Environmental Assessment - Revised

1. **Date of REVISION:** - January 30, 2017
2. **Name of Applicant:** Ecolab, Inc.
3. **Address:** Ecolab, Inc
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All communication regarding this food contact notification environmental assessment should be sent in care of the authorized representative:

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Subsequent to the submission of this Environmental Assessment (on 4/21/2017) the notifier amended the intended use and limitations / specifications statement for this notification to remove use in processed and preformaed meat and poultry. This EA has been amended to remove any references to such use. There are no resulting changes to the provided analysis.

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil-S
Date: 2017.04.30 17:42:08 -04'00'

Mariellen Pfeil / 04/30/2017
Biologist / Acting Environmental Team Lead FDA -
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification is modification to current FCN 001495 permitting the use of an aqueous peroxyacetic acid mixture composed of peroxyacetic acid, hydrogen eroxide, acetic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP). The mixture is intended as an antimicrobial agent not to exceed a maximum concentration of peroxyacetic acid of 2000 ppm, hydrogen peroxide at a maximum use concentration of 1474 ppm, and 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP) at maximum use concentration of 118 ppm:

i. Process water applied a spray, wash, rinse, dip, chill and scald water for whole or cut meat including carcases, parts, trim and organs.

Currently (per existing FCN 001495), the same upper maximum peroxyacetic acid concentration of 2000 ppm, hydrogen peroxide at a maximum use concentration of 1474 ppm, 1-hydroxyethyliden-1,1-diphosphonic acid (HEDP) at maximium use concentration of 118 ppm; is FDA approved in process water used as a spray, wash, rinse, dip, chiller water or scald water for poultry as:

ii. Process water applied a spray, wash, rinse, dip, chill and scald water for whole or cut poultry including carcases, parts, trim and organs.

b. Need for Action:

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the meat and poultry or in process water, ice or brine used in the production and preparation of meat and poultry; thereby providing for safer meat and poultry products for consumers. The food contact substance (FCS) does not have an ongoing technical affect.

Over the past six years, U.S. Department of Agriculture Food Safety and Inspection Service (USDA FSIS) has invoked several initiatives and regulatory notices ad directives for continuous improvement in reduction of microvial contamination in meat and poultry products and safequard the food supply. In recent years, FSIS has tightened performance standards for several foodborne pathogens including *Salmonell, Campylobactor,* Listeria, *Escherichia coli* O157:H7 and non-O157 STEC as well as expanding meat and poultry product

categories tested. FSIS initiated a zero-tolerance policy for raw beef products containing six additional strains of shiga-toxin producing *E. coli* and increased sample size, testing frequency, specifically to improve meat safety. Sampling and data collection has also been initiated for *Salmonella* in pork.[1] Such efforts will strengthen and improve food safety and reduce outbreaks attributed to meat and poultry product.

Increased concentration use level limits for peroxyacetic acids are therefore necessary for meat processors as well as those granted to poultry processors in effort to meet evolving microbial pathogen performance standards set domestically and abroad (export trade).

The action requested is necessary to permit food processors flexibility in their use of peroxyacetic acid to adjust concentrations and use solutions up to maximum higher 2000 ppm concentration when deemed necessary to reduce microbial contamination on food products. Such clearance will allow meat and poultry processors to implement intervention strategies across those processing steps which present highest risk of microbial contamination and continuously reduce that risk along the processing line. This will ensure that a meat or poultry processor can meet current and future microbial performance standards and ensure a safe and wholesome product for consumers.

Where bacteria are present on the surface of the meat and poultry product, the peroxyacetic acid use-solution, applied at various intervention sites within a facility's process, provides increased microbiological reduction to help the processor achieve food safety goals, ultimately providing the consumer with safer food and reduce incidence of foodborne illness attributed to meat and poultry products.

c. Locations of Use/Disposal:

The peroxyacetic acid antimicrobial agent will be used in process water as a surface treatment to meat and poultry products processed in the United States. Peroxyacetic acid product is only intended for industrial applications in a controlled, federally inspected meat and poultry establishments. All waste process water containing the FCS at these plants is expected to enter the facility's wastewater treatment system. For the purposes of this Environmental Assessment, it is assumed that treated wastewater will be discharged directly to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit. This assumption can be considered a "worst-case" scenario since it does not take into account any further treatment that may occur at a Publically Owned Treatment Works (POTW). It is further assumed that very minor or negligible quantities of the FCS are lost via evaporation throughout the process. All other wastewater is collected and pre-treated by the facility before being sent to publically owned treatment works (POTW).

5. <u>Identification of Substances Subject to Proposed Action</u>:

Raw materials composing FCS include an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4). The equilibrium reaction between acetic acid and hydrogen peroxide generates peroxyacetic acid formation. Hydrogen peroxide is a necessary component of the equilibrium reaction that results in the formation and must be present to maintain stability of the formula. The presence of HEDP in the FCS formulation increases long-term storage stability. The concentrated product is diluted at a processing establishment to desired concentrations (maximum upper limit of 2000 ppm peroxyacetic acid, 1474 ppm hydrogen peroxide, 118 ppm HEDP).

