U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: June 5, 2018

To: Jessica Urbelis Ph.D., Division of Food Contact Notifications (HFS-275)
Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, 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 1897 –An aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-l), acetic acid (AA) (CAS Reg. No. 64-19-7), l-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and, optionally, sulfuric acid (SA) (CAS Reg. No. 7664-93-9).

Notifier: Hydrite Chemical Co.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 1897, request for use of an aqueous mixture of PAA, HP, AA, HEDP, and SA, as an antimicrobial agent used in:

(1) 1800 ppm PAA, 409 HP, and 49 ppm HEDP in process water and ice use to spray, wash, rinse, or dip meat carcasses, parts, trim, and organs, and in chiller water or scald water for meat carcasses, parts, trim, and organs;
(2) 495 ppm PAA, 113 ppm HP, and 14 ppm HEDP in water, brine, and ice for washing, rinsing, or cooling of processed or pre-formed meat products;
(3) 350 ppm PAA, 80 pm HP, and 10 ppm in water and ice used for washing or chilling fruits and vegetables in a food processing facility;
(4) 2000 ppm PAA, 455 pm HP, and 55 ppm HEDP in water for washing shell eggs;
(5) 50 ppm PAA, 11 pm HP, and 1 ppm HEDP in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts or pieces; and
(6) 50 ppm PAA, 11 pm HP, and 1 ppm HEDP in surface sauces and in marinades applied on processed and preformed meat and poultry products.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated June 1, 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.

Antonetta Thompson-Wood

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN 1897), submitted by Hydrite Chemical Co. 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-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and sulfuric acid (SA) (CAS Reg. No. 7664-93-9). The food contact substance (FCS) will be used as an antimicrobial agent as described below.

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 June 1, 2018, 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.

Uses of the FCS mixture are as follows:

(1) 1800 ppm PAA, 409 HP, and 49 ppm HEDP in process water and ice use to spray, wash, rinse, or dip meat carcasses, parts, trim, and organs, and in chiller water or scald water for meat carcasses, parts, trim, and organs;
(2) 495 ppm PAA, 113 ppm HP, and 14 ppm HEDP in water, brine, and ice for washing, rinsing, or cooling of processed or pre-formed meat products;
(3) 350 ppm PAA, 80 pm HP, and 10 ppm in water and ice used for washing or chilling fruits and vegetables in a food processing facility;
(4) 2000 ppm PAA, 455 pm HP, and 55 ppm HEDP in water for washing shell eggs;
(5) 50 ppm PAA, 11 pm HP, and 1 ppm HEDP in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts or pieces; and
(6) 50 ppm PAA, 11 pm HP, and 1 ppm HEDP in surface sauces and in marinades applied on processed and preformed meat and poultry products.

The antimicrobial agent is needed to reduce or inhibit the growth of pathogenic and non-pathogenic microorganisms that may be present on and in food to provide safer foods for consumers.

When used in processing plants, the waste process water containing the FCS is expected to be disposed of through the processing plant wastewater treatment facilities, through a local publicly owned treatment works (POTW), or disposed of to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit.

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in the complete degradation of PAA, HP, and AA. Specifically, the PAA will breakdown into oxygen, and AA, while HP will break down into oxygen and water. Acetic acid is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Sulfuric acid is a strong mineral acid that dissociates readily in water to sulfate ions and hydrated protons; and is totally miscible in water. 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. Therefore, the EA focuses on the environmental impacts of HEDP.

The use level of 55 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 55 ppm x 0.8 = 44 ppm. The aquatic EIC is 55 ppm x 0.2 = 11 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 11 ppm ÷ 10 = 1.1 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 44 ppm HEDP. Similarly, discharge to surface waters of effluent containing 1.1 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 1897 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: Digitally signed 6/26/2018
Antonetta Thompson-Wood
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Office of Food Additive Safety
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Food and Drug Administration

Approved by _____Date: Digitally signed 6/26/2018
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