ENVIRONMENTAL ASSESSMENT
ALEX C. FERGUSSON, LLC
FOOD-CONTACT NOTIFICATION

1. Date: August 4, 2016

2. Name of Applicant: Alex C. Fergusson, LLC (AFCO)

3. Address:

All communications on this matter are to be sent in care of Counsel for the Notifier:

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4. Description of the 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), an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), and optionally sulfuric acid as an antimicrobial agent for use in process water and ice used in the production and preparation of meat and processed and pre-formed meat. Although sulfuric acid is identified as an optional component of the FCS formulation, it is explicitly identified as an optional component of the FCS only for the purpose of registration of the product under FIFRA, and during USDA/FSIS inspection of meat and poultry facilities, to avoid any confusion in the interpretation of the food additive status by these agencies.

The composition and intended use of the FCS mixture are identical to that described in effective FCN 1490. Specifically, the concentrations of the components of the FCS mixture are not intended to exceed:

(1) 1800 ppm peroxyacetic acid (PAA), 600 ppm hydrogen peroxide (HP), and 12 ppm 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) in process water or ice used for washing, rinsing, or cooling whole or cut meat including carcasses, parts, trim, and organs; and,

(2) 495 ppm PAA, 165 ppm HP, and 6 ppm HEDP in process water, brine, or ice used for washing, rinsing, or cooling processed and pre-formed meat.

B. Need for Action

This FCS is intended for use as an antimicrobial to inhibit the growth of undesirable or pathogenic microorganisms in process water and ice used in the production and preparation of meat and processed and pre-formed meat. The notified maximum concentration (up to 1800 ppm PAA) is intended to provide processing plants the ability to use higher treatment concentrations when circumstances of increased microbial stress necessitate. This product is especially effective against human pathogens like *Salmonella sp*. and *Listeria sp*. In meat processing operations, pathogenic microorganisms are potentially better controlled by exposure to high concentrations of PAA at lower exposure times rather than lower concentrations at higher exposure times (dose-responsive rather than time-responsive). Extending the antimicrobial treatment concentration range allows processing plants more flexibility in utilizing and managing dose-responsive interventions.

C. Locations of Use/Disposal

The antimicrobial agent is intended for use in meat processing facilities throughout the United States. The waste process water containing the FCS generated at such facilities is expected to be disposed of through the processing plant wastewater treatment facilities or collected and treated by the facility before being sent to a publicly owned treatment works (POTW). Very minor quantities of the solution are potentially lost to evaporation through the process.

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

The raw materials used in this product are hydrogen peroxide, acetic acid, HEDP, sulfuric acid (optionally) and water. Peroxyacetic acid formation is the result of an equilibrium reaction between hydrogen peroxide and acetic acid.

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. Information available to the Notifier does not suggest that there are any extraordinary circumstances, in this case, indicating any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements are not provided here.

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

Treatment of the process water at an on-site wastewater 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.[1] Specifically, the peroxyacetic acid will break down into oxygen and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water.[2] 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.

Sulfuric acid is a strong, diprotic, mineral acid that dissociates readily in water to sulfate ions and hydrated protons; it is totally miscible with water. OECD reports the second pK_a of 1.92 at 25°C. So, at environmentally relevant concentrations sulfuric acid is practically totally dissociated. This total ionization implies that sulfuric acid will not adsorb to particulate matter or accumulate in living tissues.[3]

As noted in Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006: "Sodium sulfate is not biodegradable in the legal sense of the word, but it takes part in the sulfur cycle, in which sulfate is either incorporated into living organisms or reduced to sulfides by anaerobic bacteria, deposited as sulfur, or re-oxidized in the atmosphere and oceans to sulfur dioxide and sulfate. It has been estimated that the amount of sulfur globally contributed to the atmosphere from all natural and man-made sources is about 100 to 200 million tons. If all sulfur from the above-mentioned sodium sulfate production were to go into the atmosphere, it would contribute less than 0.25% to the world's total."[4]

Sodium sulfate/sulfuric acid are substances with favorable ecological profiles. Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of sodium sulfate does not present a major hazard to the environment although locally, peak concentrations may be damaging to un-adapted flora and fauna.[5]

The remainder of the environmental assessment will therefore consider only the environmental introduction, fate and potential effects of HEDP.

