U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: June 3, 2021

To: Jessica Urbelis, Ph.D., Division of Food Contact Notifications, HFS-275
Through: Mariellen Pfeil, Supervisory Biologist, Division Science and Technology, HFS-255

From: Leah Proffitt, Biologist, Division Science and Technology, HFS-255

Subject: Finding of No Significant Impact for food-contact notification (FCN) 2133 for hypochlorous acid (CAS Reg. No. 7790-92-3).

Notifier: Cougar Creek Electrolysed Water, LLC

Attached is the Finding of No Significant Impact (FONSI) for FCN 2133 for use of hypochlorous acid, ClO2, (CAS Reg. No. 7790-92-3), where free available chlorine (FAC) will not exceed 60 ppm, as an antimicrobial agent 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 April 9, 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

Attachment:
Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2133), submitted by Cougar Creek Electrolysed Water, LLC., to provide for the safe use of hypochlorous acid, ClO2, (CAS Reg. No. 7790-92-3), where free available chlorine (FAC) will not exceed 60 ppm, as an antimicrobial agent 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.

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 April 9, 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 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, as well as in open water, on-board fish processing. 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. In the case of on-board fish processing, effluent will be released directly to the open ocean. The proposed uses are as follows:

1. process water or ice applied 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. process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed meat and poultry products;
3. process water or ice for washing, rinsing, or cooling fruits and vegetables;
4. process water or ice for washing, rinsing, or cooling whole or cut fish and seafood;
5. process water for washing or rinsing shell eggs.

Shortly after entering the treatment facility, the FCS is expected to decay to an environmental introduction concentration (EIC) of 4*10-27ppm. This EIC is also assumed to apply to all major breakdown products, including hypochlorite (OCL)-, chlorite (ClO2), and chlorate (ClO3). This EIC of 4*10-27ppm is well below the lowest endpoint of 17 µg/L (Chlorine (FAC), *Daphnia magna,* LC50). Ultimately, the FCS and its breakdown products will be reduced to chloride. The worst-case effective environmental concentration (EEC)[1] for chloride is expected to be 6 ppm[2], which is far below the endpoint for the most sensitive species (735 ppm, *Cladoceron sp.,* EC50). Any chloramines formed are projected to decay to an EIC of 1*10-10 ppm, which is 11 orders of magnitude lower than the lowest ecotoxicity endpoint of 0.016 mg/L (*Daphnia magna,* LC50).

Organohalogens (AOX) such as trihalomethanes (THM), trichloroacetic acid (TAA), and other haloacetic acids HAA), are expected to form as disinfection byproducts. Overall AOX formation comprises 1.5% of total active chlorine, or 900 ppb based on the FAC concentration of 60 ppm. The percentage of each AOX species formed from the FCS is reflected below. These are considered to be EICs:

- THM: 9.6% total AOX, or 0.096 x 900 ppb = 86.4 ppb (EEC = 8.64 ppb)
- TAA: 3.5% total AOX, or 0.035 x 900 ppb = 31.4 ppb (EEC = 3.14 ppb)
- HAA: 4.0% total AOX, or 0.040 x 900 ppb = 36.0 ppb (EEC = 3.60 ppb)

The highest EEC (8.64 ppb) is much lower than EC50 of 0.24 ppm for the most sensitive species (aquatic plants; bromoform).

[1] EEC = EIC ÷ dilution factor of 10

[2] FAC concentration ÷ 10-fold dilution factor upon discharge to surface waters

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 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 _____Date: digitally signed 06-03-2021
Leah D. Proffitt
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 06-03-2021
Mariellen Pfeil
Supervisory Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration