Attachment 7
FORM FDA 3480

ENVIRONMENTAL ASSESSMENT

1. **Date:** February 15, 2019

2. **Name of Submitter:** LPR Technologies

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4. **Description of the Proposed Action**

A. Requested Action

The action requested in this notification is to provide for the use of the Food Contact Substance (FCS), which is an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and optionally, sulfuric acid, as an antimicrobial agent to be used:

(1) At concentrations up to 2000 ppm PAA, 800 ppm hydrogen peroxide, and 133 ppm HEDP for use in process water applied as a wash, spray, dip, rinse, chiller water, low-temperature (e.g., less than 40^{o}F) immersion baths, or scald water for whole or cut poultry carcasses, parts, trim, and organs.
(2) At concentrations up to 1800 ppm PAA, 700 ppm hydrogen peroxide, and 120 ppm HEDP for use in process water or ice used in washing, rinsing, or cooling whole or cut meat carcasses, parts, trim, and organs.
(3) At concentrations up to 495 ppm PAA, 193 ppm hydrogen peroxide, and 33 ppm HEDP for use in process water, ice, or brine used in washing, rinsing, or cooling processed and pre-formed meat products.
(4) At concentrations up to 230 ppm PAA, 90 ppm hydrogen peroxide, and 15 ppm HEDP for use in process water, ice, or brine used in washing, rinsing, or cooling processed and pre-formed poultry products.
(5) At concentrations up to 50 ppm PAA, 17 ppm hydrogen peroxide, and 4 ppm HEDP for use in brines, marinades and sauces applied to the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry.
(6) At concentrations up to 50 ppm PAA, 17 ppm hydrogen peroxide, and 4 ppm HEDP for use in surface sauces and marinades applied on processed and preformed meat and poultry products.
(7) At concentrations up to 230 ppm PAA, 90 ppm hydrogen peroxide, and 15 ppm HEDP for use in process water or ice used during commercial preparation of fish and seafood.

(8) At concentrations up to 350 ppm PAA, 136 ppm hydrogen peroxide, and 23 ppm HEDP for use in process water used in washing or chilling fruits and vegetables in food processing facilities.
(9) At concentrations up to 2000 ppm PAA, 800 ppm hydrogen peroxide, and 120 ppm HEDP for use in Process water used in washing shell eggs.

Mixtures of these substances have previously been approved for the same uses, with several FCNs (No. 880, 1465, 1389, 1247, 1284, 1419, 1580, 1490, 1622, 1638,1688, 1713, 1501, 1650, 1715, 1654,1726 and 1867) permitting the use of the substances at concentrations at or above the levels proposed above.

B. Need for Action

The antimicrobial agent reduces or inhibits the growth of pathogenic and non-pathogenic microorganisms that may be present on and in food to provide safer foods for consumers.

Approval of the expanded use of the FCS will allow processors to address current needs of processors and government agencies to improve food safety. The extended concentration ranges (up to 2000 ppm PAA in poultry and up to 1800 ppm in meat) have been found to be effective in controlling *Campylobacter spp*. in poultry and newer species of bacteria, such as Shiga Toxin-Producing *Escherichia coli* (STEC) in meat. These pathogens are better controlled by exposure to higher concentrations of PAA at lower exposure times (dose-responsive rather than time-responsive). The higher concentration ranges also provide processors with more options in application methods that help better control food pathogens, such as, using high concentrations of PAA at reduced exposure times (seconds) and smaller volumes in the finishing chillers in poultry processing plants in order to treat the pathogen *Campylobacter*, more effectively.

The approval of the expanded use of the FCS will also allow treatment of brines, marinades and sauces used in poultry and meat plants as these solutions are often re-applied on the poultry and meat products over a period of time, typically over 4-hour intervals during an 8-hour processing shift. The reused marinades, brines or sauces can cross-contaminate fresh product, and therefore treatment of these solutions is essential in eliminating such cross-contamination.

C. Locations of Use/Disposal

The antimicrobial agent is intended for use in poultry, meat, fish and seafood, fruit and vegetable, and egg processing plants throughout the United States. It may also be used aboard fishing vessels during initial evisceration and cleaning of the fresh-caught seafood.

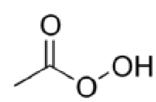
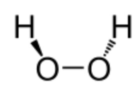
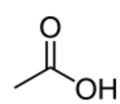
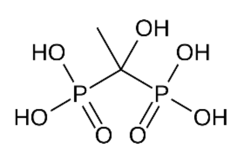
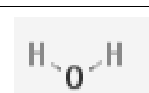
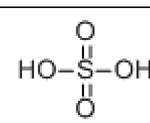
When used in processing plants, the waste process water containing the FCS is expected to be disposed of through the processing plant wastewater treatment facilities or through a local publicly owned treatment works (POTW). When used aboard fishing vessels, the wastewater containing the FCS is expected to be disposed in the ocean in compliance with local fishing discharge regulations.

