U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: February 1, 2023

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

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2266
An aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722- 84-1), acetic acid (AA) (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) as an antimicrobial agent.

Notifier: Safe Foods Chemical Innovations and LPR Technologies

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 2266 for the use of the above-described FCS as an antimicrobial agent used in process water, ice, brine, sauces, or marinades used in the production, processing, and preparation of poultry, meat, processed and pre-formed meat and poultry, fish, seafood, fruits, vegetables, and shell eggs.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated December 29, 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.

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Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2266, submitted by Safe Foods Chemical Innovations and LPR Technologies 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 (AA) (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) as an antimicrobial agent used in:

1. Process water, ice, or brine used in the production, processing, and preparation of poultry, meat, processed and preformed meat and poultry, fruits, vegetables, fish, seafood, and shell eggs.
2. Brines, marinades, and sauces applied on the surface or injected into processed or unprocessed, cooked or uncooked, whole or cut poultry.
3. Surface sauces and marinades applied on processed and preformed meat and poultry products.

The components of the FCS will not exceed:

1. 2000 ppm PAA, 1333 ppm HP, 133 ppm HEDP, and 6.5 ppm DPA in process water applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut poultry, including carcasses, parts, trim, and organs.
2. 1800 ppm PAA, 1200 ppm HP, 120 ppm HEDP, and 5.9 ppm DPA in process water or ice used in washing, rinsing, or cooling whole or cut meat carcasses, parts, trim, and organs.
3. 230 ppm PAA, 153 ppm HP, 15 ppm HEDP, and 0.8 ppm DPA in process water or ice used during commercial preparation of fish and seafood in food processing facilities.
4. 350 ppm PAA, 233 ppm HP, 23 ppm HEDP, and 1.2 ppm DPA in process water or ice used for washing or chilling fruits and vegetables in food processing facilities.
5. 2000 ppm PAA, 1333 ppm HP, 120 ppm HEDP, and 6.5 ppm DPA in wash water for shell eggs.
6. 495 ppm PAA, 193 ppm HP, 33 ppm HEDP, and 0.5 ppm DPA in process water, ice, or brine for washing, rinsing, or cooling processed and preformed meat.
7. 50 ppm PAA, 17 ppm HP, 4 ppm HEDP, and 0.1 ppm DPA in surface sauces and marinades applied on processed and preformed meat products.

Uses of the FCS listed below do not contain DPA, and the components will not exceed:

8. 230 ppm PAA, 90 ppm HP, and 15 ppm HEDP in process water, ice, or brine for washing, rinsing, or cooling processed and preformed poultry.
9. 50 ppm PAA, 17 ppm HP, and 4 ppm HEDP in brines, marinades, and sauces applied to the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry.
10. 50 ppm PAA, 17 ppm HP, and 4 ppm HEDP in surface sauces and marinades applied on processed and preformed poultry products.

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 29, 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 to inhibit the growth of undesirable or pathogenic microorganisms in the process water and or on the surface of the products.

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 metabolized by ambient aerobic microorganisms 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 and DPA. 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 133 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 106.4 ppm for sludge, and 2.66 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 106.4 ppm HEDP. Similarly, discharge to surface waters of effluent containing 2.66 ppm HEDP is not expected to have toxic effects.

DPA is water soluble and does not partition to sludge; therefore, it is assumed that the environmental introduction concentration (EIC) is equal to the highest use concentration (6.5 ppm). The DPA aquatic effective environmental concentration (EEC) is 0.65 ppm (i.e., EIC ÷ 10-fold dilution factor upon release of effluent to surface waters). There is limited ecotoxicity information available on DPA itself, so environmental toxicity was assessed using the Environmental Protection Agency's (EPA's) Ecological Structure Activity Relationships (ECOSAR) Class Program, which estimates effects based on structure-activity relationships and predictions from similar chemical classes. The lowest toxicity endpoints, according to ECOSAR, are a chronic value of 29 mg/L for fish (proxy: pyridine-alpha-acid), and 324 ppm 96 hr. LC_{50} for fish (proxy: neutral organic SAR). The expected worst-case EEC of 0.65 ppm is 2-3 orders of magnitude below these concentrations. Therefore, discharge to surface waters of effluent containing 0.65 ppm DPA is not expected to have toxic effects on aquatic life.

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 2266 is not expected to significantly affect the human environment, and therefore an EIS will not be prepared.

Prepared by

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