

Memorandum

Date: January 30, 2018

To: Elizabeth Furukawa, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275

Through: Leah Proffitt, Acting Supervisor, Environmental Review Team, Office of Food Additive Safety (HFS-255)

From: Biologist, Environmental Review Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1856 (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; 1-hydroxyethylidene-1,1-diphosphonic acid, CAS Reg. No. 2809-21-4; and optionally sulfuric acid, CAS Reg. No. 7664-93-9)

Notifier: Valley Chemical Solutions

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 1856, which is for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1, 1-diphosphonic acid, and optionally sulfuric acid as an antimicrobial in brines, sauces, and marinades applied on the surface or injected into processed or unprocessed cooked or uncooked whole or cut meat or poultry, parts and pieces thereof; and processed and preformed meat and poultry products

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated December 21, 2017, may be made available to the public. We will post digital transcriptions of the FONSI, revision sheet and the environmental assessment on the agency's public website.

Please let us know if there is any change in the identity or use of the food contact substance.

Sarah C. Winfield

Attachments: Finding of No Significant Impact
Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1856, submitted by Valley Chemical Solutions for the use of an aqueous mixture of peroxyacetic acid (PAA, CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP, CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) as an antimicrobial agent in: (1) brines, sauces, and marinades applied on the surface or injected into processed or unprocessed cooked or uncooked whole or cut meat or poultry, parts and pieces thereof; (2) brines, sauces, and marinades applied on the surface or injected into processed and preformed meat and poultry products. The FCS may be used in brines, sauces, and marinades at a level not to exceed 50 ppm PAA, 19 ppm hydrogen peroxide, and 8 ppm HEDP.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated December 21, 2017. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI), and is briefly summarized below.

Manufacture of the FCS is not expected to result in environmental introduction, nor adverse environmental impact. When the FCS is used as an antimicrobial in brines, sauces, and marinades at poultry and meat processing facilities, environmental introduction could occur via wastewater. It is expected that wastewater from an on-site wastewater treatment facility will discharge to a Publicly Owned Treatment Works (POTW) or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters. Land application of sewage treatment sludge could result in terrestrial introduction of the FCS.

Complete degradation of the FCS components (except HEDP) is expected to occur during treatment at the on-site wastewater treatment plant or POTW. Specifically, peroxyacetic acid will breakdown into oxygen, water and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid is expected to dissociate in wastewater and degrade at the wastewater treatment facility/POTW. 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. As such, the environmental impacts of these FCS components are not considered in further detail in the EA. The EA focuses on the environmental fate and effects of HEDP.

Assuming, as a worst-case, that all the water used in a processing plant is treated with the FCS, the maximum concentration of HEDP in wastewater would be equal to the use level of 8 ppm. Environmental Introduction Concentrations (EICs) were calculated assuming 80 percent of the HEDP partitions to sludge during on-site wastewater treatment (and 20 percent of the HEDP remains in the water). Expected Environmental Concentrations (EECs) were calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. Therefore, the terrestrial EEC for HEDP is 6.4 ppm ($8 \text{ ppm} * 0.80$) and the aquatic EEC for HEDP is 0.16 ppm ($[8 \text{ ppm} * 0.20] / 10$).

In evaluation of terrestrial toxicity, HEDP shows no toxicity to earthworms at levels up to 1,000 mg/kg (ppm) soil dry weight (No Observed Effect Concentration [NOEC]) and no toxicity to birds at levels up to 284 mg/kg body weight. The terrestrial HEDP EEC in sludge from the proposed use is 6.4 ppm, lower than both terrestrial toxicity levels, therefore there is no toxicity expected from land application of sludge that contains HEDP from the proposed use of the FCS. In evaluation of the aquatic toxicity of the FCS, the lowest relevant HEDP concentration for aquatic toxicity was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. Since the calculated aquatic HEDP EEC is 0.16 ppm and is lower than the

10 ppm chronic NOEC for *Daphnia magna*, the proposed use of the FCS is not expected to have an adverse effect on aquatic organisms.

We do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to those proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of materials which the FCS would otherwise replace (i.e., similar HEDP-stabilized peroxyacetic acid antimicrobial agents already on the market); such action would have no significant environmental impact. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts, mitigation measures are not identified.

The use of the FCS, as described in FCN 1856, as an antimicrobial in brines, sauces, and marinades for use in poultry and meat processing, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 01-30-2018

Sarah C. Winfield

Biologist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 01-30-2018

Leah Proffitt

Acting Supervisor, Environmental Review Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

U.S. Food and Drug Administration Revision Sheet for the December 21, 2017 EA for FCN 1856

Dated: January 30, 2018

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of December 21, 2017 for food contact notification (FCN) 1856 concluded that the action will not constitute a significant impact. The revision is issued to make a minor change and update of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to explain the following:

- On page 4 of the EA the reader is directed to Footnote 11, however, the reference that supports the preceding text is described in Footnote 10 (OECD, 2001, Sulfuric Acid).
- On page 5 of the EA the reader is directed to Footnote 12, however, the reference that supports the preceding text is described in Footnote 11 (HERA, 2006, Sodium sulfate).
- On page 5, under Item 6 b. of the EA the EIC_{water} should be reported as 1.6 ppm ($8 \text{ ppm} * 0.2 = 1.6 \text{ ppm}$) and the EEC_{water} should be reported as 0.16 ppm ($1.6 \text{ ppm} / 10 = 0.16 \text{ ppm}$).
- On page 6 of the EA Footnote 7 should refer to the following reference:
ECETOC. (2001). Peracetic Acid (CAS No. 79-21-0) and its Equilibrium Solutions. JACC No. 40. European Centre for Ecotoxicology and Toxicology of Chemicals. Brussels, January 2001. Available at: <http://www.ecetoc.org/publication/jacc-report-40-peracetic-acid-and-itsequilibriumsolutions/>
- On page 6 of the EA Footnote 8 should refer to the following reference:
ECETOC. (1993). Hydrogen Peroxide. JACC No. 22. European Centre for Ecotoxicology and Toxicology of Chemicals, January, 1993