

Memorandum

Date: June 16, 2026

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Review Team, Office of Pre-Market Additive Safety

To: Jianmei Zhu, Ph.D., Biologist, Innovative Foods Staff

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

MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S
Date: 2026.06.16 13:44:55 -04'00'

Subject: Finding No Significant Impact (FONSI) for Food Contact Notification (FCN) 2525

Notifier: Billions Europe Ltd.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2525, which is for the use of octyltriethoxysilane-modified titanium dioxide as a pigment for food-contact polymers.

This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated March 27, 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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Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2525, submitted by Billions Europe Ltd. For the use of octyltriethoxysilane-modified titanium dioxide for use as a pigment for food-contact polymers. The level of octyltriethoxysilane will not exceed 1.6 percent by weight of the FCS. The FCS will be used at levels not to exceed 25 percent by weight of the food-contact article under Conditions of Use A through H, as described in Table 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.

The Office of Pre-Market 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 27, 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.

No significant environmental release is expected upon the use of materials containing the FCS. The FCS is expected to be entirely incorporated into finished articles and will remain with the finished food-contact articles throughout the use and disposal. Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the finished article manufacturer's overall non-hazardous solid waste in accordance with established.

Finished food-contact articles containing the FCS will be utilized in patterns corresponding to the population density and will be widely distributed across the country. Disposal, recycling, and combustion rates of food contact articles manufactured with the FCS will correspond with The United States Environmental Protection Agency's (US EPA) 2020 update of data regarding municipal solid waste in the United States.

Post-consumer disposal of food-contact articles containing the FCS will be via landfill or incineration at municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. Due to EPA's regulations governing landfills at 40 CFR Part 258, leaching into the environment by food-contact articles manufactured with the FCS is not anticipated. Further, because of the regulations at 40 CFR Part 60, and others, no significant impacts are expected from incineration of the FCS at MWCs. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

Plastics containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used plastic articles containing octyltriethoxysilane-modified titanium dioxide. Because the FCS is used in a manner consistent with other colorants for polymers in the manufacture of pigmented plastics, there will be no impact on current recycling programs.

Manufacture of the FCS will consume energy and resources in amounts comparable to the manufacture and use of chemically related substances now on the market. Articles containing the FCS are expected to be disposed of according to the same patterns when used in place of current similar materials. Therefore, no net increase in the use of energy and resources from the use and disposal of food-contact articles manufactured with the FCS is expected.

No mitigation measures are needed since no significant adverse environmental effects are expected from use and disposal of food-contact articles manufactured with the FCS, nor do we expect significant environmental impacts, which would necessitate alternative actions to those proposed in this FCN. 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 2525 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by ANTONETTA THOMPSON-WOOD -S

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