U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 28, 2017

To: Vivian Gilliam Ph.D., Division of Food Contact Notifications (HFS-275)
Through: Mariellen Pfeil, Biologist, Acting Environmental Team Lead, Office of Food Additive Safety, HFS-255

From: Physical Scientist, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact for FCN 1844 – An aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (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: Valley Chemical Solutions

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 1844, request for use of an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and optionally, sulfuric acid (SA), as an antimicrobial agent in process water, brine, or ice used in the processing of meat and poultry.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated November 2, 2017 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.

Antonetta Thompson-Wood

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN 1844), submitted by Valley Chemical Solutions to provide for the safe use of an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (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). The food contact substance (FCS) will be used as an antimicrobial agent in poultry, meat, and preformed and/or processed poultry and meat products. The components of the FCS mixture will not exceed:

i. 2000 ppm PAA, 892 ppm Hydrogen peroxide and 7 ppm HEDP for use in all process water that contacts poultry carcasses, parts, trim, and organs during production, including water applied by wash, rinse, dip, chill, scald, spray and mist;
ii. 495 ppm PAA, 221 ppm Hydrogen peroxide, and 1.7 ppm HEDP for use in brine and ice that may contact poultry carcasses, parts, trim, and organs, and in process water, brine, and ice for washing, rinsing, or cooling processed and preformed poultry products;
iii. 2000 ppm PAA, 892 ppm Hydrogen peroxide and 7 ppm HEDP for use in all process water that contacts meat carcasses, parts, trim, and organs during production, including water applied by wash, rinse, dip, chill, spray, and mist;
iv. 495 ppm PAA, 221 ppm Hydrogen peroxide and 1.7 ppm HEDP for use in brine and ice that may contact meat carcasses, parts, trim, and organs, and in process water, brine, and ice for washing, rinsing, or cooling processed and preformed meat products.

The Office of Food Additive Safety has determined that allowing this food contact notification (FCN) to become effective will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on information submitted by the notifier in an environmental assessment, dated November 2, 2017, as summarized below. 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) will be used as an antimicrobial agent in poultry, meat, and preformed and/or processed poultry and meat products.
The antimicrobial agent is needed to inhibit the growth of pathogenic microorganisms and reduce microbial contamination on poultry and meat products.

The waste process water containing the FCS is expected to be disposed of through the processing plant's onsite wastewater treatment facility before discharge either to surface waters under National Pollution Discharge Elimination System (NPDES) permitting or to a publicly owned treatment works (POTW).

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in the complete degradation of PAA, hydrogen peroxide, and acetic acid. Specifically, the PAA will breakdown into oxygen, and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid dissociates in water to acetate anion and the hydrated proton. Sulfuric acid is a strong mineral acid that dissociates readily in water to sulfate ions and hydrated protons; and is totally miscible in water. Sodium sulfate has a favorable ecological profile. Due to the low aquatic toxicity and the natural recycling that occurs in the sulfur cycle, wide dispersive use of sodium sulfate does not present a major hazard to the environment. Therefore, the EA focuses on the environmental impacts of HEDP.

The use level of 7 ppm for HEDP is the maximum concentration of HEDP that may be expected in a worst-case scenario. 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. Applying the 80:20 partitioning factors yields an environmental introduction concentration (EIC) in sludge of 7 ppm x

0.8 = 5.6 ppm. The aquatic EIC is 7 ppm x 0.2 = 1.4 ppm. In order to arrive at the effective environmental concentration (EEC) in water, a 10-fold dilution factor is applied to the HEDP that remains in water to account for dilution upon release to surface water (EIC ÷ 10 = EEC). Therefore, the aquatic EEC is 1.4 ppm ÷ 10 = 0.14 ppm

HEDP shows no toxicity to terrestrial organisms at levels up to 1,000 mg/kg (ppm) soil dry weight (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*. Therefore, there is no toxicity expected from land application of sludge containing 5.6 ppm HEDP. Similarly, discharge to surface waters of effluent containing 0.14 ppm HEDP is not expected to have toxic effects.

Use of the FCS is not expected to cause a significant impact on resources and energy. No mitigation measures are needed since no 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 microbial agents; such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as an antimicrobial agent as described in FCN 1844 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 11-28-2017
Antonetta Thompson-Wood
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Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 11-28-2017
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