U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: February 1, 2019

To: Jessica Urbelis, Ph.D., Division of Food Contact Notifications (HFS-275)
Through: Mariellen Pfeil, Supervisory Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review (HFS-255)

From: Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact for food-contact notification (FCN) 1950 for 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: PeroxyChem LLP

Attached is the Finding of No Significant Impact (FONSI) for FCN 1950, request for use of an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP), and, optionally, sulfuric acid, for use as an antimicrobial agent in process water or ice for washing, rinsing, chilling or processing fruits and vegetables in a food processing facility.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated October 19, 2018, may be made available to the public. We will post digital transcriptions of the FONSI and the EA 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 1950), submitted by PeroxyChem LLP., to provide for safe use of use of an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidene-1,1- disphosphonic acid (HEDP), and, optionally, sulfuric acid, as an antimicrobial agent in process water or ice for washing, rinsing, chilling or processing fruits and vegetables in a food processing facility.

The Office of Food Additive Safety has determined that allowing this FCN to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement will not be prepared. This finding is based on information submitted by the submitter in an environmental assessment, dated October 19, 2018. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The food-contact substance (FCS) is intended to inhibit the growth of undesirable or pathogenic microorganisms and will be used in produce processing facilities throughout the United States.

The components of the mixture will not exceed 500 ppm PAA, 338 ppm HP and 34 ppm HEDP in the process water or ice used for washing, rinsing, or chilling fruits and vegetables in food processing facilities.

Waste water from the above-described use 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 pre-treatment.

The peroxygen components of the FCS (PAA, HP), and the acetic acid are expected to degrade rapidly in the presence of organic material, and sulfuric acid dissociates in the presence of water. Thus, the focus of the environmental analysis is on the stabilizer 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 use level of 34 ppm is divided by 2 to account for half of all water consumed at the processing facility being used in actual fruit and vegetable processing. This is assumed to be the EIC (17 ppm). Application of the 80:20 sludge:water adsorption factor and 10-fold dilution upon discharge to surface waters yields an EEC of 13.6 for sludge, and 0.34 for water. These concentrations are well 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 land application of sludge containing 13.6 ppm HEDP. Similarly, discharge to surface waters of effluent containing 0.34 ppm HEDP is not expected to have toxic effects.

HEDP shows no toxicity to terrestrial organisms at levels up to 1000 mg/kg soil dry weight (*Eisenia foetida*, No Observed Effect Concentration; NOEC), and the lowest relevant endpoint for aquatic toxicity was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*.

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 1950 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 02-01-2019
Leah D. Proffitt
Biologist

Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 02-01-2019
Mariellen Pfeil
Supervisory Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration