Environmental Assessment

1. Date:	August 2, 2017
2. Name of Applicant:	BioSafe Systems, LLC
3. Address:	Agent for Notifier: Mitchell Cheeseman, Ph.D. Steptoe & Johnson LLP 1330 Connecticut Avenue, NW Washington, DC 20036

4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the expanded use of the food contact substance (FCS) identified as an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, and 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP) and, optionally, sulfuric acid as an antimicrobial agent in the production and preparation of whole or cut meat. When used as intended, the components of the FCS mixture will not exceed 1800 ppm PAA, 675 ppm HP, and 51.4 ppm HEDP in process water, brine, or ice used for washing, rinsing, or cooling whole or cut meat, including carcasses, 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 food or in the process water, brine, or ice used during production.

In summary, the requested action to expand the currently approved uses of the FCS is needed to address current and future needs of meat 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 processing plants throughout the United States. Meat processors are among those industries required by the U.S. Environmental Protection Agency 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 either to surface waters under

---

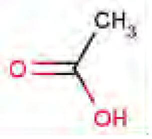
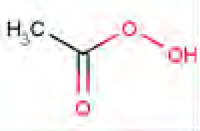
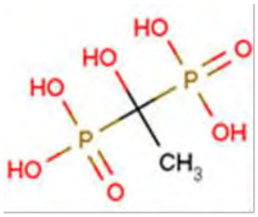
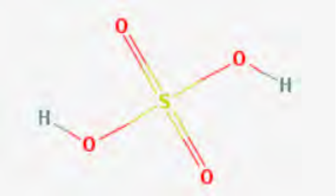
[1] 40 C.F.R. Part 432; additional information available at https://www.epa.gov/eg/meat-and-poultry-products-effluent-guidelines.

National Pollution Discharge Elimination System (NPDES) permitting or to a publicly owned treatment works (POTW). 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 consideration of the potential land application of biosolids, we have also estimated maximum potential concentrations in soil from this route of disposal. Very minor quantities are potentially lost to evaporation.

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

The raw materials used in this product are hydrogen peroxide, acetic acid, HEDP, water, and optionally sulfuric acid. 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
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)	2809-21-4	206.3		$C_2H_8O_7P_2$
Water	7732-18-5	18.01	H-O-H	H_2O
Sulfuric acid	7664-93-9	98		H_2SO_4

---

[2] https://www.epa.gov/biosolids/basic-information-about-biosolids.

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

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 this product, 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 a POTW.

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 application onto meat and the subsequent disposal of such water and spray drainage into on-site treatment plants and/or POTWs. The total amount of product used at a typical facility will vary significantly, depending on the equipment used and the amount of meat processed. The maximum at-use concentration of PAA, hydrogen peroxide, and HEDP for each application will be as follows:

Table 2: Summary of Intended Uses

Use	**PAA**	**H_20_2**	**HEDP**
Process water, brine, or ice used for washing, rinsing, or cooling whole or cut meat, including carcasses, parts, trim, and organs	1800 ppm	675 ppm	51.4 ppm

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.[3] Acetic acid undergoes dissociation in water to acetate anion and the hydrated proton, and the anion is subsequently biodegraded.[4] Furthermore, sulfuric acid will dissociate readily in the presence of water to sulfate ions and hydrated protons.[5] 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.

Although the total water usage may differ between processing plants, when the FCS is used in either application the maximum at-use concentration of HEDP in the wash water is limited to 51.4 ppm. Water is used in meat processing facilities for purposes other than carcass and meat washing (i.e. for cleaning, boiler water, cooling waters, etc.).[6] This additional water use will dilute the concentration of HEDP in the total water effluent to lower levels. Assuming, as a worst-case, that all of the water used in any processing plant is treated with the FCS, the total HEDP expected introduction concentration (EIC) would be as indicated above, namely 51.4 ppm.

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.[7] The HERA report cites 80% adsorption of HEDP to sewage treatment sludge.[8] We have estimated the potential environmental introductions of HEDP in water and sewage sludge applying the 20:80 partition factor from the HERA report. When the water from the facility treatment plant or POTW is discharged to surface waters, it will be diluted a further 10-fold.[9] The expected environmental concentration (EEC) is calculated on these bases and summarized below. Finally, we note that the EEC 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.

---

[3] U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993), p. 18, available at http://www.epa.gov/pesticides/reregistration/REDs/old_reds/peroxy_compounds.pdf.

[4] American Chemistry Council, Acetic Acid and Salts Panel, *U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category* ("ACC HPV Plan for Acetic Acid"), June 28, 2001, p. 5, available at https://iaspub.epa.gov/oppthpv/document_api.download?FILE=c13102tp.pdf.

[5] The Organization for Economic Cooperation and Development (OECD) SIDS Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), *Sulfuric Acid*, 2001, available at: http://webnet.oecd.org/HPV/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb.

[6] Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry*, 2006, Figure 3.2, p. 71.

[7] 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, pp. 19-22, available at http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf (hereafter, HERA Phosphonates).

[8] Id., Table 12, p. 22.

[9] 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), available at http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract.

