

Memorandum

Date: June 1, 2026

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2505

Notifier: International Flavors & Fragrances

To: Sean Fischer, 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

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Date: 2026.06.01 10:34:33 -0400

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2505, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2505 is for the use of an α -1,3-Glucan (9051-95-0), for use as (1) a base resin or a component of articles and films; (2) as a coating on film (non-paper substrate); (3) as a coating on paper and paperboard; and (4) as a wet strength agent added prior to the sheet forming process in the manufacture of paper and paperboard.

The FCS may be used in single and repeat use applications. The FCS may be used at levels up to 75 g/m² when used as a coating on paper and paperboard. The FCS may be used as a wet strength agent at levels up to 5% by weight of finished paper and paperboard. The FCS may be used in contact with all food types under Conditions of Use A through H and J, as described in Tables 1 and 2. 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 March 10, 2026 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. 2505

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2505, submitted by International Flavors & Fragrances for the use of α -1,3-Glucan, (1) a base resin or a component of articles and films; (2) as a coating on film (non-paper substrate); (3) as a coating on paper and paperboard; and (4) as a wet strength agent added prior to the sheet forming process in the manufacture of paper and paperboard, 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 March 10, 2026. 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. 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*.¹ The EA indicates that the fate of articles within municipal solid waste (MSW) is as follows: approximately 50.0% is deposited in land disposal sites, 11.8% is combusted, 32.1% is recovered (a combination of waste recovered for recycling and for composting) and 6.1% is processed through other food management pathways. As the FCS is a resin that is expected to be disposed primarily by land-filling or combustion (*i.e.*, not recovered for recycling, composted, or handled through other food management pathways), the disposal pattern was recalculated based on only the quantities of waste that are land disposed or combusted. On this basis, it was estimated that 19.1% of food-contact materials containing the FCS will be combusted annually and the remainder land disposed.²

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).

One use of the FCS is in the wet-end manufacture of food contact paper and paperboard. Therefore, potential environmental exposure to the FCS would occur during the papermaking process and from the disposal of the finished paper and paperboard packaging by the end-user. Further, a portion of the FCS will enter the facility wastewater processing system. Effluent from the pulp and paper processing will be treated via wastewater treatment facilities before release into the environment. Sludge containing adsorbed FCS may be landfilled or used as agricultural fertilizer. In the latter case, the concentration of the FCS in sludge is calculated to be no greater than 50 mg/kg. Accounting for dilution with base soils, the environmental concentration of the FCS is

¹Advancing 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).

² 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

expected to be significantly lower than 50 mg/kg. Given the conservatives in deriving the environmental concentration and the fact the FCS is a polysaccharide composed solely of glucose, there is no concern for environmental toxicity.

The FCS does not readily volatilize, due to it being a high molecular weight polymer; as such, it is unlikely to present any impact on the atmospheric environment. Virtually no 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.

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 2505 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

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