U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: February 27, 2026

From: Biologist, Environmental Team, Office of Pre-Market Additive Safety

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2494

Notifier: Zhejiang Honor Biomaterials Co., Ltd.

To: Lillian Mawby, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety
Through: Mariellen Pfeil, Lead Biologist, Environmental Review Team, Office of Pre-Market Additive Safety

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2026.02.27 10:24:55 -05'00'

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2494, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2494 is for the use of an 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 polymer is intended to contact all types of food under Conditions of Use B through H, as described in Table 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 November 24, 2025 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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Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

File: FCN No. 2494

[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) 2494, submitted by Zhejiang Honor Biomaterials Co., Ltd. for the use of Polylactide (polylactic acid; PLA) optionally containing up to 16 weight percent D-lactic acid polymer units, 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 November 24, 2025. 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] The EA indicates that the fate of articles containing the FCS within MSW is as follows: approximately 69.4% generally was land disposed, 16.9% was combusted, and 13.6% was recovered for recycling.[3] Although this FCS is intended to be compostable, the US does not have sites to make this a significant disposal option, and recycling is not anticipated for such articles generated by PLA. Therefore, it was calculated that approximately 80.4% of materials containing the FCS will be deposited into landfills, while 19.6% will be combusted.

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 FCS degrades over time to carbon dioxide (CO2) and water. Therefore, leaching of potential migrants from the finished food-contact article into aquatic or terrestrial environments is not anticipated to have significant impact on environmental concentrations of the FCS or its byproducts. The products of combustion are also CO2 and water. Thus, no significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Further, because of EPA, state and local regulations governing emissions from MWCs and landfill operations, no significant impacts are expected from disposal of the FCS.

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

[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] Table 8, EPA MSW data https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf).

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 2494 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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