U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: September 16, 2021

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

To: Huichen Chang, Ph.D., Consumer Safety Officer, Division of Food Contact Substances (HFS-275)

Subject: Finding of No Significant Impact for Food Contact Notification 2165 (An aqueous solution of hydrogen peroxide [CAS Reg. No. 7722-84-1])

Notifier: Cargill, Incorporated

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2021.09.17 11:34:21 -04'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2165 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2165 is for the use an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1) as a processing aid in the manufacture of corn protein. The concentration of hydrogen peroxide will not exceed 2% when applied to insoluble corn protein. The FCS is not intended for use in contact with infant formula.

After this FCN becomes effective, copies of this FONSI, the notifier's environmental assessment dated July 29, 2021, 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 -S
Date: 2021.09.16 15:50:48 -04'00'

Denis Wafula

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2165, submitted by Cargill, Incorporated for the use an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1) as a processing aid in the manufacture of corn protein. The concentration of hydrogen peroxide will not exceed 2% when applied to insoluble corn protein. The FCS is not intended for use in contact with infant formula.

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 July 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 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 in the manufacture of corn protein, there is no expected environmental introduction because the FCS will be consumed during the production of the corn protein and any unused FCS will rapidly degrade during wastewater treatment 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 alkali metal stannate (tin) salts such as sodium and potassium stannate. Although used at low concentrations, these components of the FCS (phosphate and stannate) are not expected to degrade during wastewater treatment and environmental introduction could occur via wastewater or land application of sewage treatment sludge. It is expected that wastewater from an on-site wastewater treatment facility will discharge to a Publicly Owned Treatment Works (POTW) or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters and result in aquatic introduction of the FCS. Land application of sewage treatment sludge could result in terrestrial introduction of the components of the FCS.

Assuming, as a worst-case, the FCS goes directly into wastewater, the maximum concentration of phosphate and stannate in wastewater would be equal to their concentration in the FCS solution used in the production of corn protein. Environmental Introduction Concentrations (EICs) were calculated assuming no specific affinity of the components of the FCS to either water or sludge during on-site wastewater treatment. Expected Environmental Concentrations (EECs) were calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. The aquatic EEC is 0.33 ppm (3.3 ppm/10) for phosphate and 0.067 ppm (0.67 ppm/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 is 0.45 ppm and 0.01 ppm 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 which is above the 0.33 ppm 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 0.067 ppm EEC for intended uses. Therefore, there is no toxicity expected from disposal of treated wastewater. Similarly, land application of wastewater containing 0.01 ppm 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, 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) and NPDES permitting 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 2165, as a processing aid during the manufacture of corn protein in food processing facilities 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 Date: 2021.09.16 15:52:23 -04'00' Date: see electronic signature

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