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

The Food Contact Substance is an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid, and sulfuric acid. PAA formation is the result of an equilibrium reaction between acetic acid and hydrogen peroxide. The FCS is supplied in concentrated form and is diluted at the processing plant to achieve the desired level of PAA needed to address the microbial load.

The descriptions, chemical formulae, structures and molecular weights of the components are described in Table 1 below:

Table 1: Chemical Identity of Food Contact Substance Components

Component	CAS Number	Molecular Weight	Molecular Formula	Molecular Structure
Peroxyacetic acid	79-21-0	76.05 g/mol	$C_2H_4O_3$	
Hydrogen peroxide	7722-84-1	34.0147 g/mol	H_2O_2	
Acetic acid	64-19-7	60.05 g/mol	$C_2H_4O_2$	
1-hydroxyethylidene-1,1-diphosphonic acid	2809-21-4	206.028 g/mol	$C_2H_8O_7P_2$	
Water	7732-18-5	18.015 g/mol	H_2O	
Sulfuric acid	7664-93-9	98.08 g/mol	H_2SO_4	

6. Introduction of Substances into the Environment

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

As provided in 21 CFR 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 no extraordinary circumstances apply to the manufacture of the FCS including situations where: 1). unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2). a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and 3). production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the 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

The FCS is supplied in concentrated form and is diluted at the processing plant. When diluted for use, the target levels of PAA in the process water for use will vary according to microbial load and type of application. The maximum at-use concentration of PAA, hydrogen peroxide (H_2O_2) and HEDP for each application will be as follows:

Application	**PAA**	**H_2O_2**	**HEDP**
Whole or cut poultry, including carcasses, parts, trim, and organs	2000 ppm	800 ppm	133 ppm
Whole or cut meat, including carcasses, parts, trim, and organs	1800 ppm	700 ppm	120 ppm
Processed and pre-formed meat products	495 ppm	193 ppm	33 ppm
Processed and pre-formed poultry products	230 ppm	90 ppm	15 ppm
Brines, marinades and sauces applied on the surface or injected into processed or unprocessed, cooked or uncooked, whole or cut poultry	50 ppm	17 ppm	4 ppm

Application	**PAA**	**H_2O_2**	**HEDP**
Surface sauces and marinades applied on processed and preformed meat and poultry products	50 ppm	17 ppm	4 ppm
Fish and seafood	230 ppm	90 ppm	15 ppm
Fruits and vegetables	350 ppm	136 ppm	23 ppm
Shell eggs	2000 ppm	800 ppm	120 ppm

Treatment of the process water at the on-site wastewater treatment plant or at the POTW is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide and acetic acid, based on the half-life of these substances (described in detail in section 7 of this EA). Specifically, peroxyacetic acid will break down into oxygen and acetic acid, and hydrogen peroxide will break down into oxygen and water. Therefore, these substances are not expected to be introduced into the environment in any significant extent as a result of the proposed use of the FCS. Consequently, the remainder of this section will consider only the environmental introduction of HEDP.

As a worst-case analysis, the remainder of this EA will focus on the use profile with the highest concentration of HEDP, i.e., whole or cut poultry.

Poultry Processing Facilities

The defeathered, eviscerated carcasses in a poultry processing plant will typically be sprayed with an antimicrobial agent before being chilled in immersion chiller baths. The carcass is carried on a shackle or conveyer through a spray cabinet prior to submersion in a chiller bath. Poultry parts and organs may also be chilled by submersion in the chiller baths. Chiller baths typically include a "main chiller" bath as well as a "finishing chiller" bath, both containing an antimicrobial agent.

The FCS is diluted for use either as a spray application, or immersion application in the main chiller or finishing chiller, or in a post-chill dip for carcasses, parts, trim, or organs.

The poultry industry added finishing chillers as a response to the U.S. Department of Agriculture Food Safety and Inspection Service's (FSIS) new performance standards for *Campylobacter* and *Salmonella*.[1] It is currently believed that the best control of these two pathogenic organisms occurs when Campylobacter (a dose-responsive organism) is treated at high dosage levels (up to 2000 ppm for this FCS) at a limited contact time in a finishing chiller, or by post-chill spray or dip, while Salmonella (a time-responsive organism) and other general microorganisms are treated at lower concentrations (<100 ppm) over an extended period of time in the main chiller.

