

## Memorandum

**Date:** June 14, 2023

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

**To:** Lillian Mawby, Ph.D., Division of Food Contact Substances (HFS-275)

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2291: An aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (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 sulfuric acid (CAS Reg. No. 7664-93-9).

**Notifier:** Enviro Tech Chemical Services, Inc

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S  
Date: 2023.06.14 10:21:51 -0400

Attached is the FONSI for FCN 2291 for the use of the above-described FCS as an antimicrobial agent used in process water or ice used in the production, processing, and preparation of (1) whole or cut meat including hides, carcasses, parts, trim, and organs, (2) whole or cut poultry including carcasses, parts, trim, and organs, and (3) fruits and vegetables.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated June 7, 2023, 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: 2023.06.14 09:34:49 -0400

**Attachment:** Finding of No Significant Impact

## FINDING OF NO SIGNIFICANT IMPACT

**Proposed Action:** Food Contact Substance (FCS) Notification (FCN) 2291, submitted by Enviro Tech Chemical Services, Inc for the use of an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (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 sulfuric acid (CAS Reg. No. 7664-93-9) as an antimicrobial agent used in process water or ice used in the production, processing, and preparation of (1) whole or cut meat including hides, carcasses, parts, trim, and organs, (2) whole or cut poultry including carcasses, parts, trim, and organs, and (3) fruits and vegetables.

The FCS will be used at levels not to exceed:

1. 2000 ppm PAA, 800 ppm HP, and 80 ppm HEDP in process water or ice used for washing, rinsing, or cooling whole or cut meat, including hides, carcasses, parts, trim, and organs;
2. 2000 ppm PAA, 770 ppm HP, and 100 ppm HEDP in process water or ice applied as a spray, wash, rinse, dip, chiller water, low temperature (e.g., less than 40 °F) immersion baths, or scald water for washing, rinsing, or cooling whole or cut poultry, including carcasses, parts, trim, and organs, and
3. 500 ppm PAA, 115 ppm HP, and 14 ppm HEDP in process water or ice used for washing or chilling fruits and vegetables in food processing facilities.

The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

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 June 7, 2023. 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 eliminate pathogenic microorganisms on (1) whole or cut meat including hides, carcasses, parts, trim, and organs, (2) whole or cut poultry including carcasses, parts, trim, and organs, and (3) fruits and vegetables

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.

The complete and rapid degradation of PAA, HP, and acetic acid is expected during treatment of the process wastewater or immediately after discharge of treated wastewater to the environment. Specifically, the PAA will decompose into oxygen and acetic acid. While HP will decompose into oxygen and water. Acetic acid will be rapidly biodegraded to carbon dioxide and water. Sulfuric acid dissociates readily in water to sulfate ions and hydrated protons which are not of environmental concern at the expected use levels. 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 column. The maximum HEDP use level of 100 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 80 ppm for sludge, and 2 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 80 ppm HEDP. Similarly, discharge to

surface waters of effluent containing 2 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 2291 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  
Date: 2023.06.14 09:35:41 -04'00'

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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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