
Memorandum

Date: June 8, 2020

To: Vanee Komolprasert, 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 2062. 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), sulfuric acid (SA) (CAS Reg. No. 7664-93-9), and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4)

Notifier: Agri-Neo Inc.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2062, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2062 is for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, sulfuric acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice.

After this FCN becomes effective, copies of this FONSI, an EA Revision Sheet, and the notifier's environmental assessment, dated May 22, 2020, 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

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2062, submitted by Agri-Neo Inc. for the use 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), sulfuric acid (SA) (CAS Reg. No. 7664-93-9), and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4) as an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice. The components of the FCS *on grains* will not exceed 114 ppm PAA, 1,704 ppm HP, 193 ppm AA, 25 ppm SA, and 12.5 ppm HEDP.

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 22, 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 agent during the tempering and before milling of grains of wheat, corn, and rice, 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.

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.

Based on the label instruction, a maximum of 5 L on FCS concentrate is diluted in 35 L water resulting in an HEDP concentration of 275 ppm *in solution*. 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 concentration of HEDP in the aqueous solution before application to grains for tempering; i.e. 275 ppm. Environmental Introduction Concentrations (EICs) were calculated assuming 80 percent partitions to sludge during on-site wastewater treatment and 20 percent 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 220 ppm ($275 \text{ ppm} * 0.80$) and the aquatic EEC for HEDP is 5.5 ppm ($[275 \text{ ppm} * 0.20] / 10$).

HEDP in effluent or sludge applied to land is not expected to have any significant adverse environmental impacts based on the available terrestrial toxicity endpoints for plants, invertebrates, and avian species, which range from a plant No Observed Effect Concentration (NOEC) of 100 ppm to a 14-day NOEC 1000 ppm in earthworms. The worst-case theoretical terrestrial EEC for HEDP is 220 ppm, which is below the 14-day NOEC in earthworms. With respect to the NOEC of terrestrial plants, we note that the worst-case calculation in the EA assumes no degradation or dilution of HEDP before or after land application, which is not likely. As such, soil HEDP levels are not expected to exceed 100 ppm. Similarly, discharge to surface waters of effluent containing 5.5 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; 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 2062, as an antimicrobial agent for use as an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 06-08-2020

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 06-11-2020

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 Month 22, 2020 EA for FCN 2062

June 8, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of May 22, 2020 for food contact notification (FCN) 2062 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 align the intended use of the FCS as stated in the EA with the final regulatory listing:

Under Item 4.a) Requested Action, the EA states:

The action requested in this submission is to permit the use of the food contact substance (FCS) Neo-Temper® as an antimicrobial agent for use on grains during tempering and before milling.

We note that the regulatory listing of the FCN states that the intended use of the FCS is as ‘an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice.’

Therefore, this sentence is revised to:

The action requested in this submission is to permit the use of the food contact substance (FCS) Neo-Temper® as an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice.

Under Item 4.b) Requested Action, the EA states:

The FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on soft, hard and durum wheat, corn and rice grains.

Again, to align with the regulatory language, this sentence is revised to:

The FCS is intended for use as an antimicrobial agent to inhibit the growth of undesirable or pathogenic microorganisms on grains of wheat, corn, and rice.

Further, these revisions clarify that the intended use of the FCS is ...

- 1) not intended for contact with all types of grains (as implied in 4 a) and,
- 2) not limited on the types of wheat it can contact during tempering (as implied in 4 b).