Memorandum

Date: June 2, 2020

To: Elizabeth Furukawa, Ph.D., 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 Substance Notification (FCN) 2046 for 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-hydroxyethylidine-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (SA) (CAS Reg. No. 7664-93-9).

Notifier: Ecolab Inc.

Attached is the Finding of No Significant Impact (FONSI) for FCN 2046 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2046 is for the use of an aqueous mixture of peroxyacetic acid (PAA), hydrogen peroxide (HP), acetic acid (AA), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), and/or dipicolinic acid (DPA), and optionally sulfuric acid as detailed below.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated March 23, 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance (FCS) Notification (FCN) 2011: submitted by Ecolab Inc., for the safe 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-hydroxyethylidine-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (SA) (CAS Reg. No. 7664-93-9) as an antimicrobial agent as specified below.

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 March 23, 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 and is briefly summarized below.

The FCS is for use as an antimicrobial agent in the following applications:

1) process water, ice, or brine used in the production, processing, and preparation of poultry, meat, processed and pre-formed meat and poultry, fruits, vegetables, fish, seafood, shell eggs, and hard-boiled, peeled eggs.
2) brines, marinades, and sauces applied on the surface or injected into processed or unprocessed, cooked or uncooked, whole or cut, meat and poultry.
3) surface sauces and marinades applied on processed and preformed meat and poultry products.
4) the commercial sterilization of aseptic filling systems and food packaging prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging

The components of the FCS will not exceed:

i. 2000 ppm PAA, 1474 ppm HP, 136 ppm HEDP, and 6.7 ppm DPA in process water, ice, or brine applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut poultry, including carcasses, parts, trim, and organs.

ii. 495 ppm PAA, 1180 ppm HP, 29 ppm HEDP, and 0.44 ppm DPA in process water, ice, or brine for washing, rinsing, or cooling processed and pre-formed poultry.

iii. 2000 ppm PAA, 1474 ppm HP, 121.5 ppm HEDP, and 6.7 ppm DPA in process water, ice, or brine applied as a wash, spray, dip, rinse, chiller water, low-temperature (less than 40°F) immersion bath, or scald water for whole or cut meat, including carcasses, parts, trim, and organs.

iv. 495 ppm PAA, 1180 ppm HP, 33.5 ppm HEDP, and 0.44 ppm DPA in process water, ice, or brine for washing, rinsing, or cooling processed and pre-formed meat.

v. 500 ppm PAA, 1000 ppm HP, 34 ppm HEDP, and 2 ppm DPA in process water and ice used for washing, rinsing, chilling, or processing fruits and vegetables in food processing facilities.

vi. 230 ppm PAA, 280 ppm HP, 15 ppm HEDP, and 0.8 ppm DPA in process water, ice, or brine used during commercial preparation of fish and seafood in food processing facilities.

vii. 2000 ppm PAA, 947 ppm HP, 120 ppm HEDP, and 6.7 ppm DPA in wash water for shell eggs in food processing facilities.

viii. 2000 ppm PAA, 1447 ppm HP, 85 ppm HEDP, and 6.7 ppm DPA in spray, wash, dip, rinse, mist, or chiller water of hard-boiled, peeled eggs.

ix. 50 ppm PAA, 33 ppm HP, 8 ppm HEDP, and 0.1 ppm DPA in brines, marinades, and sauces applied to the surface or injected into processed or unprocessed, cooked or uncooked, whole or cut, meat and poultry.

x. 50 ppm PAA, 33 ppm HP, 8 ppm HEDP, and 0.1 ppm DPA in surface sauces and marinades applied on processed and pre-formed meat and poultry products.

xi. 4500 ppm PAA, 6600 ppm HP, 600 ppm HEDP, and 9 ppm DPA in the commercial sterilization of aseptic filling systems and food packaging prior to filling. The surfaces of polymeric food packaging will be drained, rinsed, and drained again following application of the FCS mixture.

FDAs review of the use of the FCS in aseptic filling systems is limited to the extent that the FCS residues may transfer from the non-food contact surfaces of the aseptic filling system to food packaging materials. The FCS is not for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging. Such uses were not included as part of the intended use of the substance in the FCN.

Waste water 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 peroxygen components of the FCS (PAA, HP) are expected to degrade rapidly in the presence of organic material, and, SA totally dissociates in the presence of water to sulfate ions (SO_{42-}) 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. Also, AA is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Thus, the focus of the environmental analysis is on HEDP and DPA, and the EA discusses the use profile with the highest concentrations of both components (i.e. number xi above). HEDP is a chelating agent and exhibits unique partitioning behavior such that 80% adsorbs to wastewater treatment sludge, while the remaining 20% stays in the water. DPA is water soluble and does not partition to sludge; therefore, it is assumed that the environmental introduction concentration (EIC) is equal to the use concentration (9 ppm). The DPA aquatic effective environmental concentration (EEC) is 0.9 ppm (i.e. EIC ÷ 10-fold dilution factor upon release of effluent to surface waters). There is little ecotoxicity information available on DPA itself, so environmental toxicity was assessed using the Environmental Protection Agency's (EPA's) Ecological Structure Activity Relationships (ECOSAR) Class 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 0.9 ppm 2 orders of magnitude below these concentrations. Therefore, discharge to surface waters of effluent containing 0.9 ppm DPA is not expected to have toxic effects on aquatic life.

Similarly, the HEDP use level of 600 ppm is used to estimate environmental introduction concentrations. Application of the 80:20 sludge:water adsorption factor and 10-fold dilution upon discharge to surface waters yields an EEC of 480 ppm for sludge, and 12 ppm for water. The sludge EEC is less than half the toxicity endpoint for soil (1000 mg/kg NOEC red worms). If applied as a soil amendment, the sludge will be mixed with other soil and its concentration further diluted. The aquatic EIC of 12 ppm is within the range of the most sensitive aquatic toxicity endpoint (10 - 12.5 mg/L NOEC *Daphnia magna*). Furthermore, the EEC estimation is based on a very conservative assumption that 100% of the FCS is discharged via a wastewater treatment facility with no additional dilution. Therefore, discharge to surface waters of effluent containing 12 ppm HEDP is not expected to have toxic effects.

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 2046 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 06-02-2020
Leah D. Proffitt
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 06-02-2020
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