

Memorandum

Date: January 18, 2023

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

To: Sean Fischer, Ph.D., Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2262 for hypochlorous acid (CAS Reg. No. 7790-92-3).

Notifier: Seriously Clean Ltd.

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2023.01.19 15:54:51 -0500

Attached is the FONSI for FCN 2262 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2262 for use of an aqueous solution 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 fish and seafood; fruits and vegetables; and shell eggs. The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment dated January 3, 2023, 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 -S Digitally signed by Denis Wafula
Date: 2023.01.18 09:25:26 -0500

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2262, submitted by Seriously Clean Ltd. for the use of an aqueous solution of hypochlorous acid, ClO_2 , (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 fish and seafood; fruits and vegetables; and shell eggs. The FCS is not for use in contact with infant formula and human milk. 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 January 3, 2023. 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 food-contact substance (FCS) is intended to reduce or eliminate the growth of pathogenic and non-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. in process water or ice for washing, rinsing, rehydrating, or cooling fruits and vegetables;
2. in ice for cooling whole or cut fish and seafood; and
3. in 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^{-27} ppm. This EIC is also assumed to apply to all major breakdown products, including hypochlorite (OCl^-), chlorite (ClO_2^-), and chlorate (ClO_3^-). This EIC of 4×10^{-27} ppm is well below the lowest endpoint of 17 $\mu\text{g/L}$ (Chlorine (FAC) for freshwater invertebrates. Ultimately, the FCS and its breakdown products will be reduced to chloride. The worst-case effective environmental concentration (EEC) for chloride is expected to be 6 ppm, 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 $0.096 \times 900 \text{ ppb} = 86.4 \text{ ppb}$ (EEC = 8.64 ppb)
TAA: 3.5% total AOX, or $0.035 \times 900 \text{ ppb} = 31.4 \text{ ppb}$ (EEC = 3.14 ppb)
HAA: 4.0% total AOX, or $0.040 \times 900 \text{ ppb} = 36.0 \text{ ppb}$ (EEC = 3.60 ppb)

Analyses provided in the EA show that these EECs are much lower than ecotoxicity levels provided in the literature.

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 production and preparation 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 **Denis Wafula -S** Digitally signed by Denis Wafula
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