

Memorandum

Date: September 16, 2021

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

Subject: Finding of No Significant Impact for Food Contact Substance Notification (FCN) 2168 for an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg No 79-21-0), hydrogen peroxide (HP) (CAS Reg No 7722-84-1), acetic acid (CAS Reg No 64-19-7), dipicolinic acid (DPA) (CAS Reg No 499-83-2), and optionally sulfuric acid (CAS Reg No 7664-93-9)

Notifier: Enviro Tech Chemical Services, Inc.

To: Kenneth McAdams, Division of Food Contact Substances, HFS-275

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

Mariellen Pfeil -S

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Date: 2021.09.17 11:31:40 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for FCN 2168 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2168 is 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 (CAS Reg No 64-19-7), dipicolinic acid (DPA) (CAS Reg No 499-83-2), and optionally sulfuric acid (CAS Reg No 7664-93-9) as an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice. The FCS may be applied to grain at a level not to exceed 3 percent by weight of the grain. The concentrations of the components of the FCS when it is applied to grain will not exceed 6000 ppm PAA, 8800 ppm HP, and 16 ppm DPA. The FCS is not for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA) dated August 10, 2021 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.

Denis Wafula -S

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Denis Wafula

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2168, submitted by Enviro Tech Chemical Services, Inc., for the use an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg No 79-21-0), hydrogen peroxide (HP) (CAS Reg No 7722-84-1), acetic acid (CAS Reg No 64-19-7), dipicolinic acid (DPA) (CAS Reg No 499-83-2), and optionally sulfuric acid (CAS Reg No 7664-93-9) as an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice. The FCS may be applied to grain at a level not to exceed 3 percent by weight of the grain. The concentrations of the components of the FCS when it is applied to grain will not exceed 6000 ppm PAA, 8800 ppm HP, and 16 ppm DPA. The FCS is not for use in contact with infant formula and human milk.

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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA) dated August 10, 2021. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below.

The antimicrobial agent is needed to reduce or inhibit the growth of undesirable or pathogenic microorganisms on wheat, corn, and rice grains during the tempering and before milling of the grains. Wastewater from the above-described uses will be either discharged ultimately to a publicly owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite pre-treatment.

The FCS is diluted to achieve a concentration of 6000 ppm PAA, 8800 ppm HP, and 16 ppm. PAA, HP, acetic acid and sulfuric acid are expected to rapidly degrade during or soon after wastewater treatment. PAA will degrade to oxygen and acetic acid while HP will rapidly degrade to oxygen and water especially in the presence of organic matter. Acetic acid will be removed predominantly by biodegradation and it is not expected to accumulate in the environment. Similarly, sulfuric acid will dissociate into sulfate ions and hydrated protons. Sulfate ions will be incorporated into the sulfur biogeochemical cycle and are not expected to accumulate in the environment. Therefore, the focus of the environmental analysis is on DPA. Due to its chemical properties, it is expected that 100 % of the introduced DPA will partition to water and none to sludge.

The DPA use level of 16 ppm is used to estimate environmental introduction concentrations. Assuming complete partition to water and 10-fold factor dilution upon discharge to surface waters, the effective environmental concentration (EEC) for water is 1.6 ppm. Because there is little information available on DPA, environmental toxicity was assessed using EPA's ECOSAR program, which estimates effects based on structure-activity relationships and predictions from similar chemical classes. The lowest toxicity endpoints, according to ECOSAR, are a chronic value of 29 mg/L for fish (proxy: pyridine-alpha-acid), and a chronic value of 89 mg/L (proxy: neutral organic SAR). The expected worst-case EEC of 1.6 ppm is orders of magnitude below these concentrations.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant 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 use of the FCS as described in FCN 2168 is not expected to significantly affect the human environment, and therefore an environmental impact statement will not be prepared.

Prepared by **Denis Wafula -S** Digitally signed by Denis Wafula -S
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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 **Mariellen Pfeil -S** Digitally signed by Mariellen Pfeil -S
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