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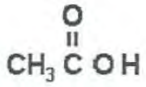
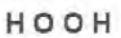
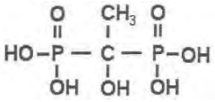
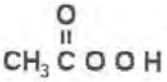
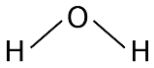
[1] United States Department of Agriculture Food Safety and Inspection Service (USDA FSIS) Notice 80-15 Raw Pork Products Exploratory Sampling Project (2015), available at http://www.fsis.usda.gov/wps/wcm/connect/25967a65-6013-4f38-80d8-61a100fe9f10/80-15.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=25967a65-6013-4f38-80d8-61a100fe9f10

Table 1: Chemical Identity of Substances of the Proposed Action

Chemical Substance	CAS No.	Structure	Molecular Weight (g/mol)
Acetic Acid	64-19-7		60.05
Hydrogen Peroxide	7722-84-1		34.01
1-hydroxyethylidene-1,1-diphosphonic acid (HEDP)	2809-21-4		206.03
Peroxyacetic Acid	79-21-0		76.05
Water	7732-18-5		18.01

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

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

The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. Ecolab, Inc. asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as I) 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 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 and Disposal

Introduction of dilute solutions of the product into the environment will take place primarily via release in 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 including spray, wash, rinse, dip, process

water, ice, brine and chill and scald applications onto poultry and meat carcasses, parts, trim, organs and the subsequent disposal of such water and spray drainage into the processing plant wastewater treatment facility.

Table 2: Summary of Intended Uses

Use	Peroxyacetic acid	Hydrogen Peroxide	HEDP
Spray, wash, rinse, dip, chill and scald water for whole or cut poultry including carcases, parts, trim and organs	2000 ppm	1474 ppm	118 ppm
Spray, wash, rinse, dip, chill and scald water for whole or cut meat including carcases, parts, trim and organs	2000 ppm	1474 ppm	118 ppm

Treatment of the process water at an on-site waste water treatment facility and/or at a Publicly Owned Treatment Works (POTW) is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid. Specifically, the peroxyacetic acid will break down into oxygen and acetic acid, while hydrogen peroxide will breakdown into oxygen and water.[2] Acetic acid undergoes dissociation in water to acetate anion and the hydrated proton. The anion is subsequently rapidly biodegraded by ambient aerobic microorganisms to carbon dioxide and water.[3] 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 therefore consider only the environmental introduction of HEDP.

Meat Processing Facilities – updated information for FCN 001495 modification. No Food Contact Notification modification is requested for poultry application or use limits.

Assuming, in the worst-case, that all of the water used in a processing plant is treated with the FCS, the total HEDP expected introduction concentrations (EICs) would be shown below. The HERA 2004 publication on phosphonates indicates that 80% - 90% of HEDP can be expected to adsorb to wastewater treatment sludge.[4] 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. To calculate the expected environmental concentrations (EECs), we have incorporated a conservative 10-fold dilution factor for discharge to surface waters of the effluent from an onsite treatment facility or POTW,[5] as indicated below.

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[2]Environmental Protection Agency, Reregistration Eligibility Decision: Peroxy Compounds (December 1993), p. 18.

[3]U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001.

[4]Human and Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products: Phosphonates (2004), available at http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

[5]Rapaport, Robert A.,1988 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.

Table 3: Worst-case EICs and Estimated Environmental Concentrations (EECs) for HEDP (ppm)

Use	HEDP Use Level=EIC_{Total}	EIC_{Sludge} = EEC_{Sludge}	EIC_{Water}	EEC_{Water}
Spray, wash, rinse, dip, chill and scald water for whole or cut poultry including carcases, parts, trim and organs	118	94.4	23.6	2.36
Spray, wash, rinse, dip, chill and scald water for whole or cut meat including carcases, parts, trim and organs	118	94.4	23.6	2.36

EEC_{Sludge} Value calculated as = EIC_{Total} x 80%

EIC_{Water} Value calculated as = EIC_{Total} x 20%

EEC_{Water} Value calculated as = EIC_{Water}/10

Because large-scale facilities do not typically process more than one type of food; we will use the level of 118 ppm for HEDP as the worst-case EIC_{Total} for all processing facilities using the FCS in the intended applications. Further, even if a POTW receives and mixes water from two different facilities employing the FCS, the maximum EEC will never be greater than the highest single-use concentration, calculated as 2.36 ppm HEDP. Therefore, the discussion of impacts from the use of the FCS will focus on comparing the meat/poultry processing EECs to appropriate ecotoxicity endpoints that are provided under Item 8.