Table 3: Worst-case EICs for HEDP

Use	EIC Total	EIC$_{\text{sludge}}$	EIC$_{\text{water}}$	EEC$_{\text{sludge}}$	EEC$_{\text{water}}$
Meat	51.4 ppm	41.1 ppm[10]	10.3 ppm[11]	41.1 ppm	1.0 ppm[12]

7. Fate of Emitted Substances in the Environment

As discussed above, treatment of the process water at an on-site waste water treatment facility or at a POTW is expected to result in complete degradation of PAA, hydrogen peroxide, and acetic acid. 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.[13] 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 when the concentration decreased to 250 ppm and 100 ppm, respectively.[14] In biodegradation studies of acetic acid using activated sludge, 99% degraded in 7 days under anaerobic conditions.[15] Acetic acid is not expected to concentrate in the wastewater discharged to the treatment facility/POTW.

Sulfuric acid is a strong mineral acid that is used as a catalyst during peracetic acid formation, and to stabilize the pH of the final equilibrium solution. It is totally miscible with water and readily dissociates to sulfate ions and hydrated protons, neither of which is of any toxicological concern at the use levels proposed by this FCN.[16] Small quantities of terrestrial or aquatic discharges are not expected to have any environmental effects, as sulfate is a ubiquitous anion already present in the ecosystem.[17] Furthermore, sources of sulfate such as sulfuric acid and sodium sulfate are widely distributed in nature, and present in nearly all bodies of fresh and salt water.[18] To this end, sulfate has a favorable ecological profile, participates in the sulfur cycle, and is a source of one of the most common ions found in all living organisms, where natural and industrial sources are virtually indistinguishable from one another.[19] Finally, due to the low aquatic and terrestrial toxicity and natural recycling that occurs in the sulfur cycle of earth's biosphere, there is no anticipated ecological impact on land, in water, or by air.[20]

HEDP will slowly degrade to carbon dioxide, water and phosphates. Decomposition of HEDP occurs at a moderately slow pace; a Dissolved Organic Carbon removal of 33% after 28

---

[10] 51.4 ppm × 80% = 41.1 ppm.

[11] 51.4 ppm × 20% = 10.3 ppm.

[12] 10.3 ppm ÷ 10 = 1.0 ppm.

[13] 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.

[14] 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.

[15] ACC HPV Plan for Acetic Acid, Appendix 1, p. 1.

[16] OECD SIDS, Sulfuric Acid.

[17] HERA, *Sodium Sulfate*, January 2006, available at http://www.heraproject.com/files/39-F-06_Sodium_Sulfate_Human_and_Environmental_Risk_Assessment_V2.pdf.

[18] Id., p. 4.

[19] Id., p. 5.

[20] Id.

days was observed in an inherent biodegradability test (Zahn-Wellens test).[21] Phosphate anions are strongly bound to organic matter and soil particles, further phosphate is a required macronutrient of plants. Based on the EEC for HEDP, we do not expect that any phosphates released from HEDP will result in a measurable increase in phosphates that are already present in soils that are modified with waste water sludge or water that receives treated effluent.

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.[22] Therefore HEDP is expected to degrade, albeit slowly, in soil. HEDP present in the soil as a result of land application 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 for earthworms in soil, while the 14-day LC_{50} for birds was >284 mg/kg body weight.[23] Using worst-case methodology, we have calculated a maximum estimated concentration in sludge of 41.1 ppm, not accounting for dilution upon mixing with soil, which is well below these ecotoxicity endpoints. 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

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
Crassostrea virginica	96 hr EC_{50}	89
Selenastrum capricornutum	96 hr EC_{50}	3
Selenastrum capricornutum	96 hr NOEC	1.3

---

[21] HERA Phosphonates, Table 7, p. 16.

[22] HERA Phosphonates, Table 9, p. 18.

[23] HERA Phosphonates, Table 13, p. 30.

[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, , *Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands*, Chemosphere 2002, 47(6), 655-665, May 2002, p. 662 (2004). Short term values for *Selenastrum capricornutum*, and short and long term values for algae found in HERA Phosphonates (2004) (Tables 13 and 14, p. 29-31).

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 1.0 ppm is 10-fold lower than the 10 ppm chronic NOEC for *Daphnia magna*.

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 FCS is expected to compete with, and to some degree replace similar HEDP-stabilized peroxyacetic acid antimicrobial agents already on the market. 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, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures.

---

[25] Jaworska, et al (2004).

[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 (2004).

11. Alternatives to the Proposed Action

No potential 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 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.

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

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: August 2, 2017

[redacted]

Mitchell Cheeseman, PhD

14. References

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.

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.

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.

ECETOC, *JACC No. 22, Hydrogen Peroxide*, January, 1993.

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.

HERA on Ingredients of Household Cleaning Products, *Sodium Sulfate*, January 2006.

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.

OECD, *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A guideline to Application*, OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 54 Environmental Directorate, Paris, 2006.

The Organization for Economic Cooperation and Development (OECD SIDS Voluntary Testing Programme for International High Production Volume Chemicals, *Sulfuric Acid*, 2001.

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.

U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993).

Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry*, 2006.

15. Attachments

No attachments.