

Memorandum

Date: March 20, 2018

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 1867 – 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), water, and sulfuric acid (SA) (CAS Reg. No. 7664-93-9) as an antimicrobial agent in food processing.

Notifier: LPR Technologies

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 1867, request for use of an aqueous mixture of PAA, HP, AA, HEDP, water, and SA, as an antimicrobial agent used in:

1. Process water, ice, or brine used in the production, processing and preparation of poultry, meat, fish, seafood, fruits, vegetables, and shell eggs;
2. Brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry or parts and pieces; and
3. Surface sauces and 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 March 16, 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 1867), submitted by LPR Technologies to provide for the safe use of an aqueous mixture of PAA (CAS Reg. No. 79-21-0), HP (CAS Reg. No. 7722-84-1), AA (CAS Reg. No. 64-19-7), HEDP (CAS Reg. No. 2809-21-4), water, and 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 March 16, 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.

The components of the FCS mixture will not exceed:

1. 2000 ppm PAA, 800 ppm HP, and 133 ppm HEDP in process water 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 carcasses, parts, trim, and organs.
2. 1800 ppm PAA, 700 ppm HP, and 120 ppm HEDP in process water or ice used in washing, rinsing, or cooling whole or cut meat carcasses, parts, trim, and organs.
3. 495 ppm PAA, 193 ppm HP, and 33 ppm HEDP in process water, ice, or brine used in washing, rinsing, or cooling processed and pre-formed meat products.
4. 230 ppm PAA, 90 ppm HP, and 15 ppm HEDP in process water, ice, or brine used in washing, rinsing, or cooling processed and pre-formed poultry products.
5. 50 ppm PAA, 17 ppm HP, and 4 ppm HEDP in brines, sauces, and marinades applied to the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry.
6. 50 ppm PAA, 17 ppm HP, and 4 ppm HEDP in surface sauces and marinades applied on processed and preformed meat and poultry products.
7. 230 ppm PAA, 90 ppm HP, and 15 ppm HEDP in process water or ice used during commercial preparation of fish and seafood.
8. 350 ppm PAA, 136 ppm HP, and 23 ppm HEDP in process water used in washing or chilling fruits and vegetables in food processing facilities.
9. 2000 ppm PAA, 800 ppm HP, and 120 ppm HEDP in process water used in washing shell eggs.

The food contact substance (FCS) will be used as an antimicrobial agent in:

1. Process water, ice, or brine used in the production, processing and preparation of poultry, meat, fish, seafood, fruits, vegetables, and shell eggs;
2. Brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry or parts and pieces; and
3. Surface sauces and 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 or through a local publicly owned treatment works (POTW). When used aboard fishing vessels, the wastewater containing the FCS is expected to be disposed in the ocean in compliance with local fishing discharge regulations.

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 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 133 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 $133 \text{ ppm} \times 0.8 = 106.4 \text{ ppm}$. The aquatic EIC is $133 \text{ ppm} \times 0.2 = 26.6 \text{ ppm}$. 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 ($EIC \div 10 = EEC$). Therefore, the aquatic EEC is $1.4 \text{ ppm} \div 10 = 2.66 \text{ ppm}$

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 106.4 ppm HEDP. Similarly, discharge to surface waters of effluent containing 2.66 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 1867 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed 03-20-2018

Antonetta Thompson-Wood
Physical Scientist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____ Date: digitally signed 03-20-2018

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