U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: July 9, 2024

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2370

Notifier: China Shenhua Coal to Liquid and Chemical Co., Ltd

To: Sean Fischer, 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)

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2370, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2370 is for the use of polyglycolic acid as a base polymer for disposable drinking straws and disposable kitchenware.

The FCS will be blended with ≥ 15 percent by weight polybutylene adipate terephthalate (PBAT). The FCS may be used in contact with all food types under Conditions of Use D through G, as described in Tables 1 and 2[1]. 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 notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated April 15, 2024 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.

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Date: 2024.07.09 09:10:11 -04'00'

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Attachment: Finding of No Significant Impact (FONSI)

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2370, submitted by China Shenhua Coal to Liquid and Chemical Co., Ltd for the use of polyglycolic acid as a base polymer for disposable drinking straws and disposable kitchenware, excluding 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 April 15, 2024. 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 is expected to be entirely incorporated into and remain with the finished food-contact polymer and will be sold to manufacturers engaged in the production of the finished food contact articles. Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The FCS is expected to be utilized in patterns corresponding to the population density and then disposed of nationwide. While the FCS is intended to increase the biodegradability of finished food contact articles, items manufactured with the FCS are not expected to be disposed via this pathway as access to commercial compositing facilities for food ware are not widely available in the U.S. Rather, the FCS is expected to be disposed of via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*[2] with 8.7% recycled or composted, 15.8% combusted; and 75.6% landfilled.

As the purpose of the FCS is to increase biodegradability of food-contact articles containing it, it is indicated that the total percentage of the FCS that will biodegrade is 84.3% (the sum of the 75.6% of landfilled materials and the 8.7% that is to be recycled or composted). However, there are a limited number of compost facilities in the United States, and therefore the fates described above still hold.

Post-consumer disposal of food-contact articles manufactured with the FCS via landfill or incineration at municipal waste combustors (MWCs) will be in compliance with 40 CFR Parts 258 and 60, respectively. Additionally, the expected annual carbon dioxide equivalent emissions resulting from combustion of articles manufactured with the FCS, calculated according to the confidential annual market volume, are below the 25,000 metric ton EPA reporting threshold (40 CFR 98). As such, no significant environmental release of the FCS is anticipated.

If articles are subjected to composting conditions, the FCS will biodegrade to glycolic acid, a naturally occurring substance, and serve as an energy source for aquatic biota.[3,4]. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

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[2] Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020 (https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf).

[3] Schada von Borzyskowski, L., Severi, F., Krüger, K. et al. Marine Proteobacteria metabolize glycolate via the β-hydroxyaspartate cycle. Nature 575, 500–504 (2019)

[4] Wright, R.T., Shah, N.M. The trophic role of glycolic acid in coastal seawater. I. Heterotrophic metabolism in seawater and bacterial cultures. Marine Biology 33, 175–183 (1975). https://doi.org/10.1007/BF00390723

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 that 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 2370 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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