FDA U.S. FOOD & DRUG ADMINISTRATION

# Memorandum

**Date:** March 10, 2020

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

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2036 – 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), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (CAS Reg. No. 7664-93-9).

**Notifier:** Biosan LLC

**To:** Ken McAdams, Division of Food Contact Substances (HFS-275)

Attached is the FONSI for FCN 2036, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2036 is for the use of an aqueous mixture of PAA, HP, AA, HEDP, DAP and, optionally, SA for use as an antimicrobial agent used:

1) in process water, ice or brine used in washing, rinsing, scalding, or cooling whole or cut meat and poultry carcasses, parts, trim, and organs.
2) in process water, ice, or brine used in washing, rinsing, or cooling processed and preformed meat and poultry products.
3) in process water or ice for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities.
4) in process water and ice used to commercially prepare fish and seafood.
5) in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts or pieces.
6) in surface sauces and in marinades applied on processed and preformed meat and poultry products.
7) alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures 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

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated February 5, 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.

Mariellen Pfeil

Attachment: Finding of No Significant Impact

# FINDING OF NO SIGNIFICANT IMPACT

A Food Contact Substance Notification (FCN 2036), submitted by Biosan LLC to provide 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-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), dipicolinic acid (DPA) (CAS Reg. No. 499-83-2), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) for use as an antimicrobial agent used:

1) in process water, ice or brine used in washing, rinsing, scalding, or cooling whole or cut meat and poultry carcasses, parts, trim, and organs.
2) in process water, ice, or brine used in washing, rinsing, or cooling processed and preformed meat and poultry products.
3) in process water or ice for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities.
4) in process water and ice used to commercially prepare fish and seafood.
5) in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts or pieces.
6) in surface sauces and in marinades applied on processed and preformed meat and poultry products.
7) alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their enclosures 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:

1) 2000 ppm PAA, 1474 ppm HP, 121.5 ppm HEDP, and 1.64 ppm DPA in process water, ice, or brine used in washing, rinsing, scalding, or cooling whole or cut meat carcasses, parts, trim, and organs.
2) 2000 ppm PAA, 1474 ppm, HP, 136 ppm HEDP, and 4 ppm DPA in process water, ice, or brine used in washing, rinsing, scalding, or cooling whole or cut poultry carcasses, parts, trim, and organs.
3) 495 ppm PAA, 365 ppm HP, 33.5 ppm HEDP, and 0.44 ppm DPA in process water, ice, or brine used in washing, rinsing, or cooling processed and pre-formed meat products.
4) 495 ppm PAA, 365 ppm HP, 29 ppm HEDP, and 0.44 ppm DPA in process water, ice, or brine used in washing, rinsing, or cooling processed and pre-formed poultry products.
5) 500 ppm PAA, 1000 ppm, HP, 34 ppm HEDP, and 0.68 ppm DPA in process water or ice used in washing, rinsing, chilling or processing fruits and vegetables in food processing facilities.
6) 230 ppm PAA, 280 ppm, HP, 15 ppm HEDP, and 0.38 ppm DPA in process water and ice used to commercially prepare fish and seafood.
7) 50 ppm PAA, 33 pm HP, 8 ppm HEDP, and 0.1 ppm DPA in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts or pieces,
8) 50 ppm PAA, 33 pm HP, 8 ppm HEDP, and 0.1 ppm DPA in surface sauces and in marinades applied on processed and preformed meat and poultry products.
9) 4500 ppm PAA, 6600 ppm HP, 180 ppm HEDP, and 9 ppm DPA when applied to aseptic filling systems and glass and plastic food packaging and their enclosures prior to filling. If the FCS mixture is applied at a rate exceeding 0.0175 milliliters treatment solution per ounce container capacity, the FCS mixture must be drained from the container and rinsed with sterile water and drained again. FDA's review of the use of the FCS to sterilize 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

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 February 5, 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 reduce and/or eliminate pathogenic and non-pathogenic microorganisms that may be present on the food during production

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 (SO42-) 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 9 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 i
s 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 is almost 3 orders of magnitude below these concentrations. Therefore, discharge to surface waters of effluent containing 0.05 ppm DPA is not expected to have toxic effects on aquatic life.

Similarly, the HEDP use level of 180 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 144 ppm for sludge, and 3.6 ppm for water. These concentrations are well below the toxicity endpoints for soil (1000 mg/kg NOEC red worms) and water (10 mg/L NOEC Daphnia magna). Therefore, there is no toxicity expected from land application of sludge containing 144 ppm HEDP. Similarly, discharge to surface waters of effluent containing 3.6 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 2036 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 03-10-2020
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