

## Memorandum

**Date:** December 6, 2023

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

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2331

**Notifier:** PJIM Polymer Scientific 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) 2331, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2331 is for the use of polyglycolic acid (CAS Reg. No. 26124-68-5) as a base polymer for disposable drinking straws and disposable kitchenware. The FCS should be blended with  $\geq 15$  percent by weight polybutylene adipate terephthalate (PBAT) and may be used in food-contact articles intended to contact all types of food under Conditions of Use D through G, as described in Tables 1 and 2<sup>1</sup>. The FCS is also not intended for contact with infant formula and human milk; such uses were thus no 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 November 27, 2023 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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Attachment: Finding of No Significant Impact (FONSI)

<sup>1</sup> <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) 2331, submitted by PJIM Polymer Scientific Co., Ltd. for the use of polyglycolic acid, blended with  $\geq 15$  percent by weight polybutylene adipate terephthalate (PBAT), as a base polymer for disposable drinking straws and disposable kitchenware and may be used in food-contact articles intended to contact all types of food under Conditions of Use D through G, excluding 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 November 27, 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 (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. Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population density and then disposed of nationwide via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*.<sup>2</sup> The EA indicates that the fate of articles containing the FCS within MSW is as follows: 8.7% will be recycled, composted, or managed by other food pathways; 15.8% will be combusted; and 75.6% will be landfilled.

Post-consumer disposal of food-contact articles manufactured with the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. The expected annual carbon dioxide equivalent emissions, calculated according to the confidential annual market volume, are below the 25,000 metric ton EPA reporting threshold (40 CFR 98).

As the purpose of the FCS is to increase biodegradability of food-contact articles containing it, the notifier indicates 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.

The FCS is non-volatile and should not combust; as such, it is unlikely to present any impact on the atmospheric environment. Only minute levels of leaching of potential migrants from the finished food-contact article into aquatic or terrestrial environments indicates that there is no anticipated significant impact on environmental concentrations of the FCS, including during combustion of the food-contact articles. Thus, no significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Further, because of EPA's regulations governing emissions from MWCs, no significant impacts are expected from incineration of the FCS at MWCs. Finally, due to the confidential market volume, as well as the percentage of product that will be landfilled<sup>3</sup> and the aforementioned limited number of compost facilities in the United States, it is unlikely that the increased levels of glycolic acid introduced to the environment due to potential biodegradation will

<sup>2</sup> 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](https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf)).

<sup>3</sup> EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems. 40 C.F.R. Part 258 and Appendix 2.

result in the eutrophication of waterways<sup>4,5</sup>. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

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 2331 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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Prepared by

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Approved by

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<sup>4</sup> Schada von Borzyskowski, L., Severi, F., Krüger, K. et al. Marine Proteobacteria metabolize glycolate via the  $\beta$ -hydroxyaspartate cycle. *Nature* 575, 500–504 (2019)

<sup>5</sup> 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>