

Memorandum

Date: September 19, 2018

From: Staff Fellow, Division of Biotechnology and GRAS Notice Review, HFS-255

To: Vivian Gilliam, Consumer Safety Officer, Division of Food Contact Notifications, HFS-275

Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety (HFS-255)

Subject: Finding of No Significant Impact for Food Contact Notification 1911: 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-hydroxyethylidine-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9)

Notifier: Xgenex, LLC

Attached is the Finding of No Significant Impact (FONSI) for Food Contact substance Notification (FCN) 1911, which is for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidine-1, 1-diphosphonic acid, and optionally sulfuric acid as an antimicrobial in process water, ice, and brine used in the production, processing, and preparation of meat and poultry products, fish, seafood, fruits, and vegetables.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated August 3, 2018, 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.

Denis Wafula

Attachments:

Finding of No Significant Impact

Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1911, submitted by Xgenex, LLC 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-hydroxyethylidine-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 process water, ice, and brine used in the production, processing, and preparation of meat and poultry products, fish, seafood, fruits, and vegetables. The components of the FCS mixture will not exceed:

1. 2000 ppm PAA, 950 ppm HP, and 57 ppm HEDP in process water and ice that contacts whole or cut poultry or meat carcasses, parts, trim, and organs;
2. 350 ppm PAA, 165 ppm HP, and 10 ppm HEDP in process water and ice that contacts fruits and vegetables in a food processing facility; and
3. 230 ppm PAA, 110 ppm HP, and 7 ppm HEDP, in process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed meat and poultry, or in process water or ice used to commercially prepare fish and seafood.

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), August 3, 2018. 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 the production, processing, and preparation of meat and poultry products, fish, seafood, fruits, and vegetables, 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.

It is expected that wastewater treatment at the on-site wastewater treatment plant or POTW will result in the complete degradation of all the components of the FCS except HEDP. 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 57 ppm used meat and poultry products. 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 45.6 ppm ($57 \text{ ppm} \times 0.80$) and the aquatic EEC for HEDP is 1.14 ppm ($[57 \text{ ppm} \times 0.20] / 10$).

Terrestrial toxicity studies show that at the intended use levels, the maximum concentrations of HEDP that could be expected to be present in the treated wastewater or land-applied sludge are not expected to have any adverse environmental impacts. 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 (45.6) ppm is 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. The relevant 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 1.14 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, because 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 1911, as an antimicrobial in the production, processing, and preparation of meat and poultry products, fish, seafood, fruits, and vegetables will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 09-19-2018
Denis Wafula
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____ Date: digitally signed 09-21-2018
Mariellen Pfeil
Supervisory Biologist, 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 August 3, 2018 EA for FCN 1911

Dated: September 18, 2018

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of August 3, 2018 for food contact notification (FCN) 1911 concluded that the action will not constitute a significant impact. The revision is issued to make changes and clarifications 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 1 Section 4a of the EA, the reader is directed to note that the description of the food groups that the FCS can contact was clarified and the description listed in the FONSI is the accurate one.
- In section 4c (pages 2-4) of the EA, the notifier implies that after use the solution containing the FCS will either drain off the food and pool on the floor of the food processing facilities (as in the case of meat processing facilities) or run into the drains to unspecified locations. It should be noted that in all instances apart from on-board seafood processing, wastewater containing the FCS is expected to be disposed of through the processing plants' on-site wastewater treatment facility before discharging either to surface waters under National Pollution Discharge Elimination System (NPDES) permitting or to a publicly-owned treatments works (POTW).
- On page 7, the structural formula of sulfuric acid should have the normal letter 'S'.
- On page 10 of the EA, footnote 4 should refer to the following reference:

U.S. High Production Volume (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category. Acetic Acid and Salts Panel, American Chemistry Council, June 28, 2001.
- On page 13 Section 8 of the EA, the correct species names in the table titled 'Environmental Toxicity Data for HEDP' should be *Leuciscus idus melanotus* instead of *Leciscus idus melanotus* and *Palaemonetes pugio* instead of *Palanemonetes pugio*. In the same table, the notifier states that all the data originates from Jarworska et al. (2002) however, data for *Selenastrum capricornutum* (96 hr LC50) and the two Algae end points are sourced from Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning products, Phosphonates, 2004.