Memorandum

Date: February 28, 2023

From: Supervisory Biologist, Environmental Team, Division of Science and Technology

To: Katherine Wilkening, Ph.D., Division of Food Contact Substances

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2274: An aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, optionally, sulfuric acid, and optionally, 1-hydroxyethylidene-1,1-diphosphonic acid and/or dipicolinic acid as an antimicrobial agent in process water, ice, brines, sauces, and marinades used in the production and preparation of food.

Notifier: Keller and Heckman LLP on behalf of Hydrite Chemical Co.

Attached is the FONSI for FCN 2274 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2274 is 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), optionally, sulfuric acid (CAS Reg. No. 7664-93-9), and optionally, 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4) and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2) as an antimicrobial agent in process water, ice, brines, sauces, and marinades used in the production and preparation of food as follows:

1) 1800 ppm PAA, 1203 ppm HP, 60 ppm HEDP, and 1.64 ppm DPA in process water and ice used to spray, wash, rinse, or dip meat carcasses, parts, trim, and organs, and in chiller water for meat carcasses, parts, trim, and organs;
2) 2000 ppm PAA, 1474 ppm HP, 100 ppm HEDP, and 2.01 ppm DPA in process water and ice used to spray, wash, rinse, or dip poultry carcasses, parts, trim, and organs, and in chiller water, low-temperature (e.g., less than 40 °F) immersion baths, or scald water for poultry carcasses, parts, trim and organs;
3) 495 ppm PAA, 367 ppm HP, 23 ppm HEDP, and 0.50 ppm DPA in water, brine, or ice for washing, rinsing, or cooling processed and pre-formed meat products;
4) 230 ppm PAA, 323 ppm HP, 12 ppm HEDP, and 0.44 ppm DPA in water, brine, or ice for washing, rinsing, or cooling processed and pre-formed poultry products;
5) 600 ppm PAA, 880 ppm HP, 32 ppm HEDP, and 1.20 ppm DPA in water or ice used for washing or chilling fruits and vegetables in a food processing facility;
6) 230 ppm PAA, 280 ppm HP, 12 ppm HEDP, and 0.38 ppm DPA in process water or ice used to commercially prepare fish and seafood;
7) 50 ppm PAA, 33 ppm HP, 2 ppm HEDP, and 0.05 ppm DPA in brines, sauces and marinades applied on the surface or injected into processed or unprocessed, cooked or uncooked, whole or cut poultry

parts and pieces; and surface sauces and marinades applied on processed and pre-formed meat and poultry products;

8) 2000 ppm PAA, 947 ppm HP, 60 ppm HEDP, and 1.29 ppm DPA in water for washing shell eggs;

9) 987 ppm PAA, 1447 ppm HP, 53 ppm HEDP, and 1.97 ppm DPA in spray, wash, dip, rinse, mist, or chiller water for hard boiled, peeled eggs; and,

10) 234 ppm PAA, 344 ppm HP, 13 ppm HEDP, and 0.47 ppm DPA during the tempering and before the milling of grains of wheat, corn, and rice.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated February 24, 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.

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2023.02.28 14:39:34 -05'00'

Mariellen Pfeil

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2274, submitted by Hydrite Chemical Co. for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, optionally, sulfuric acid, and optionally, 1-hydroxyethylidene-1,1-diphosphonic acid and/or dipicolinic acid as an antimicrobial agent in process water, ice, brines, sauces, and marinades used in the production and preparation of food.

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 February 24, 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 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 acid is expected to decompose rapidly in the during wastewater treatment to form acetic acid and oxygen. 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. Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Sulfuric acid dissociates readily in water to sulfate ions and hydrated protons and readily incorporates into the natural sulfur cycle. 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. DPA stays in the aqueous environmental compartment. The maximum HEDP and DPA use levels (i.e., the use on whole and cut poultry) of 100 ppm and 2.01 ppm, respectively are used to estimate environmental introduction concentrations and assume no process-related dilution of the component.

Application of the 80:20 HEDP sludge: water adsorption factor and 10-fold dilution upon discharge to surface waters yields an HEDP EEC of 80 ppm for sludge, and 2 ppm for water. The aqueous EEC for DPA is 0.2 ppm. These concentrations are below the HEDP toxicity endpoints for soil (1000 ppm NOEC earthworms) and water (10 ppm NOEC *Daphnia magna*) and the DPA toxicity endpoint for water (7.69 ppm chronic value for green algae). Therefore, there is no toxicity expected from any land application of sludge containing HEDP. Similarly, discharge to surface waters of effluent containing HEDP and/or DPA 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 2274 is not expected to significantly affect the human environment, and therefore an EIS will not be prepared.

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2023.02.28 14:40:22 -05'00'

Prepared by _____

Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition Food and Drug Administration