

Memorandum

Date: April 16, 2019

To: Elizabeth Furukawa, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275

Through: Leah D. Proffitt, Biologist, Environmental Review Team, Office of Food Additive Safety (HFS-255)

From: Biologist, Environmental Review Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1946 (An aqueous mixture of peroxylic acid (PLA), hydrogen peroxide (HP), lactic acid, water, optional 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), optional sulfuric acid, and optional phosphoric acid)

Notifier: Valley Chemical Solutions

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1946, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

The Food Contact Substance (FCS) that is the subject of FCN 1946 is an aqueous mixture of peroxylic acid (PLA; CAS Reg. No. 75033-25-9), hydrogen peroxide (HP; CAS Reg. No. 7722-84-1), lactic acid (CAS Reg. No. 50-21-5), water (CAS Reg. No. 7732-18-5), optional 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP; CAS Reg. No. 2809-21-4), optional sulfuric acid (CAS Reg. No. 7664-93-9), and optional phosphoric acid (CAS Reg. No. 7664-38-2). The FCS is intended for use as an antimicrobial agent in process water, ice, or brine used in the production, processing, and preparation of meat and poultry products.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated February 15, 2019, may be made available to the public. We will post digital transcriptions of the FONSI, revision sheet and the environmental assessment 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.

Sarah C. Winfield

Attachments:

Finding of No Significant Impact

Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1946, submitted by Valley Chemical Solutions for the use of an aqueous mixture of peroxylic acid (PLA), hydrogen peroxide (HP), lactic acid, water, optional 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), optional sulfuric acid, and optional phosphoric acid as an antimicrobial agent in process water, ice, or brine used in the production, processing, and preparation of meat and poultry products. The components of the FCS mixture will not exceed:

1. 1000 parts per million (ppm) PLA, 2384 ppm HP, and 5.5 ppm HEDP in process water or ice that contacts meat or poultry carcasses, parts, trim, and organs; or
2. 495 ppm PLA, 1180 ppm HP, and 2.7 ppm HEDP in process water, ice, or brine that contacts processed and pre-formed meat and 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 (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated February 15, 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 (FONSI) and is briefly summarized below.

Manufacture of the FCS is not expected to result in environmental introduction, nor adverse environmental impact. When the FCS is used as an antimicrobial in process water, ice, or brine used in the production, processing, and preparation of meat and poultry products, environmental introduction could occur via wastewater. It is expected that wastewater from an on-site wastewater treatment facility will discharge to a Publicly Owned Treatment Works (POTW) or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters. Land application of sewage treatment sludge could result in terrestrial introduction of the FCS.

Complete degradation of the FCS components (except HEDP) is expected to occur during treatment at the on-site wastewater treatment plant or POTW. Specifically, PLA will breakdown into oxygen and lactic acid, while hydrogen peroxide will break down into oxygen and water. Lactic acid is expected to dissociate in wastewater and degrade at the wastewater treatment facility/POTW. Sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern at the proposed use levels. Similarly, phosphoric acid readily dissociates into phosphate ions and hydrated protons, neither of which are a toxicological or environmental concern at the proposed use levels. As such, the environmental impacts of these FCS components are not considered in further detail in the EA. The EA focuses on the environmental fate and effects of HEDP.

Assuming, as a worst-case, that the FCS goes directly into wastewater, the maximum concentration of HEDP in wastewater would be equal to the highest use concentrations of HEDP, which is 5.5 ppm. Environmental Introduction Concentrations (EICs) for HEDP were calculated assuming 80 percent of the HEDP partitions to sludge during on-site wastewater treatment (and 20 percent of the HEDP remains in the water). Expected Environmental Concentrations (EECs) of HEDP were calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. Therefore, the terrestrial EEC for HEDP is 4.4 ppm ($5.5 \text{ ppm} \times 0.80$) and the aquatic EEC for HEDP is 0.11 ppm ($[5.5 \text{ ppm} \times 0.20] / 10$).

Terrestrial toxicity studies with HEDP demonstrated no effects on earthworms and plants at levels up to 1,000 ppm soil dry weight and the 14-day LC50 for birds was determined to be greater than 284 mg/kg body weight. The terrestrial HEDP EEC is 4.4 ppm, a worst-case concentration that assumes no dilution from mixing nor degradation of HEDP and is over 50-times lower than terrestrial toxicity study endpoints, therefore, there is no toxicity expected from land

application of sludge that contains HEDP from the proposed use of the FCS. In evaluation of the aquatic toxicity of the FCS, the lowest relevant HEDP concentration for aquatic toxicity was determined to be the chronic No Observed Effect Concentration (NOEC) of 10 ppm for *Daphnia magna*. The calculated aquatic HEDP EEC of 0.11 ppm is a conservative estimate, as it assumes the concentration of HEDP in wastewater is the same as the at-use concentration. The aquatic HEDP EEC of 0.11 ppm is close to 100-fold lower than the 10 ppm chronic NOEC for *Daphnia magna*. Therefore, the proposed use of the FCS is not expected to have an adverse effect on aquatic organisms.

We do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to those proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of materials which the FCS would otherwise replace (*i.e.*, similar antimicrobial agents already on the market); such action would have no significant environmental impact. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts, mitigation measures are not identified.

The use of the FCS, as described in FCN 1946, as an antimicrobial in process water, ice, or brine used in the production, processing, and preparation of meat and poultry products, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: see electronic signature

Sarah C. Winfield

Biologist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: see electronic signature

Leah D. Proffitt

Biologist, Environmental Review Team

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Food and Drug Administration

U.S. Food and Drug Administration

Revision Sheet for the February 15, 2019 EA for FCN 1946

Dated: April 16, 2019

The U.S. Food and Drug Administration (FDA) in its review of the February 15, 2019 Environmental Assessment (EA) for Food Contact Substance Notification (FCN) 1946 concluded that the action will not constitute a significant impact. The revision is issued to make a minor change and update of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to correct the following:

On page 6, the EA states:

*“...resulting in maximum expected environmental concentrations (EEC) of approximately **0.2 ppm** for HEDP in wastewater from poultry and meat processing. (bold added for emphasis)”*

As discussed in the FONSI (and other places in the EA), the maximum aquatic EEC is 0.11 ppm (not 0.2 ppm).