U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 15, 2021

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

Through: Mariellen Pfeil, Lead Biologist, Office of Food Additive Safety, HFS-255

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2021.11.16 11:51:11 -05'00'

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

Subject: Finding of No Significant Impact for food-contact notification (FCN) 2171 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 (AA) (CAS Reg. No. 64-19-7), 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (SA) (CAS Reg. No. 7664-93-9).

Notifier: PeroxyChem, LLC

Attached is the Finding of No Significant Impact (FONSI) for FCN 2171 for use of the above-described FCS as an antimicrobial agent used in the production, processing, and preparation of poultry, and processed and pre-formed poultry.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated September 10, 2021, 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 -S Digitally signed by Leah D. Proffitt -S Date: 2021.11.15 09:46:52 -05'00'

Leah D. Proffitt

Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt
File: FCN No. 2171

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2171), submitted by PeroxyChem, LLC, to provide 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-hydroxyethylidine-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (SA) (CAS Reg. No. 7664-93-9), as an antimicrobial agent used in the production, processing, and preparation of poultry, and processed and pre-formed poultry.

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, dated Sept. 10, 2021. 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 components of the FCS will not exceed:

1. 2000 ppm PAA, 1333 ppm HP, 120 ppm HEDP, and 2.7 ppm DPA in process water, ice, or brine 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. 230 ppm PAA, 153 ppm HP, 14 ppm HEDP, and 0.3 ppm DPA in process water, ice, or brine for washing, rinsing, or cooling processed and pre-formed poultry.

The food-contact substance (FCS) is intended to inhibit the growth of undesirable or pathogenic microorganisms and will be used in food processing facilities throughout the United States. Waste water from the proposed 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 (SO_4^{2-}) 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. 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 highest use concentration (2.7 ppm). The DPA aquatic effective environmental concentration (EEC) is 0.27 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 0.27 ppm is 2 orders of magnitude below these concentrations. Therefore, discharge to surface waters of effluent containing 0.27 ppm DPA is not expected to have toxic effects on aquatic life.

Similarly, the higher 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. The sludge EEC is well below the toxicity endpoint for soil (1000 mg/kg NOEC *Eisenia foetida*). If applied as a soil amendment, the sludge will be mixed with other soil and its concentration further diluted. The aquatic EEC of 2.4 ppm is an order of magnitude below the range of the most sensitive aquatic toxicity endpoint (10 - 12.5 mg/L NOEC *Daphnia magna*). Therefore, discharge to surface waters of effluent containing 120 ppm HEDP is not expected to have toxic effects.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

Consequently, we find that use of the FCS as antimicrobial agent used in the production, processing, and preparation of poultry, and processed and pre-formed poultry in will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by Leah D. Proffitt -S Digitally signed by Leah D. Proffitt -S Date: 2021.11.15 09:47:29 -05'00' Date: see electronic signature

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