

Memorandum

Date: March 21, 2022

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2198: Hypochlorous acid (CAS Reg. No. 7790-92-3).

Notifier: Bioionix, Inc.

To: Jessica Urbelis, Ph.D. Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

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

Mariellen Pfeil -S

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2198, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2198 is for the use of hypochlorous acid 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; plant-based proteins used as meat substitutes; shell eggs and cheese, except in contact with infant formula and human milk.

The FCS will be manufactured by a device on-site and the concentration of available free chlorine at the point of use of the FCS will not exceed 60 ppm for any purpose but is limited to a maximum of 6 ppm for cheese salt brining. 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 and vegetables;
- (4) in process water or ice for washing, rinsing or cooling whole or cut fish and seafood;
- (5) in process water for washing or rinsing shell eggs;
- (6) in process water or ice for washing, rinsing or cooling plant-based proteins used as meat substitutes; and
- (7) in process water or ice for washing, rinsing or cooling cheese and in brine for producing cheese.

When used in water to process fruits and vegetables, the treatment will be followed by potable water rinse to remove, to the extent possible, residues of the FCS. Treated seafood products intended to be consumed raw shall be followed by a potable water rinse prior to consumption.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated December 29, 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.

Brittany Ott -S Digitally signed by Brittany Ott -S
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Brittany Ott

Attachments: Finding of No Significant Impact (FONSI); EA Revision Sheet

cc: HFS-255 Ott
File: FCN No. 2198

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2198, submitted by Bioionix, Inc., for the use of hypochlorous acid 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; plant-based proteins used as meat substitutes; shell eggs and cheese, except for use in contact with infant formula and human milk, as specified 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 (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated December 29, 2021. 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 FCS will be manufactured by a device on-site and the concentration of available free chlorine at the point of use of the FCS will not exceed 60 ppm for any purpose but is limited to a maximum of 6 ppm for cheese salt brining. 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 preformed meat and poultry products;
- (3) in process water or ice for washing, rinsing or cooling fruits and vegetables;
- (4) in process water or ice for washing, rinsing or cooling whole or cut fish and seafood;
- (5) in process water for washing or rinsing shell eggs;
- (6) in process water or ice for washing, rinsing or cooling plant-based proteins used as meat substitutes; and
- (7) in process water or ice for washing, rinsing or cooling cheese and in brine for producing cheese.

When used in water to process fruits and vegetables, the treatment will be followed by potable water rinse to remove, to the extent possible, residues of the FCS. Treated seafood products intended to be consumed raw shall be followed by a potable water rinse prior to consumption. The FCS is not intended for use in contact with infant formula and human milk. As such, these uses were not included as part of the intended use of the substance in the FCN.

The FCS will contain up to 60 ppm of free available chlorine at the pH of a weak acid. Additionally, residual chemicals may also be generated in the final solution due to the degradation of oxychlorine species (chlorate and chlorite) and trihalomethane by-products (bromodichloromethane, chlorodibromomethane, bromoform, and chloroform). The anticipated and/or estimated levels of each potential residual chemical was examined under the “worst case scenario” assumption of 60 ppm of free available chlorine. As chlorine does degrade quickly, with a half-life up to 5 hours in freshwater systems,

the fact that municipal water treatment plants utilize chlorine during water treatment, typically followed by sulfonation to remove the chlorine compounds, and that there is a factor of 10 dilution assumed when the wastewater is reintroduced to the environment, the calculated levels of chlorine and residual chemicals fall below the environmentally significant thresholds assigned to each. This indicates that the FCS will not have an anticipated significant impact to the environment.

Hypochlorite solutions are generally non-volatile¹, although different chlorine species may be present. However, when examining the relative abundance and volatility of these species, it can be determined that only very low concentrations will be available in the atmospheric compartment, and so there is no significant environmental impact anticipated.

We do not expect a net increase in the use of energy and resources from the use of the FCS as notified here as this use will be substitutional to the same and similar materials already on the market. Nor do we expect significant environmental impacts, which would necessitate mitigative actions. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2198 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by
signature

Brittany Ott -S Digitally signed by Brittany Ott
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Brittany Ott, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by
signature

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Lead Biologist, Environmental Team
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¹ European Union Risk Assessment Report, Sodium Hypochlorite Final Report, November 2007, pg. 74.
Available at: <https://echa.europa.eu/documents/10162/330fee6d-3220-4db1-add3-3df9bbc2e5e5>

U.S. Food and Drug Administration Revision Sheet for the FCN 2198 Environmental Assessment (Dated Dec. 29, 2021)

March 21, 2022

The U.S. Food and Drug Administration (FDA) in its review of the above-described dated Environmental Assessment (EA) identified several errors of an editorial nature and amended them as direct edits to the EA using the Acrobat Edit tool. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to include a necessary literature citation for a statement made regarding application of a 10-fold dilution factor before release of treated water to the environment. Additionally, the acronym for EEC needs to be explained.

These revisions are as follows:

1. Page 11, 2nd paragraph — Citation to be added to a statement:

The text: ***Thus, we estimate the concentrations of trihalomethanes, trichloroacetic acid and other chloroacetic acids prior to treatment to be not more than 86.4 ppb, 31.4 ppb, and 36 ppb, respectively. These concentrations would be reduced 10-fold upon dilution in surface waters.***

Is revised to:

Thus, we estimate the concentrations of trihalomethanes, trichloroacetic acid and other chloroacetic acids prior to treatment to be not more than 86.4 ppb, 31.4 ppb, and 36 ppb, respectively. These concentrations would be reduced 10-fold upon dilution in surface waters [Rapaport, R.A., 1988. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7:107-115].

2. Page 11, 2nd paragraph — Text revisions to clarify the acronym for “EEC”:

The text: ***EECs for compounds for the aqueous compartment are [...]***

Is revised to:

Therefore, based upon the above analysis, the estimated environmental concentrations (EECs) for these substances in [...]