FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: October 4, 2019

To: Kenneth McAdams, Division of Food Contact Substances, HFS-275
Through: Sarah C. Winfield, Biologist, Environmental Team, Office of Food Additive Safety, HFS-255

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

Subject: Finding of No Significant Impact for Food Contact Substance Notification (FCN) 2011 for 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), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (CAS Reg. No. 7664-93-9).

Notifier: LPR Technologies

Attached is the Finding of No Significant Impact (FONSI) for FCN 2011 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2011 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 (AA) (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) as an antimicrobial agent in food processing.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated September 19, 2019, 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

Food Contact Substance (FCS) Notification (FCN) 2011: submitted by LPR Technologies, for the safe 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), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) as an antimicrobial agent in food processing, as specified below.

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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA) dated September 19, 2019. 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 FCS is for use as an antimicrobial agent in the following applications:

1. Process water or ice used in washing, rinsing, or cooling whole or cut meat carcasses, parts, trim, and organs at no more than 1800 ppm PAA, 700 ppm HP, 120 ppm HEDP, and 0.5 ppm DPA.
2. Process water, ice, or brine used in washing rinsing or cooling processed and preformed meat products, at no more than 495 ppm PAA, 193 ppm HP, 33 ppm HEDP, and 0.5 ppm DPA.
3. Surface sauces and marinades applied on processed and preformed meat products at no more than 50 ppm PAA, 17 ppm, HP, 4 ppm, HEDP, and 0.1 ppm DPA

Waste water 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 pre-treatment.

The peroxygen components of the FCS (PAA, HP) are expected to degrade rapidly in the presence of organic material, and, SA totally dissociates in the presence of water to sulfate ions (SO42-) and hydrated protons. As part of the sulfur cycle, sulfate is either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate. Also, AA is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Thus, the focus of the environmental analysis is on HEDP and DPA, and the EA discusses the use profile with the highest concentrations of both components (i.e. number 1 above). 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 is water soluble and does not partition to sludge; therefore, it is assumed that the environmental introduction concentration (EIC) is equal to the use concentration (0.5 ppm). The DPA aquatic effective environmental concentration (EEC) is 0.05 ppm (i.e. EIC ÷ 10-fold dilution factor upon release of effluent to surface waters). There is little 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 a chronic value of 89 mg/L (proxy: neutral organic SAR). The expected worst-case EEC of 0.05 ppm is almost 3 orders of magnitude below these concentrations. Therefore, discharge to surface waters of effluent containing 0.05 ppm DPA is not expected to have toxic effects on aquatic life.

Similarly, the HEDP use level of 120 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 96 ppm for sludge, and 2.4 ppm 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 96 ppm HEDP. Similarly, discharge to surface waters of effluent containing 2.4 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 2011 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 10-04-2019
Leah D. Proffitt
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 10-04-2019
Sarah C. Winfield
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration