U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: July 23, 2025

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2452

Notifier: Versalis S.p.A.

To: Kenneth McAdams, Regulatory Review Scientist, Office of Pre-Market Additive Safety, Division of Food Contact Substances

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

MARIELLEN PFEIL S Digitally signed by MARIELLEN PFEIL -S Date: 2025.07.25 12:05:41 -04'00'

Attached is the FONSI for FCN 2452, which is for the use of ethylene/1-butene copolymer (CAS Reg. No. 25087-34-7) as a component of food contact articles. 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 May 28, 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.

Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2025.07.23 12:51:59 -04'00'

Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2452, submitted by Versalis S.p.A. for the use of ethylene/1-butene copolymer (CAS Reg. No. 25087-34-7) as a component of food contact articles. The FCS may contain up to 25 weight percent polymer units derived from 1-butene and may be used in contact with all food types under Conditions of Use A through H. [1] The density of the FCS will range from 0.895 to 0.904 g/cm^3, and the melt flow rate (190 °C) of the FCS will range from 1.0 to 4.0 g/10 minutes. Additives permitted for use in butene polymers complying with 21 CFR 177.1570 and in olefin polymers complying with 21 CFR 177.1520(c), items 3.1 and 3.2 also may be used in the FCS, provided that the limitations and specifications on the use of the additives are met. 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 May 28, 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.

Finished food-contact articles containing the FCS will be used in patterns corresponding to population density and will be widely distributed across the country. Food-contact articles containing the FCS are expected to be disposed of either by landfilling or by incineration at municipal solid waste (MSW) combustors. Recycling is not anticipated. The disposal will occur at rates proportional to the national MSW disposal patterns for similar products. It is anticipated that, due to EPA regulations at 40 CFR Part 258, there will be no significant introduction of the FCS or its components into the environment resulting from land disposal of such articles. Incineration of food-contact articles containing the FCS will not significantly alter the emissions from properly operating MSW combustion facilities and will therefore not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws.

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. It is reasonable to expect that the manufacture of the FCS and its fabrication in food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

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.

[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

As evaluated in the EA, the proposed use of the FCS as described in FCN 2452 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Denis Wafula -S Digitally signed by Denis Wafula -S Date: 2025.07.23 12:52:45 -04'00'

Denis Wafula, Ph.D.
Biologist, Environmental Review Team
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program
Food and Drug Administration

Approved by MARIELLEN PFEIL -S Digitally signed by MARIELLEN PFEIL -S Date: 2025.07.25 12:06:41 -04'00'

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