

Memorandum

Date: April 9, 2018

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

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

From: Staff Fellow, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1872: 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: Hydrite Chemical Co.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 1872, which 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 to control microorganisms in process water, ice, and brine used in the production and preparation of meat, poultry, processed and pre-formed meat and poultry products, fish and seafood, fruits and vegetables, and shell eggs; and in sauces and marinades used in the production and preparation of poultry and processed and pre-formed meat and poultry products.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated February 28, 2018, 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

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1872, submitted by Hydrite Chemical Co. 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. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) in the production and preparation of meat, poultry, processed and pre-formed meat and poultry products, fish and seafood, fruits and vegetables, and shell eggs; and in sauces and marinades used in the production and preparation of poultry and processed and pre-formed meat and poultry products. The components of the FCS application mixture will not exceed:

- 1) 1200 ppm PAA, 862 HP, and 60 ppm HEDP in process water and ice used to spray, wash, rinse, or dip meat carcasses, parts, trim, and organs, and in chiller water or scald water for meat carcasses, parts, trim, and organs;
- 2) 2000 ppm PAA, 1436 ppm HP, and 100 ppm HEDP in process water and ice used to spray, wash, rinse, or dip poultry carcasses, parts, trim, and organs and in chiller water, immersion baths (e.g., less than 40o F), or scald water for poultry carcasses, parts, trim, and organs;
- 3) 466 ppm PAA, 335 ppm HP, and 23 ppm HEDP in water, brine, and ice for washing, rinsing, or cooling of processed or pre-formed meat products;
- 4) 230 ppm PAA, 165 ppm HP, and 12 ppm HEDP in water, brine, and ice for washing, rinsing, or cooling of processed or pre-formed poultry products;
- 5) 230 ppm PAA, 165 pm HP, and 12 ppm HEDP in process water and ice used to commercially prepare fish and seafood;
- 6) 230 ppm PAA, 165 pm HP, and 12 ppm HEDP in water and ice used for washing or chilling fruits and vegetables in a food processing facility;
- 7) 1200 ppm PAA, 862 pm HP, and 60 ppm HEDP in water for washing shell eggs;
- 8) 46 ppm PAA, 33 pm HP, and 2 ppm HEDP in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts and pieces; and
- 9) 46 ppm PAA, 33 pm HP, and 2 ppm HEDP in surface sauces and in marinades applied on processed and preformed meat and poultry products.

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 EA, dated February 28, 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 agent for its intended uses, 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.

Except for HEDP, it is expected that wastewater treatment at the on-site wastewater treatment plant or POTW will result in the complete degradation of the other components of the FCS. Specifically, peroxyacetic acid will degrade to form oxygen, water and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid is expected to be rapidly metabolized by ambient aerobic microorganisms to form carbon dioxide and water. Sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which presents toxicological or environmental concerns 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 at the highest possible use level.

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 used in poultry processing, or 100 ppm. Environmental Introduction Concentrations (EICs) were calculated with the assumption that 80 percent of the HEDP partitions to sludge during on-site wastewater treatment and 20 percent in the water. Expected Environmental Concentrations (EECs) were calculated by incorporating a ten-fold dilution factor when the disposed wastewater mixes with surface waters. Therefore, the terrestrial EEC for HEDP is 80 ppm (100 ppm × 0.80) and the aquatic EEC for HEDP is 2 ppm ($[100 \text{ ppm} \times 0.20] \times 0.1$).

Terrestrial toxicity studies with HEDP show that at the suggested use levels, the concentrations present in the water or land-applied sludge are not expected to have any adverse environmental impacts. This is because HEDP shows no toxicity to terrestrial organisms at levels up to 1,000 mg/kg (ppm) soil dry weight. The expected terrestrial HEDP EEC for the FCS is 80 ppm, a worst case concentration that assumes no dilution from mixing or degradation. In evaluation of the aquatic toxicity of the FCS, the lowest relevant HEDP concentration for aquatic toxicity was determined to be the chronic No Observed Effect Concentration (NOEC) of 10 ppm for *Daphnia magna*. The calculated aquatic HEDP EEC of 2 ppm is a conservative estimate that assumes the concentration of HEDP in wastewater is the same as in the solution applied to the target foods. The aquatic HEDP EEC is below the 10 ppm chronic NOEC for *Daphnia magna* and it is expected that the proposed use of the FCS will not 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 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 1872, as an antimicrobial agent for use in the processing of the food types described above will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 04-19-2018

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Approved by _____ Date: digitally signed 04-10-2018

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