Assuming, in the worst-case, that all of the water used in any processing plant is treated with the FCS, the total HEDP expected introduction concentrations (EICs) would be as shown in the table below. Specifically, 80 - 90% of HEDP will adsorb to wastewater treatment sludge.[5] FDA calculates the sludge partition EICs of HEDP by multiplying the stated HEDP use level

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

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

[3] The Organisation for Economic Co-operation and Development (OECD) SIDS Voluntary Testing Program for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001.

[4] Human and Environmental Risk Assessment (HERA) on ingredients of Household Cleaning Products, Sodium Sulfate, January 2006.

[5] *Ibid.*

concentration by 80% (use level × 0.8). The remaining 20% (use level × 0.2) is attributed to HEDP remaining in wastewater. To estimate 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,[6] as indicated below.

Use	HEDP Use Level = EIC_{Total}	EIC_{Sludge} = EEC_{Sludge}	EIC_{Water}	EEC_{Water}
Meat Processing	12 ppm	9.6 ppm	2.4 ppm	0.24 ppm
Processed and Preformed meat	6 ppm	4.8 ppm	1.2 ppm	0.12 ppm

Because large-scale facilities do not typically process more than one type of food, we will use the use level of 12 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, *i.e.,* 2.4 ppm HEDP. Therefore, the discussion of impacts from use of the FCS will focus on comparing the meat processing EECs to appropriate ecotoxicity endpoints that are provided under Item 8.

7. Fate of Emitted Substances in the Environment

Due to the very low EEC expected from the highest use concentration, consideration of biodegradation is unnecessary. 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

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 LC_{50} for birds was >248 mg/kg body weight.[7] Using extremely conservative methodology, we have estimated an upper-bound concentration in sludge, not accounting for dilution upon mixing with soil of 9.6 ppm, which is well below these ecotoxicity endpoints. 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

[6] 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.

[7] 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.

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.[8] When wastewater encounters the land, any increase in phosphates in soil will be only a minimal amount of the total phosphorus concentrations that already exist in the environment.[9]

Aquatic Toxicity

The available data on the aquatic toxicity of HEDP has been summarized in the public literature, and is shown in the following table.[10]

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 melonatus	48 hr LC_{50}	207 – 350
Daphnia magna	24 – 48 hr EC_{50}	165 – 500
Palaemonetes pugio	96 hr LC_{50}	1770
Crassostrea virginica	96 hr EC_{50}	89
Selenastrum capricornutum[a]	96 hr LC_{50}	3
Selenastrum capricornutum	96 hr NOEC	1.3
Algae[a]	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 – 80
Daphnia Magna	28 day NOEC	10 - <12.5
Algae[a]	14 day NOEC	13

[a] *The source for this endpoint is the HERA Phosphonates, 2004.*

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

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8 *Ibid*.

9 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.

10 Jaworska, J.; Van Genderen-Takken, H.; Han stveit, A.; van de Plassche, E.; Feijtel, T. Environmental risk assessment ofphosphonates, used in domestic industry and cleaning agents in the Netherlands. Chemosphere 2002, 47, 655-665.

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*. Although FDA has previously noted that uncertainties intrinsic to its derivation make the usefulness of the NOEC/NOEL debatable, the agency has previously indicated that a NOEC for *Daphnia Magna* is an appropriate benchmark for environmental toxicology.[11] The highly conservative upper-bound EEC of 0.24 ppm is greater than 40-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 waste solution because the components readily degrade. The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, 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. Therefore, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse effects are identified herein which would necessitate alternative actions to that proposed in this 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 processors is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Mark A. Hepp, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Dr. Hepp has a Ph.D. in chemistry with 20 years of experience in reviewing and preparing food-contact notifications, environmental assessments and findings of no significant impact for both the federal government and the private sector.

David J. Ettinger, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. J.D. with 16 years of experience with FCN submissions and environmental assessments.

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[11] *See e.g.* environmental reviews of FCN 1379 and 1419.

13. Certification

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

David J. Ettinger
Counsel for Notifier