Memorandum

Date: July 13, 2020

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

To: Vivian Gilliam, Ph.D., Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil. Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2070 –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 optionally, sulfuric acid (SA) (CAS Reg. No. 7664-93-9).

Notifier: Hydrite Chemical Co.

Attached is the FONSI for FCN 2070, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2070 is for the use of an aqueous mixture of PAA, HP, AA, HEDP and, optionally, SA for use as an antimicrobial agent in process water and ice used for washing or chilling fruits and vegetables in a food processing facility.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated July 1, 2020 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 Substance Notification (FCN 2070), submitted by Hydrite Chemical Co. to provide for the 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 optionally sulfuric acid (SA) (CAS Reg. No. 7664-93-9) for use as an antimicrobial agent in process water and ice used for washing or chilling fruits and vegetables in a food processing facility The components of the FCS application mixture will not exceed 600 parts-per-million (ppm) PAA, 430 ppm HP, and 31 ppm HEDP in water and ice used for washing and chilling fruits and vegetables in a food processing facility. In addition, because the intended use of the food contact substance that is the subject of this FCN is identical and substitutional for the intended uses described in FCN 1872 (item #6) and in FCN 1897 (item #3), this FCN replaces those notified uses.

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 by the notifier in an environmental assessment (EA), dated July 1, 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.

The antimicrobial agent is needed to inhibit the growth of undesirable or pathogenic microorganisms in food processing water and ice used in the production and preparation of fruits and vegetables.

When used in fruit and vegetable processing plants, the waste process water containing the FCS is expected to enter the wastewater treatment unit at the plants. Treated wastewater will be discharged directly to the 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 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. AA is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Sulfuric acid dissociates readily in water to sulfate ions and hydrated protons. 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.

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 antimicrobial 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 2070 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 07-13-2020
Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration

Approved by _____Date: digitally signed 07-14-2020
Mariellen Pfeil
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