FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: February 22, 2021

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

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.02.22 13:52:20 -05'00'

From: Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for food-contact notification (FCN) 2188 for hypochlorous acid (CAS Reg. No. 7790-92-3).

Notifier: Clarentis Technologies LLC

Attached is the Finding of No Significant Impact (FONSI) for FCN 2188 for use of hypochlorous acid (CAS Reg. No. 7790-92-3), as an antimicrobial agent in in an aqueous solution in the production and preparation of whole or cut meat and poultry; processed and preformed meat and poultry; fish and seafood; fruits and vegetables; and shell eggs.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated December 3, 2021, 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 -S Digitally signed by Leah D. Proffitt -S Date: 2022.02.22 13:03:10 -05'00'

Leah D. Proffitt

Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt
File: FCN No. 2188

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2188), submitted by Clarentis Technologies LLC, to provide for the safe use of hypochlorous acid (CAS Reg. No. 7790-92-3), as an antimicrobial agent in in an aqueous solution in the production and preparation of whole or cut meat and poultry; processed and preformed meat and poultry; fish and seafood; fruits and vegetables; and shell eggs, as described further 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, dated December 3, 2021. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

The FCS will be manufactured by a device on-site and the concentration of available free chlorine will not exceed 60 ppm. The aqueous solution containing the FCS may be used in processing facilities as follows:

(1) in process water or ice which comes into contact with food as a spray, wash, rinse, dip, chiller water, and scalding water for whole or cut meat and poultry, including carcasses, parts, trim, and organs;

(2) in process water, ice, or brine used for washing, rinsing, or cooling of processed and pre-formed meat and poultry products;

(3) in process water or ice for washing, rinsing or cooling fruits, vegetables, whole or cut fish and seafood; and

(4) in process water for washing or rinsing shell eggs.

When used in water to process fruits, vegetables, ready-to-eat meats, and fish and seafood products intended to be consumed raw, the treatment will be followed by either a 10-minute drain step or a potable water rinse to remove, to the extent possible, residues of the FCS.

The food-contact substance (FCS) is intended to inhibit the growth of undesirable or pathogenic microorganisms and will be used in food processing facilities throughout the United States. Wastewater from the proposed 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.

Effective environmental concentrations (EECs) for the oxychlorine species are calculated at 4×10^{-27} µg/L, which is 25 orders of magnitude lower than the most sensitive species (aquatic invertebrate 17 µg/L). For trihalomethane species the notifier conservatively assumes 10-fold dilution upon discharge to surface waters, for a final EEC of 6 ppm. This concentration is three orders of magnitude lower than the most sensitive species based on LC50 and EC50, which is Cladoceron with an EC50 of 735 ppm (mg/L).

Use of the FCS as an antimicrobial agent in food processing is not expected to result in a net increase in the use of energy and resources, since the raw material used to produce the FCS are already in common use in other chemical and industrial processes.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

Consequently, we find that use of the FCS as an antimicrobial agent in an aqueous solution in the production and preparation of whole or cut meat and poultry; processed and preformed meat and poultry; fish and seafood; fruits and vegetables; and shell eggs will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by Leah D. Proffitt -S Digitally signed by Leah D. Proffitt -S Date: 2022.02.22 13:03:56 -05'00' Date: see electronic signature

Leah D. Proffitt
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S Date: 2022.02.22 13:52:58 -05'00' Date: see electronic signature

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