

Memorandum

Date: 10/4/24

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2384

Notifier: Ingenia Polymers Corporation

To: Adriana Alexander, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Pre-Market Additive Safety

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2384, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2384 is for the use of polylactide (polylactic acid; PLA) optionally containing up to 16 weight percent D-lactic acid polymer units (CAS Reg. No. 9051-89-2), as a component of food-contact articles.

The finished polymers are intended to contact all types of food under Conditions of Use B through H, as described in Tables 1 and 2.¹ The FCS may additionally be used under Conditions of Use A as a polymer processing aid in polyolefins at a maximum level of 750 parts per million by weight of the finished polymer. 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 August 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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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) 2384, submitted by Ingenia Polymers Corporation for the use of polylactide (polylactic acid; PLA) optionally containing up to 16 weight percent D-lactic acid polymer units, as a component of food-contact articles, excluding contact with infant formula and human milk.

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 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. 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 As the FCS is expected to be primarily disposed of through combustion or land-filling (i.e., not recycled, composted³, or handled through other food management pathways), the disposal pattern was recalculated based on only the quantities of MSW that are land disposed or combusted. On this basis, it is estimated that 19.1% of food-contact materials containing the FCS will be combusted annually.

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 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

²Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020. Available at:

https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf

³ Even though the FCS is compostable, these materials are not likely to be recovered for composting given that commercial composting (i.e., at monitored sites operating at the elevated temperatures, with mixing and aeration, etc.) is not a widely-used disposal option in the United States. Excluding these means of disposal and assuming that all food-contact articles manufactured with the FCS are land disposed or combusted, it is estimated that approximately 80.9% of the materials will be deposited in land disposal sites and about 19.1% will be combusted.

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>

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>

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).

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.

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2384 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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