
Memorandum

Date: October 26, 2020

To: Jessica Urbelis, Ph.D., Consumer Safety Officer, Division of Food Contact Substances, HFS-275

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

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

Subject: Finding of No Significant Impact for Food Contact Notification 2099 (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 (CAS Reg. No. 2809-21-4), and, optionally, sulfuric acid (CAS Reg. No. 7664-93-9))

Notifier: Alex C. Fergusson, LLC

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2099, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2099 is for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid, and, optionally, sulfuric acid as an antimicrobial agent in process water or ice used for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment, dated September 2, 2020, and EA revision sheet, may be made available to the public. We will post digital transcriptions of the FONSI 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.

Denis Wafula

Attachments: Finding of No Significant Impact (FONSI), EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2099, submitted by Alex C. Fergusson, LLC. for the use of an aqueous mixture of peroxyacetic acid (PAA) (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) as an antimicrobial agent in process water or ice used for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities. The components of the FCS mixture in process water or ice will not exceed: 500 ppm PAA, 208 ppm HP, and 24 ppm HEDP. The FCS is not for use in contact with components of infant formula. Such uses were not included as part of the intended use of the substance in the FCN.

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 September 2, 2020. 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 for washing or chilling fruits and vegetables, environmental introduction could occur via wastewater or land application of sewage treatment sludge. 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 and result in aquatic introduction of the FCS. Land application of sewage treatment sludge could result in terrestrial introduction of the FCS.

Apart from HEDP, other components of the FCS are expected to completely degrade during wastewater treatment. Specifically, peroxyacetic acid will breakdown into oxygen, water and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic 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. 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 concentration of HEDP in the solution applied to fruits and vegetables, or 24 ppm. Environmental Introduction Concentrations (EICs) 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) were calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. Therefore, the terrestrial EEC for HEDP is 19.2 ppm ($24 \text{ ppm} * 0.80$) and the aquatic EEC for HEDP is 0.48 ppm ($[24 \text{ ppm} * 0.20] / 10$).

The estimated EEC for HEDP are below the toxicity endpoints for soils (1000 ppm No Observed Effect Concentration [NOEC] for earthworms) and water (10 ppm chronic NOEC for *Daphnia magna*). Therefore, there is no toxicity expected from land application of sludge containing 19.2 ppm HEDP. Similarly, discharge to surface waters of effluent containing 0.48 ppm HEDP is not expected to have toxic effects.

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

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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 2099, as an antimicrobial agent in process water or ice used for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 10-26-2020

Denis Wafula, Ph.D.

Biologist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 10-27-2020

Mariellen Pfeil

Lead Biologist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

U.S. Food and Drug Administration Revision Sheet for the September 2, 2020 EA for FCN 2099

October 26, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of September 2, 2020 for food contact notification (FCN) 2099 concluded that the action will not constitute a significant impact. This revision is issued to make a minor correction 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 a typographical error:

Under Item 8. a

The chronic 14-day NOEC for *Oncorhynchus mykiss* should be 60-80 mg/L instead of 6080 mg/L