

Memorandum

Date: September 21, 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) 2312

Notifier: Pliith Biomaterials Co. Ltd.

To: Elizabeth Furukawa, 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) 2312, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2312 is for the use of polylactide (polylactic acid; PLA) optionally containing up to 4 weight percent D-lactic acid polymer units (CAS Reg. No. 9051-89-2) as components of food-contact articles intended to contact all types of food under Conditions of Use B through H, as described in Tables 1 and 2¹. 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), with revision sheet, dated August 16, 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.

Brittany Ott -S

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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) 2312, submitted by Pliith Biomaterials Co. Ltd. for the use of polylactide (polylactic acid; PLA) optionally containing up to 4 weight percent D-lactic acid polymer units, as components of food-contact articles intended to contact all types of food under Conditions of Use B through H, 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 August 16, 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 intended for use of polylactide (polylactic acid; PLA) optionally containing up to 4 weight percent D-lactic acid polymer units, as components of food-contact articles intended to contact all types of food under Conditions of Use B through H in Tables 1 and 2.

The FCS is expected to be entirely incorporated into and remain with the finished food-contact article 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 packaging 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*.² The EA provides an alternate analysis based upon data in this report which indicates possible recycling of articles, and further describes that no impacts to recycling are expected. However, as this report indicates that recycling of PLA plastics is not anticipated, we recalculate the normalized ultimate consumer disposal to be as municipal solid waste that is combusted (24.4%) or disposed in sanitary landfills (75.6%) to express conservatism of the analysis³. Our analysis shows that no significant environmental impacts result from this recalculation.

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).

PLA may decompose into lactic acid, which can be converted into methane (CH₄) in an anaerobic environment and is estimated to be 321 – 343 mL CH₄ / g PLA consumed.⁴ Considering the FCS total annual market volume (confidential) the amount of methane produced from this notified use is a very small fraction of roughly the 68 Mt total annual emissions from waste as a result of all human activities.^{4, 5} While not specifically applied to this situation in the EA, we note further, that existing regulations under the EPA's Greenhouse Gas

² Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020 (https://www.epa.gov/sites/default/files/2020-11/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf).

³ *Ibid.* Table 8 of this report (Plastics in Products In MSW, by resin, subcategory: Total Plastics in Containers & Packaging) indicates that 2,460,000 tons of 14,530,000 tons of plastics in this subcategory are combusted (16.9%), 69.4% (10,090,000 tons of 14,530,000 tons) are landfilled, and 13.6% (1,980,000 tons of 14,530,000) are recycled. This table further indicates that recycling of PLA resins is negligible. Thus, disposal of PLA is anticipated to distribute as follows: 24.4% (= 100 x 16.9 ÷ 69.4) combusted and the remainder 75.6% landfilled.

⁴ Tseng et al., 2019. Biodegradability and methane fermentability of polylactic acid by thermophilic methane fermentation. Biosource Technology Reports. <https://doi.org/10.1016/j.biteb.2019.100327>

⁵ <https://www.iea.org/reports/methane-tracker-2021/methane-and-climate-change>

Reporting Program and the Clean Air Act require landfills to report annual methane generation exceeding 25,000 metric tons of carbon dioxide equivalent, and landfills of a certain size to install and operate a gas collection and control systems, providing additional support that significant impacts are not anticipated.⁶

Finally, 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. 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 PLA 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 2312 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by **Brittany Ott -S** Digitally signed by Brittany Ott -S
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⁶ <https://www.epa.gov/lmop/frequent-questions-about-landfill-gas> and <https://www.epa.gov/stationary-sources-air-pollution/municipal-solid-waste-landfills-new-source-performance-standards>