For economic feasibility, water from the finishing chiller is recycled into the main chiller waters hence maintaining the concentration of the PAA in the main chiller. This use of recycled chilling water in the main chiller is permitted under 9 CFR 416.2(g)(3). The finishing chiller will typically contain the maximum concentration of the FCS. However, since the volume of water present in the main chiller is much larger (approximately 20 times that of the finishing chiller), the FCS is significantly diluted in the main chiller. With respect to environmental impact, the contents of the main chiller will enter the wastewater treatment system and ultimately be released into the environment.

A 10-fold dilution factor accounts for the expected dilution in surface waters of effluent from an on-site wastewater treatment facility or POTW. This information is reported by Rapaport (1988).[2] The environmental introduction concentrations (EIC) and expected environmental concentration (EEC) of each use is presented in Item 7 of the EA.

7. Fate of Substances Released into the Environment

As previously mentioned, treatment of the process water at the on-site wastewater treatment plant or at the POTW is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide and acetic acid. PAA and hydrogen peroxide rapidly degrade upon contact with organic matter, transition metals, and upon exposure to sunlight. According to the European Center for Ecotoxicology and Toxicology of Chemicals (ECETOC), 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.[3] The half-life of hydrogen peroxide in natural rivers ranged from 2.5 days when initial concentration was 10,000 ppm, to 20.1 days when initial concentration decreased to 100 ppm.[4] Biodegradability studies of acetic acid showed 99% degradation in 7 days under anaerobic conditions.[5] Acetic acid is not expected to concentrate in the waste water discharged to POTW. In wastewater, sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern at the proposed use levels.[6] Therefore, peroxyacetic acid, hydrogen peroxide, acetic acid and sulfuric acid are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. The remainder of this EA will therefore consider only the environmental introduction of HEDP.

The 2004 Human and Environmental Risk Assessment (HERA) reports that decomposition of HEDP contained in the discharged waste water occurs at a moderately slow pace, 33% in 28 days.[7] HEDP that is removed via sedimentation or filtration slowly degrades into carbon dioxide, water and phosphates. Phosphate anions are strongly bound to organic matter and soil particles, and phosphate is a required macronutrient of plants. The HERA report estimates a half-life of HEDP in soil of 373 days. Therefore, any aquatic or soil biodegradation of HEDP is not expected to lower the estimated EEC for HEDP.

The 2004 HERA publication on phosphonate indicates that 80-90% can be expected to adsorb to wastewater sludge. Therefore, the sludge partition EICs of HEDP are calculated by multiplying the stated HEDP use level concentration by 80% (use level x 0.8). Multiplying the use level by 20% (use level x 0.2) provides the HEDP concentration remaining in wastewater. The expected environmental concentrations (EECs) were calculated using a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW, as determined by Rapaport (Rapaport 1988). A summary of these calculations is shown below.

Application	**HEDP**	**EEC_{sludge} and EIC_{sludge}[a]**	**EIC_{water}**	**EEC_{water}[b]**
Whole or cut poultry, including carcasses, parts, trim, and organs	133	106.4	26.6	2.66
Whole or cut meat, including carcasses, parts, trim, and organs	120	96	24	2.4
Processed and pre-formed meat products	33	26.4	6.6	0.66
Processed and pre-formed poultry products	15	12	3	0.3
Brines, marinades and sauces applied on the surface or injected into processed or unprocessed, cooked or uncooked, whole or cut poultry	4	3.2	0.8	0.08
Surface sauces and marinades applied on processed and preformed meat and poultry products	4	3.2	0.8	0.08
Fish and seafood	15	12	3	0.3
Fruits and vegetables	23	18.4	4.6	0.46
Shell eggs	120	96	24	2.4
[a]EIC_{sludge} = HEDP x 80% [b]EEC_{water} = (HEDP x 20%) ÷ 10 dilution factor)				

8. Environmental Effects of Released Substances

Terrestrial Toxicity
According to the 2004 HERA report, HEDP in sludge is not expected to have any adverse environmental impact based on toxicity endpoints for terrestrial organisms. Specifically, HEDP shows no toxicity to terrestrial organisms (plants, earthworms, worms in soil, etc.) at levels up to 1000 mg/kg soil dry weight (No Observed Effect Concentration; NOEC). Therefore, there is no toxicity expected from land application of sludge containing 106.4 ppm HEDP.

Aquatic Toxicity

The 2004 HERA study demonstrates that toxic effects of HEDP result from chelation of nutrients, rather than direct toxicity to aquatic organisms. Chelation is not toxicologically relevant in the evaluation of the toxic effects of HEDP because eutrophication, not nutrient depletion, has been demonstrated as the controlling toxicological mode when evaluating wastewater discharges from food processing facilities.

