FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: July 19, 2018

To: Anita Chang, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275
Through: Mariellen Pfeil, Supervisory 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 1888 (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-hydroxyethylidine-1,1-diphosphonic acid, CAS Reg. No. 2809-21-4; and optionally sulfuric acid, CAS Reg. No. 7664-93-9)

Notifier: Evonik Corporation

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1888, 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 1888 is an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidine-1,1- diphosphonic acid (HEDP), and optionally sulfuric acid for use as an antimicrobial to control microorganisms in process water and ice used in the production and preparation of fruits and vegetables. The components of the FCS will not exceed 80 ppm peroxyacetic acid, 433 ppm hydrogen peroxide, and 9.8 ppm HEDP in process water for washing or chilling fruits and vegetables in food processing facilities.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated May 2, 2018, 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) 1888, submitted by Evonik Corporation for the 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. 64-19-17), 1-hydroxyethylidine-1,1- diphosphonic acid (HEDP; CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) as an antimicrobial to control microorganisms in process water and ice used in the production and preparation of fruits and vegetables. The components of the FCS will not exceed 80 ppm peroxyacetic acid, 433 ppm hydrogen peroxide, and 9.8 ppm HEDP in process water for washing or chilling fruits and vegetables in food processing facilities.

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 May 2, 2018. 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 to control microorganisms in process water and ice used in the production and preparation of fruits and vegetables, 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, 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 all the water used in a processing plant is treated with the FCS, the maximum concentration of HEDP in wastewater would be equal to the use level of 9.8 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 7.84 ppm (9.8 ppm * 0.80) and the aquatic EEC for HEDP is 0.196 ppm ([9.8 ppm * 0.20] / 10).

In evaluation of terrestrial toxicity, HEDP shows no toxicity to worms at levels up to 1,000 mg/kg (ppm) soil dry weight (No Observed Effect Concentration [NOEC]) and no toxicity to birds at levels up to 284 mg/kg body weight. The terrestrial HEDP EEC in sludge from the proposed use is 7.84 ppm, lower than both terrestrial toxicity levels, 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 NOEC of 10 ppm for *Daphnia magna*. Since the calculated aquatic HEDP EEC is 0.196 ppm and is lower than the 10 ppm chronic NOEC for *Daphnia magna*, 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 HEDP-stabilized peroxyacetic acid 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 1888, as an antimicrobial to control microorganisms in process water and ice used in the production and preparation of fruits and vegetables, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: Digitally signed 7/19/2018
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Approved by _____Date: Digitally signed 7/19/2018
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U.S. Food and Drug Administration

Revision Sheet for the May 2, 2018 EA for FCN 1888

Dated: July 19, 2018

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of May 2, 2018 for Food Contact Substance Notification (FCN) 1888 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 explain the following:

- On page 3 of the EA the reader is directed to Reference 7 to support the statement "HEDP slowly biodegrades into phosphates at a rate of about 1% per day when chelated with transition metal ions." However, the reference states:

  > *In natural waters chelating agents and therefore the phosphonates always occur in the form of metal complexes. Studies on the chemical degradation of phosphonates should therefore always include the presence of metals. Degradation of the amine linkage containing phosphonates NTMP, EDTMP, and DTPMP was negligible in metal-ion free oxygenated solutions, but Ca, Mg, and Fe(II) brought about conversion to free phosphate at a rate of approximately 1 percent per day [99]. Although the degradation was classified as hydrolysis, the conversion rate dropped to negligible levels in the absence of O_2, indicating that redox reactions play a role. HEDP, which does not contain an amine linkage, degrades approximately 20-times more slowly.*

  Therefore, we believe the EA should have stated that "HEDP slowly biodegrades into phosphates at a rate of about **20-times more slowly** than 1% per day when chelated with transition metal ions" to accurately reflect the reference.

- On page 3 of the EA the reader is directed to Reference 2 to support the statement "Because of the nature of the carbon-phosphorus bond in HEDP, it adsorbs very strongly to mineral surfaces and rarely exists free in solution." We were unable to find this information in Reference 2. As this information is not needed to support the FONSI, please disregard this sentence.

- On page 4 of the EA states "… the 28 day NOEC for Daphnia Magna was < 12.5 mg/L" summarizing information from the preceding table of environmental toxicity data for HEDP. However, the 28 day NOEC for *Daphnia magna* is a range: 10 - ≤ 12.5 mg/L.