2015-11/documents/meat-poultry-products_tdd_2004_0.pdf.

[9] *Id.*, Table 6-3, "Characteristics of Wastewater Generated at Two Hog and Three Cattle Processing Facilities," p. 6-6.

[10] Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry*, 2006, Figure 3.2, p. 71 (summing values from the personal hygiene (~9%), cooling water (5%), knife sterilizing (5%), lairage washing (~3%), vehicle washing (~4%), and cleaning (~32%) categories, and assuming that all of the sprays and rinses are used during processing).

the very worst-case, that all of the water used in a meat processing plant is treated with the FCS, the maximum amount of HEDP and DPA entering a facility's wastewater treatment plant as a result of the requested use of the FCS (the EIC) in pork or beef processing facilities would be 12 ppm and 0.5 ppm respectively.

iii. Fruit and Vegetable Processing Facilities

Water is used extensively in almost all aspects of processing fruits and vegetables, including during cooling, washing, and conveying of produce.[11] When the FCS is used at the maximum level under the proposed action, HEDP and DPA would be present in water at a maximum level of 10 ppm and 0.25 ppm, respectively. Water is used in produce processing for a variety of applications that will not utilize the FCS, including blanching, filling, cleaning and sanitizing of plant equipment and facilities, and for processed product cooling,[12] resulting in significant dilution of HEDP and DPA into the total water effluent. Assuming, in the very worst-case, that all of the water used in a fruit and vegetable processing plant is treated with the FCS, the level of HEDP and DPA in water entering the plant's wastewater treatment facility, the environmental introduction concentration (EIC) would be 10 ppm and 0.25 ppm, respectively.

iv. Processed and Preformed Meat and Poultry

Because there are many different types of RTE meat and poultry produced using a variety of methods, it is difficult to establish water usage levels. It is expected that water not containing the FCS will be used in plants for activities such as cleaning and sanitation, resulting in significant dilution of HEDP into the total water effluent. Because it is difficult to establish water usage levels, we assume, in the very worst-case, that all of the water used in a processed and pre-formed meat and poultry plant is treated with the FCS, and the environmental introduction concentration (EIC) of HEDP and DPA would be 14 ppm and 0.1 ppm, respectively.

7. Fate of Emitted Substances in the Environment

HEDP will slowly degrade to carbon dioxide, water and phosphates. Phosphate anions are strongly bound to organic matter and soil particles, and phosphate is a required macronutrient of plants. However, given the maximum level estimated to be released, we would not expect that phosphate released from HEDP would result in measurable increases in phosphate in soil or water receiving treated effluent. Decomposition of HEDP occurs at a moderately slow pace; a Dissolved Organic Carbon removal of 23-33% after 28 days was observed in an inherent biodegradability test (Zahn-Wellens test).[13] Therefore, increases in phosphate in soils amended with wastewater sludge, or in water receiving treated effluent are not expected.

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[11] FDA, *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, Section VIII.C.2.

[12] A joint publication of the Division of Pollution Prevention and Environmental Assistance and Division of Water Resources of the North Carolina Department of Environment and Natural Resources, and Land-of-Sky Regional Council, *Water Efficiency Manual for Commercial, Industrial, and Institutional Facilities*, August 1998, p. 87, available at http://www.allianceforwaterefficiency.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=1016.

[13] HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, *Phosphonates (CAS 6419-19-8; 2809-21-4; 15827-60-8)*, Draft 06/09/2004, Table 7, p. 16, available at http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf.

The Human and Environmental Risk Assessment Project (HERA) report on phosphonates indicates that the treatment steps at an onsite wastewater treatment facility or POTW will remove at least a portion of any HEDP in the process water.[14] The HERA report cites 80% adsorption of HEDP to sewage treatment sludge.

Information in the literature indicates that DPA, a polysubstituted pyridine derivative, readily biodegrades in both freshwater and marine water aerobic and anaerobic conditions,[15] and in both anaerobic and aerobic soil conditions.[16] In presenting a review on the microbial metabolism of pyridines, including DPA, Kaiser, *et al*. describe aerobic metabolism of DPA to carbon dioxide, ammonium, and water, and anaerobic metabolism to dihydroxypyridine which is then rapidly photodegraded to organic acids (i.e., propionic acid, acetic acid), carbon dioxide, and ammonium.[17] Further information indicates that DPA is soluble in water, with the estimated water solubility of 5,000 mg/L and an octanol-water partition coefficient estimated to be 0.57.[18] Based upon this information, it is reasonable to conclude that DPA will substantially remain with water and not be absorbed to sludge, and that DPA will be readily biodegraded during treatment at POTWs and on-site treatment facilities.

We have estimated the potential environmental introductions of HEDP and DPA in water and sewage sludge based upon the information above. We have considered the poultry application as the worst-case scenario because it has the highest use level for both HEDP and DPA. For HEDP, we also have applied the 20:80 partition factor from the HERA report. (See Table 3 below).

