FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: October 3, 2019

To: Anita Chang, Ph.D., Consumer Safety Officer, Division of Food Contact Substances (HFS-275)
Through: Sarah Winfield, Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

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

Subject: Finding of No Significant Impact for Food Contact Notification 1995 (an aqueous mixture of peroxylactic acid (PLA); hydrogen peroxide, (HP), lactic acid, optionally 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), optionally sulfuric acid, optionally dipicolinic acid (DPA), and optionally phosphoric acid

Notifier: Valley Chemical Solutions

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1995, which is for the use of an aqueous mixture of peroxylactic acid (PLA; CAS Reg. No. 75033-25-9), hydrogen peroxide (HP; CAS Reg. No. 7722-84-1), lactic acid (CAS Reg. No. 50-21-5), optionally 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP; CAS Reg. No. 2809-21-4), optionally sulfuric acid (CAS Reg. No. 7664-93-9), optionally dipicolinic acid (DPA; Cas Reg. No. 499-83-2), and optionally phosphoric acid (CAS Reg. No. 7664-38-2) as an antimicrobial agent in process water, brine, or ice in the processing of meat and poultry.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated July 30, 2019, 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) 1995, submitted by Valley Chemical Solutions for the use of an aqueous mixture of peroxylactic acid (PLA), hydrogen peroxide (HP), lactic acid, optionally 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), optionally sulfuric acid, optionally dipicolinic acid (DPA), and optionally phosphoric acid as an antimicrobial agent in process water, brine, or ice in the processing of meat and poultry. The components of the FCS will not exceed:

1. 1000 parts per million (ppm) peroxylactic acid, 2480 ppm hydrogen peroxide, 5.7 ppm HEDP, and 1.64 ppm DPA in process water or ice that contacts meat or poultry carcasses, parts, trim, and organs.

2. 268 ppm peroxylactic acid, 665 ppm hydrogen peroxide, 1.53 ppm HEDP, and 0.44 ppm DPA in process water, ice, or brine that contacts processed and pre-formed meat and poultry. The FCS is not for use in contact with components of infant formula. 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 submitted by the notifier in an environmental assessment (EA), dated July 30, 2019. 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 in process water, brine, or ice in the processing of meat and poultry, 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 and DPA) is expected to occur during treatment at the on-site wastewater treatment plant or POTW. Specifically, PLA will breakdown into oxygen and lactic acid, while hydrogen peroxide will break down into oxygen and water. Lactic 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 expected use levels. Similarly, phosphoric acid readily dissociates into phosphate ions and hydrated protons, neither of which are a toxicological or environmental concern at the expected 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 and DPA.

Assuming, as a worst-case, that the FCS goes directly into wastewater, the maximum concentration of HEDP and DPA in wastewater would be equal to the highest use concentrations of the substances which are 5.7 ppm for HEDP and 1.64 ppm for DPA. Environmental Introduction Concentrations (EICs) for HEDP were calculated assuming 80 percent of the HEDP partitions to sludge during on-site wastewater treatment (and 20 percent of the HEDP remains in the water). Expected Environmental Concentrations (EECs) of HEDP were calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. Therefore, the terrestrial EEC for HEDP is 4.6 ppm (5.7 ppm × 0.80) and the aquatic EEC for HEDP is 0.11 ppm ([5.7 ppm × 0.20] / 10). Since DPA is expected to primarily remain in water because it does not partition into sludge; only an aquatic EEC is calculated using the same dilution assumptions as for HEDP to yield a value of 0.16 ppm (1.6 ppm/10).

Terrestrial toxicity studies with HEDP demonstrated no effects on earthworms and plants at levels up to 1,000 ppm soil dry weight and the 14-day LC_{50} for birds was determined to be greater than 284 mg/kg body weight. The terrestrial HEDP EEC is 4.6 ppm, a worst-case concentration that assumes no dilution from mixing nor degradation of HEDP and is over 50-times lower than terrestrial toxicity study endpoints, therefore, there is no toxicity expected from land application of sludge that contains HEDP from the proposed use of the FCS. 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 0.11 ppm is a conservative estimate which assumes the concentration of HEDP in wastewater is the same as the at-use concentration. The aquatic HEDP EEC of 0.11 ppm is close to 100-fold lower than the 10 ppm chronic NOEC for *Daphnia magna*. Therefore, the proposed use of the FCS is not expected to have an adverse effect on aquatic organisms.

Because there is little information available on the environmental toxicity of DPA, the EPA's Ecological Structure Activity Relationships (ECOSAR) program, which estimates aquatic toxicity based on structure-activity relationships and predictions from similar chemical classes was utilized in determining its environmental effects. 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 for daphnids (proxy: neutral organic SAR). The expected worst-case EEC of 0.16 ppm is 2 orders of magnitude below these concentrations.

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, because 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 1995, as an antimicrobial agent for use in process water, brine, or ice in the processing of meat and poultry, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 10-03-2019
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Food and Drug Administration

Approved by _____Date: digitally signed 10-03-2019
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