

Memorandum

Date: September 27, 2022

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

To: Anita Chang, Ph.D., Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2236: 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 (HEDP) (CAS Reg. No. 2809-21-4), and optionally, octanoic acid (CAS Reg. No. 124-07-2) and peroxyoctanoic acid (CAS Reg. No. 33734-57-5)

Notifier: Safe Foods Corporation

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
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Attached is the FONSI for FCN 2236 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2236 is for the use of 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 (HEDP) (CAS Reg. No. 2809-21-4), and optionally, octanoic acid (CAS Reg. No. 124-07-2) and peroxyoctanoic acid (CAS Reg. No. 33734-57-5) as an antimicrobial agent used in process water or ice used in washing, rinsing, or cooling whole or cut meat carcasses, parts, trim, and organs. The maximum concentration of all peroxyacids in the FCS will be 1800 parts per million (ppm), the maximum concentration of hydrogen peroxide will be 1050 ppm, and the maximum concentration of HEDP will be 117 ppm.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated August 17, 2022, may be made available to the public. We will post digital transcriptions of the FONSI 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 -S Digitally signed by Denis Wafula -S
Date: 2022.09.27 15:26:48 -04'00'

Denis Wafula

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2236, submitted by Safe Foods Corporation for the use of 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 (HEDP) (CAS Reg. No. 2809-21-4), and optionally, octanoic acid (CAS Reg. No. 124-07-2) and peroxyoctanoic acid (CAS Reg. No. 33734-57-5) as an antimicrobial agent used in process water or ice used in washing, rinsing, or cooling whole or cut meat carcasses, parts, trim, and organs. The maximum concentration of all peroxyacids in the FCS will be 1800 parts per million (ppm), the maximum concentration of hydrogen peroxide will be 1050 ppm, and the maximum concentration of HEDP will be 117 ppm.

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 August 17, 2022. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below.

The antimicrobial agent is needed reduce or inhibit the growth of pathogenic and non-pathogenic microorganisms that may be present on and in food.

Wastewater from the above-described uses will be either discharged ultimately to a publicly owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite treatment.

Peroxyacetic and peroxyoctanoic acids are expected to decompose rapidly in the environment to form octanoic acid, acetic acid, and oxygen. Octanoic acid and acetic acid are expected to rapidly degrade biotically to carbon dioxide and water. Hydrogen peroxide is also expected to rapidly decompose to oxygen and water during treatment of the process wastewater or immediately after discharge of treated wastewater to the environment. Thus, the focus of the environmental analysis is on HEDP. HEDP is a chelating agent and exhibits unique partitioning behavior such that 80% adsorbs to wastewater treatment sludge, while the remaining 20% stays in the water. The HEDP use level of 117 ppm is used to estimate environmental introduction concentrations. Application of the 80:20 sludge: water adsorption factor and 10-fold dilution upon discharge to surface waters yields an EEC of 93.6 ppm for sludge, and 2.3 ppm for water. These concentrations are below the toxicity endpoints for soil (1000 mg/kg NOEC red worms) and water (10 mg/L NOEC *Daphnia magna*). Therefore, there is no toxicity expected from any land application of sludge containing 93.6 ppm HEDP. Similarly, discharge to surface waters of effluent containing 2.3 ppm HEDP is not expected to have toxic effects.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant adverse impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be continued use of currently approved antimicrobial agents; such action would have no significant environmental impact.

As evaluated in the EA, the use of the FCS as described in FCN 2236 is not expected to significantly affect the human environment, and therefore an EIS will not be prepared.

Prepared by **Denis Wafula -S** Digitally signed by Denis Wafula -S
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Denis Wafula, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by **Mariellen Pfeil -S** Digitally signed by Mariellen Pfeil -S
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