Table 3: Worst-case EICs for HEDP and DPA Using Poultry Processing as the Worst Case

Use	EIC Total	EIC_{sludge}	EIC_{water}
Poultry - HEDP	14 ppm	11.2 ppm[19]	2.8 ppm[20]
Poultry - DPA	0.88 ppm	-	0.88 ppm

When the water from the facility or POTW is discharged to surface waters, HEDP and DPA will be diluted a further 10-fold, resulting in an estimated environmental concentration of

[14] *Id.*, at Table 12, p. 22.
[15] Amador, J.A. and Tatlor, B.P., *Coupled metabolic and photolytic pathway for degradation of pyridinecarboxylic acids, especially dipicolinic acid*, Applied and Environmental Microbiology, 56(5): 1352-1356 (1990); Seyfried B. and Schnink, B. *Fermentive degradation of dipicolinic acid (Pyridine-2,6- dicarboxylic acid) by a defined coculture of strictly anaerobic bacteria*, Biodegradation, 1(1), 1-7 (1990); Kaiser, J.P., Feng, Y., and Bollag, J.M., *Microbial metabolism of pyridine, quinolone, acridine, and their derivatives under aerobic and anaerobic conditions*, Microbiological Reviews, 60(3): 483-498 (1996).
[16] Naik, M.N. et al, *Microbial Degradation and Phytotoxicity of Picloram and Other Substituted Pyridines*, Soil Biology and Biochemistry, 4: 313-323 (1972), see p. 320; Sims, G.K. and Sommers, L.E., *Biodegradation of Pyridine Derivatives in Soil Suspensions*, 5:503-509 (1986).
[17] Kaiser, p. 488.
[18] https://chem.nlm.nih.gov/chemidplus/rn/499-83-2.
[19] Example Calculation 14.0 ppm*80% = 11.2 ppm
[20] Example Calculation 14.0 ppm*20% = 2.8 ppm

0.28 ppm and 0.088 ppm, respectively.[21] Finally, we note that the HEDP EIC for sludge is a maximum for terrestrial impacts, as any sludge used as a soil amendment will likely be significantly diluted by soil or sludge from other sources.

8. Environmental Effects of Released Substances

a. Terrestrial Toxicity

The HERA report discusses biodegradation of HEDP and estimates a half-life in soil of 373 days. Therefore HEDP is expected to degrade, albeit slowly, in soil. HEDP shows no toxicity to terrestrial organisms at levels up to 1000 mg/kg soil dry weight (No Observed Effect Concentration; NOEC).[22] Our maximum estimated concentration in sludge (11.2 ppm) is well below the NOEC, and the maximum concentration in soil when used as a soil amendment should have an even larger margin of safety with respect to the NOEC. Therefore, the FCS is not expected to have any terrestrial environmental toxicity concerns at levels at which it is expected to be present in sludge or soil. Moreover, the much smaller level of HEDP present in the surface water is not expected to have any adverse environmental impact with respect to sedimentation based on the terrestrial toxicity endpoints available for plants, earthworms, and birds.[23]

As noted above, DPA is soluble in water and very little, if any, DPA is expected to partition to sludge. Accordingly, terrestrial releases of DPA from the intended uses of the FCS are anticipated to be negligible and no toxicity concerns are expected.

b. Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized, and is showing in the following table:

Table 4: Summary of Environmental Toxicity Data for HEDP[24]

Species	Endpoint	mg/L
Short Term		
Lepomis macrochirus	96 hr LC_{50}	868
Oncorhynchus mykiss	96 hr LC_{50}	360
Cyprinodon variegatus	96 hr LC_{50}	2180
Ictalurus punctatus	96 hr LC_{50}	695
Leuciscus idus melonatus	48 hr LC_{50}	207 – 350
Daphnia magna	24 – 48 hr EC_{50}	165 – 500
Palaemonetes pugio	96 hr EC_{50}	1770

[21] Rapaport, R.A., *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution*, Environmental Toxicology and Chemistry 7(2), 107-115 (1988).
[22] Jaworska, J., et al, *Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands*, Chemosphere 2002, 47(6), 655-665, May 2002.
[23] *Id.*
[24] Short term values for *Lepomis macrochirus*, *Oncorhynchus mykiss*, *Cyprinodon variegatus*, *Ictalurus punctatus*, *Leuciscus idus melonatus*, *Daphnia magna*, *Palaemonetes pugio*, *Crassostrea virginica*, *Chlorella vulgaris*, *Pseudomonas putida*, and long term values for *Oncorhynchus mykiss*, *Daphnia Magna* found in Jaworska, et al, p. 662 (2002). Short term values for *Selenastrum capricornutum*, and short and long term values for algae found in HERA (2004) (Tables 13 and 14, p. 29-31).

