

## Memorandum

**Date:** September 6, 2022

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

**To:** Sharon Koh-Fallet, Ph.D., Branch Chief, Regulatory Review Branch (HFS-275)

**Subject:** Finding of No Significant Impact for Food Contact Notification 2245 (An aqueous solution of hydrogen peroxide [CAS Reg. No. 7722-84-1])

**Notifier:** Perfect Day, Inc

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S  
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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2245 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2245 is for the use an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1) as a processing aid added prior to pasteurization in the manufacture of frozen dessert mixes and ready-to-drink beverages containing whey protein. The FCS will not exceed 0.005% of the pre-pasteurized ingredient mixture. 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, the notifier's environmental assessment dated August 11, 2022, 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.

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Denis Wafula

**Attachment:** Finding of No Significant Impact (FONSI)

## FINDING OF NO SIGNIFICANT IMPACT

**Proposed Action:** Food Contact Substance (FCS) Notification (FCN) 2245, submitted by Perfect Day, Inc, for the use an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1) as a processing aid added prior to pasteurization in the manufacture of frozen dessert mixes and ready-to-drink beverages containing whey protein. The FCS will not exceed 0.005% of the pre-pasteurized ingredient mixture. 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 August 11, 2022. 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.

Manufacture of the FCS is not expected to result in environmental introduction, nor adverse environmental impact. When the FCS is used as a processing aid added prior to pasteurization in the manufacture of frozen dessert mixes and ready-to-drink beverages containing whey protein, there is no expected environmental introduction because the FCS will decompose during pasteurization to water and molecular oxygen. As such, the environmental impacts of the FCS are not considered in further detail in the EA. The EA focuses on the environmental fate and effects of the minor stabilizer components of the FCS.

Due to its inherent instability, hydrogen peroxide is formulated with a stabilizer system that is composed of low concentrations of alkali stannate salts such as sodium or potassium stannate and or alkali phosphate salts such as sodium or potassium phosphate. The stabilizers are expected to remain in the pasteurized foods and excreted after consumption of the foods with assumption that they are not absorbed in the body. The concentration of the excreted stabilizers is diluted by mixing with domestic wastewater before disposal into Publicly Owned Treatment Works (POTW). The stabilizers are not assumed to degrade during wastewater treatment and environmental introduction could occur via discharge treated wastewater or land application of sewage treatment sludge.

We note that the notifier discusses the potential introductions of the stabilizers into the environment and we concur with the conclusion that the use of the FCS as intended in this FCN does not present any significant adverse environmental effect. However, we find that the notifier's assumptions while showing that vanishingly small concentrations of phosphate and stannate might be introduced into the environment, are extremely conservative and unrealistic. Briefly, assuming, as a worst-case, the stabilizers are not absorbed in the body, the maximum concentration of phosphate and stannate in wastewater would be equal to their concentration in the FCS solution used in the production of the targeted foods and the amounts of the foods that are consumed. Environmental Introduction Concentrations (EICs) were calculated including dilution of all excreted stabilizers with other domestic wastewater. Expected Environmental Concentrations (EECs) were calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. The aquatic EEC is 0.0053 ppb (0.053 ppb/10) for phosphate and 0.0015 ppb (0.015 ppb/10) for stannate. The terrestrial EEC for phosphate and stannate assumes further dilution of sludge due to dewatering and mixing with soils and it will be 0.0009 ppb and 0.00025 ppb for phosphorous and stannate respectively.

The estimated EEC for both phosphate and stannate is below the toxicity endpoints for both aquatic and terrestrial environments. For phosphate, the relevant aquatic ecotoxicity endpoint for fish, *Daphnia*, and algae, are reported to be above 100 mg/L (100 ppm) which is above the 0.0053 ppb worst-case aquatic EEC, indicating no toxicity. The relevant aquatic ecotoxicity endpoints for the most sensitive microalgae (*Skeletonema costatum*

and *Thalassiosira guillardii*) was 0.2 mg/L (0.2 ppm) for tin which is higher than the 0.0015 ppb EEC for the intended uses. Therefore, there is no toxicity expected from disposal of treated wastewater. Similarly, land application of wastewater containing 0.00025 ppb stannate is not expected to have toxic effects because the reported relevant toxicological endpoints (for *Sinapis alba* seeds based on root growth inhibition) are range between 125 mg/kg to 417 mg/L (125 ppm to 417 ppm).

We note that although the levels of phosphate in the treated wastewater do not present any significant environmental toxicity, in some instances even low concentrations of phosphate can contribute to eutrophication of the receiving waters. It is expected that EPA regulations through the Clean Water Act (CWA) will mitigate for any environmental issues through the establishment of receiving water quality standards, and when necessary, through the establishment of limits on the amount of phosphorous discharged into waterbodies.

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; such action would have no significant environmental impact. Furthermore, as 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 2245, as a processing aid added prior to pasteurization in the manufacture of frozen dessert mixes and ready-to-drink beverages containing whey protein will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by **Denis Wafula -S** Digitally signed by Denis Wafula -S  
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