7. Fate of Emitted Substances in the Environment

As noted and referenced above, treatment of the process water at an on-site waste water treatment facility or at a POTW is expected to result in completed degradation of peroxyacetic acid, hydrogen peroxide and acetic acid. The U.S. High Production Volume (HPV) Chemical Challenge Program determined that 99% of acetic acid degraded in 7 days under anaerobic conditions, and therefore acetic acid is not expected to concentrate in waste water that is discharged into municipal treatment plants.[6] Peroxyacetic acid and hydrogen peroxide rapidly degrade on contact with organic matter, transition metals, and exposure to sunlight. According to ECETOC, the half-life for peroxyacetic acid in buffered solutions was 64 hours (pH=7) for a 748 ppm solution and 48 hours (pH=7) for a 95 ppm solutions. The half-life for hydrogen peroxide varies based on the surface water.[7]

Removal of HEDP via sludge binding during wastewater treatment is the primary process pathway for removal of HEDP from wastewater.

[6]U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001

[7]ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals. JACC No. 40, “Peracetic Acid and its Equilibrium Solutions”, January 2001 and JACC No. 22, “Hydrogen Peroxide”, January 1993.

8. Environmental Effects of Released Substances

Terrestrial Toxicity

HEDP present in the sludge is not expected to have any adverse environmental impact based on the terrestrial toxicity endpoints available for plants, earthworms, and birds. Specifically, the NOEC for soil dwelling organisms was >1,000 mg/kg soil dry weight for earthworms in soil, while the 14-day LD50 for birds was >248 mg/kg body weight.[8] Using extremely conservative methodology, we have estimated an upper-bound concentration in sludge, not accounting for dilution upon mixing with soil of 94.4 ppm (i.e., 94.4 mg HEDP/kg sludge), which is well below the earthworm ecotoxicity endpoint cited. Therefore, no terrestrial environmental toxicity concerns exist at levels at which it is expected to be present in sludge. 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.[9]

Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized in public literature, and is shown in the following table[10]

Table 4: Summary of Environmental Toxicity Data for HEDP

Environmental Toxicity Data for HEDP		
Species	**Endpoint**	**mg/L**
Short Term		
Lepomis macrochirus	96 hr LC_{50}	868
Oncorhynchus mykiss	96 hr LC_{50}	360
Cyprinodon variegates	96 hr LC_{50}	2180
Ictalurus punctatus	96 hr LC_{50}	695
Leciscus idus melanatus	48 hr LC_{50}	207 – 350
Daphnia magna	24 – 48 hr LC_{50}	165 – 500
Planemonetes pugio	96 hr LC_{50}	1770
Crassostrea virginica	96 hr LC_{50}	89
Selenastrum capricornutum	96 hr LC_{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		
Oncorhychus mykiss	14 day NOEC	60 – 80
Daphnia Magna	28 day NOEC	10 - <12.5
Algae	14 day NOEC	13

Note: *Algae endpoint source found in HERA Phosphonates (2004)

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[8]Human and Environmental Risk Assessment (HERA) on ingredients of European Household Cleaning Products: Phosphonates (2004), Table 13, available at http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf

[9] *Ibid.*

[10]Jaworska, J.; Van Genderen-Takken, H.; Hanstveit, A.; van de Plassche, E.; Feijtel, T. Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in The Netherlands. Chemosphere 2002, 47(6), 655-665.

According to Jaworska *et.al* 2002, 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 EC_{50}/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. According to Jaworska, *et.al* 2002, the lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. The EEC_{Water} of 2.36 ppm is approximately 4-fold lower than the 10 ppm chronic NOEC for *Daphnia magna*.

9. Use of Resources and Energy

The notified use of the FCS mixture will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree, replace similar HEDP stabilized peroxyacetic acid antimicrobial agents already on the market. The manufacture of the antimicrobial agent will consume comparable amounts of energy and resources as similar products; and the raw materials used in the production of the mixture are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the diluted FCS mixture. Therefore, the mixture is not reasonably expected to result in any environmental issues that require mitigation measures of any kind.

11. Alternatives to Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification modification. 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 environmental impact. The addition of the antimicrobial agent to the options available to food processors is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Ms. Deborah Klein, Senior Regulatory Specialist II, Ecolab, Inc., 370 Wabasha Street, St. Paul, MN 55102. B.S. Animal Science with 37 years of experience with meat and poultry processing and regulatory and FCN submissions to USDA, FDA, and BCS.

Mr. Nathan Pechacek, Senior Manager, Regulatory Affairs, MS, DABT, Ecolab Inc., 386 Wabasha Street, St. Paul, MN 55102. B.S in Environmental Science and Ecology, minor in Chemistry; M.S. in Toxicology and Microbiology; Certified Toxicologist by the American Board of Toxicology, 17 years experience with FCN submissions and environmental risk assessments.

13. Certification

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

Date: January 30, 2017

[redacted]

Deborah Klein

[redacted]

Nathan Pechacek, MS, DABT