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

1. Date: May 18, 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 in process water used in the production and preparation of shell eggs. The concentrations of the components of the FCS mixture are not intended to exceed 2000 ppm peroxyacetic acid (PAA), 800 ppm hydrogen peroxide (HP), and 96 ppm 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP).

FCN 1501 already provides for the use of a substantially identical peroxyacetic acid solution[1] as a component of shell egg wash solutions; *i.e.* the identical use proposed here. A

[1] Peroxyacetic acid solutions are made by many manufacturers using the same raw materials that are available to all in the commodity chemical markets. Thus, the only differences between various products are the final concentrations of PAA, HP and HEDP. Impurity profiles are expected to fluctuate around the typical variations in the raw materials which are the same for all PAA solution manufacturers.

comparison of the compositions of the solutions identified in the instant FCN with that identified in FCN 1501 is shown as follows:

	PAA	HP	HEDP
This FCN	2000	800	96
FCN 1501	2000	933	120

Importantly, the maximum PAA concentration (the active ingredient) in the instant notification is identical to the maximum concentration authorized by FCN 1501. Because both the proposed use and the maximum concentration of PAA are identical to that authorized by FCN 1501, it is clear that there can be no new environmental introductions of PAA when this notification becomes effective and is then able to compete in the same markets as the product currently marketed by a different manufacturer under FCN 1501.

It is also notable that the maximum proposed use levels of HP and HEDP in the instant notification are very similar but slightly ***below*** those previously authorized by FCN 1501. Again, because the proposed use is identical, and the maximum concentrations of these substances are slightly less than those authorized by FCN 1501, it is again clear that there can be no new environmental introductions of HP and HEDP when this notification becomes effective and is then able to compete in the same markets as the product that is currently marketed by a different manufacturer under FCN 1501. Because the proposed use levels of hydrogen peroxide and HEDP are slightly below those already authorized by FCN 1501, any estimated environmental introductions of these two substances would be expected to slightly decrease as a result of this FCN becoming effective

B. Need for Action

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present in wash water or on the shell eggs. It is needed to provide additional options for increased flexibility in the development of effective food safety programs and procedures at egg processing facilities.

C. Locations of Use/Disposal

The antimicrobial agent is intended for use in egg processing facilities throughout the United States. As indicated in the environmental assessment for FCN 1501, the waste process water containing the FCS generated at facilities is expected to be disposed of through the processing plant wastewater treatment facilities, and discharged directly to surface water in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit, or collected and treated by the facility before being sent to a publicly owned treatment works (POTW). Very minor quantities of the solution are 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.[2] 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.[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.

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.[4]

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

Assuming that all of the water used in an egg processing plant is treated with the FCS, the HEDP concentration in the untreated plant waste water would be equivalent to the at-use concentration of 96 ppm. Waste water containing the FCS is first disposed of through on-site wastewater treatment facilities or through local publically owned treatment works (POTW) where a significant dilution would occur, prior to discharge to surface waters. We use an on-site treatment plant that treats only water containing the FCS as an illustrative worst-case employing no dilution factor at the treatment facility. Approximately 80% of the HEDP is expected to absorb to sludge at the treatment facility while the remainder will remain with the water.[5] Thus,

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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 Category; American Chemistry Council, June 28, 2001.

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

5 Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning Products: Phosphonates (2004).

the HEDP concentration in the sludge would be 80% of the at-use level or 77 ppm and the concentration in the water following treatment would be 20% or 20 ppm.

7. Fate of Emitted Substances in the Environment

The sludge is expected to be applied to land as a soil amendment where significant dilution will occur upon mixing with soil and perhaps sludge from other sources. The water is expected to be discharged to surface waters where at least a 10-fold dilution will occur upon mixing with surface waters.[6] Thus, the very conservatively Estimated Environmental Concentration in sludge would be 77 ppm, and the Estimated Environmental Concentration in water would be 2 ppm (20 ppm ÷ 10-fold dilution).

HERA reports that decomposition of HEDP occurs at a moderately slow pace using standard test methods, 33% in 28 days. The primary literature indicates however, that phosphonate utilizing bacteria are ubiquitous in the environment.[7] HEDP removed via sludge would be expected, in the worst-case, to be slowly degraded to carbon dioxide, water and phosphates. Phosphate anions are strongly bound to organic matter and soil particles, further, phosphate is a required macronutrient of plants.

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).[8] Our upper-bound estimated concentration in sludge, not accounting for dilution upon mixing with soil is 77 ppm, which is almost 13-fold below this the NOEC level. The maximum concentration in soil when used as a soil amendment should have an even larger margin of safety with respect to the NOEC level. Therefore, there is no toxicity expected below l000 mg/kg and the FCS is not expected to have any terrestrial environmental toxicity concerns 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] When wastewater

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[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] D. Schowanek and W. Verstraete, Phosphonate Utilization by Bacterial Cultures and Enrichments from Environmental Samples; Applied and Environmental Microbiology, 54 (1990), p. 895-903.

[8] 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.

[9] *Ibid*.

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.[10]

b. Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized (Jaworska, *et al*.), and is shown in the following table:

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 EC50/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*. Although FDA has previously noted that uncertainties intrinsic to its derivation make the usefulness of the

10 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.

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 2 ppm is approximately 5-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, with the exception of HEDP, readily degrade. Impacts to energy and resources relating to the use of HEDP are not anticipated as the use of HEDP is substitutional to other peroxy antimicrobials stabilized with HEDP. 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 over 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

Date: May 18, 2016