Crassostrea virginica	96 hr EC_{50}	89
Selenastrum capricornutum	96 hr EC_{50}	3
Selenastrum capricornutum	96 hr NOEC	1.3
Algae	96 hr NOEC	0.74
Chlorella vulgaris	48 hr NOEC	≥100
Pseudomonas putida	30 minute NOEC	1000
Long Term		
Oncorhynchus mykiss	14 day NOEC	60 – 180
Daphnia Magna	28 day NOEC	10 – <12.5
Algae	14 day NOEC	13

According to Jaworska et al,[25] the primary adverse effects of HEDP result from chelation of nutrients rather than direct toxicity of HEDP. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been demonstrated to be the controlling toxicological mode when evaluating wastewater discharges from food processing facilities. The lowest short-term LC_{50} values published for *Selenastrum capricornutum* (3 ppm), *Daphnia magna* (165 ppm), and *Crassostrea virginica* (89 ppm) are acute toxicity endpoints considered to result from this chelation effect. These values are not relevant when excess nutrients are present as expected in food processing wastewaters. The lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable,[26] based on the available environmental toxicology data, reliance upon the NOEC for *Daphnia magna* is appropriate.[27] The conservatively estimated EEC of 0.28 ppm is well below the 10 ppm chronic NOEC for *Daphnia magna*, and the FCS is not expected to have any aquatic toxicity.

There is little publicly available ecotoxicology data for DPA. A review of EPA's ECOTOX database provides one study indicating a freshwater fish 96-hour LC_{50} of 322 mg/L for fathead minnow.[28] In the absence of literature data, we have evaluated DPA using the Ecological Structure Activity Relationships (ECOSAR) Class Program, which is a computerized predictive system maintained and developed by the U.S. EPA that estimates aquatic toxicity. The program estimates a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms, such as fish, aquatic invertebrates, and aquatic plants, by

[25] Jaworska, et al (2002).
[26] Blok J. and Balk F., *Environmental regulation in the European Community*, in Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment, (GM Rand, Ed.), Taylor & Francis, New York, 1995, chapter 27 ("NOEC determinations are likely more statistically variant (uncertain) than EC_{50} determinations"); also see Organisation for Economic Co-operation and Development (OECD), *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application*, OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 54, Environment Directorate, Paris, 2006 (recommending that that NOECs be abandoned), available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2006)18&doclanguage=en.
[27] Jaworska, et al (2002).
[28] See enclosed ECOTOX report. The ECOTOX database can be accessed here: https://cfpub.epa.gov/ecotox/advanced_query.htm.

using computerized Structure Activity Relationships (SARs).[29] This program is a sub-routine of the Estimation Program Interface (EPI) Suite – a structure-function predictive modeling suite also developed and maintained by the U.S. EPA.[30] The ECOSAR results for DPA predict the following acute and chronic toxicity endpoints tabulated below.[31] The complete ECOSAR report for this analysis is attached to this EA.

ECOSAR Class	Organism	Endpoint	mg/L
Pyridine-alpha-acid	Fish	96 hr LC50	324
	Fish	Chronic value (ChV)	29
Neutral Organic SAR	Fish	96 hr LC50	2657
	Daphnid	48 hr LC50	1322
	Green Algae	96 hr EC50	570
	Fish	ChV	222
	Daphnid	ChV	89
	Green Algae	ChV	111

These values are all much higher than the “worst-case” scenario of an EECaq of 0.088 ppm, which is over 300 times lower than the lowest chronic toxicity endpoint for the most sensitive species. Thus, the use of DPA at such a minimal level is not expected to result in any adverse environmental effects.

9. Use of Resources and Energy

The use of the FCS will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. The raw materials that are used in production of the mixture are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the mixture components is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilutions of antimicrobial product. Therefore, mitigation measures of any kind are not required.

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[29] Information on ECOSAR can be found at https://www.epa.gov/tsca-screening-tools/ecologicalstructure-activity-relationships-ecosar-predictive-model.

[30] EPISuite predicts various physical-chemical properties and environmental fate endpoints and also include models for environmental transport. Running the tool will give the user an indication of the transport and persistence of a chemical. Information on EPI Suite is available at https://www.epa.gov/tsca-screeningtools/epi-suitetm-estimation-program-interface.

[31] *See* EPI Suite – ECOSAR Program Results for CAS 499-83-2 included as an Attachment to this EA. Chronic toxicity was estimated through application of acute-to-chronic ratios per methods outlined in the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

11. Alternatives to the Proposed Action

No potential significant adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no significant environmental impact. The addition of the antimicrobial agent to the options available to food processers is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Ms. Attwood has eight years of experience preparing environmental submissions to FDA for the use of peroxyacetic acid antimicrobials.

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Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011 including oversight of FDA's initial NEPA review for the regulations implementing the Food Safety Modernization Act.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: October 16, 2017

[redacted]

Mitchell Cheeseman, PhD

14. References

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15. Attachments

ECOSAR modeling.

ECOTOX Report for Dipicolinic Acid.