Jaworska et al.,[8] and the HERA 2004 study on phosphonates have summarized the aquatic toxicity data for HEDP as shown in the table below:

Environmental Toxicity Data for HEDP		
Species	**Endpoint**	**mg/L**
Short Term		
Lepomis macrochirus[1]	96 hr LC_{50}	868
Oncorhynchus mykiss[1]	96 hr LC_{50}	360
Cyprinodon variegates[1]	96 hr LC_{50}	2180
Ictalurus punctatus[1]	96 hr LC_{50}	695
Leciscus idus melanatus[1]	48 hr LC_{50}	207-350
Daphnia magna[1]	24-48 hr EC_{50}	165-500
Planemonetes pugio[1]	96 hr EC_{50}	1770
Crassostrea virginica[1]	96 hr EC_{50}	89
Selenastrum capricornutum[2]	96 hr EC_{50}	3
Selenastrum capricornutum[1]	96 hr NOEC	1.3
Algae[2]	96 hr NOEC	0.74
Chlorella vulgaris[1]	48 hr NOEC	≥100
Pseudomonas putida[1]	30 minute NOEC	1000
Long Term		
Oncorhychus mykiss[1]	14 day NOEC	60-180
Daphnia magna[1]	28 day NOEC	10- <12.5
Algae[2]	14 day NOEC	13

[1]Data cited in Jaworska *et al.*
[2]Data cited in HERA Phosphonates, 2004

Jaworska et al. and HERA, 2004 found acute toxicity endpoints for HEDP ranged from 0.74 to 2180 mg/L, while chronic toxicity NOECs were 60-180 mg/L for the 14-day NOEC for *Oncorhychus mykiss*, and 10 - <12.5 mg/L for the 28-day NOEC for *Daphnia magna*. The highest short-term EC_{50} values reported by Jaworska et al. and HERA, 2004 for algae, *Selenastrum capricornutum* (3 ppm), *Daphnia magna* (165-500 ppm), and *Crassostrea virginica* (89 ppm), are considered to result from chelation effect, rather than intrinsic toxicity. Therefore, these values are not relevant in food processing wastewaters, where excess nutrients are present. The lowest relevant endpoint for food processing uses was determined by Jaworska et al. to be chronic NOEC of 10ppm for *Daphnia magna*.[9] In comparison, the HEDP maximum (worst-case) EEC value of 2.66 ppm in water for the proposed use of the FCS in poultry is well below the endpoint of 10 ppm chronic NOEC for *Daphnia magna*.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of waste solution because the components readily degrade. The FCS is expected to compete with, and to some degree replace similar HEDP stabilized peroxy antimicrobial agents already on the market. Thus, the FCS will consume comparable amounts of energy and resources as similar products. The raw materials that are used to manufacture the FCS are commercially manufactured chemicals that are produced for use in a variety of chemical reactions and production processes. Therefore, the energy used for the production of the FCS 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 dilute FCS mixture. Thus, the use of the FCS as proposed does not require mitigating measures.

11. Alternatives to the Proposed Action

No adverse environmental impacts are identified herein that would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would result in continued use of currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no significant environmental impact. The addition of the FCS to the options available to food processors is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Beatrice Maingi, Senior Manager, Regulatory Affairs & QA/QC Laboratory, LPR Technologies, 1501 E. 8th Street, North Little Rock, AR 72114. M.A and B.S. in Chemistry and MBA, 9 years of experience preparing regulatory submissions to international regulatory jurisdictions, 3 years preparing regulatory submissions to FSIS.

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of LPR Technologies.

Date: February 15, 2019

[redacted]

Beatrice Maingi
Senior Manager, Regulatory Affairs & QA/QC Laboratory
LPR Technologies

14. References

[1] USDA FSIS Federal Register Notice, "New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcements of Implementation Schedule," 76 Fed. Reg. 15282.
[2] Rapaport, Robert A., 1988. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7(2), 107-115. Found online at: http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/full
[3] European Center for Ecotoxicology and Toxicology of Chemicals, JACC No. 40: Peracetic Acid and Its Equilibrium Solutions, January 2001.
[4] European Center for Ecotoxicology and Toxicology of Chemicals, JACC No. 22: Hydrogen Peroxide, January 1993.
[5] U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemical Council, June 28, 2001.
[6] The Organization for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals, Sulfuric Acid, 2001, available online at http://www.inchem.org/documents/sids/sids/7664939.pdf
[7] HERA-Human and Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates, www.heraproject.com-Phosphonates
[8]Jaworska, J.; Van-Genderen-Takken, H.; Hanstveit, A.; van de Plasche, E.; Feijtel, T. Environmental risk assessment of phosphonates used in domestic laundry and cleaning agents in the Netherlands. *Chemosphere* 2002, 47, 655-665.
[9] *Ibid*