

Memorandum

Date: July 6, 2022

To: Vivian Gilliam, Division of Food Contact Substances (HFS-275)

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Mariellen Pfeil -S

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Date: 2022.07.06 16:42:07 -04'00'

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2238: A copolyester made from dimethyl terephthalate (DMT), ethylene glycol (EG), and 2,2,4,4-tetramethyl-1,3-cyclobutanediol (TMCD) (CAS Reg. No. 185625-67-6)

Notifier: Eastman Chemical Company

Attached is the FONSI for FCN 2238, which is for the use of a copolyester made from dimethyl terephthalate (DMT), ethylene glycol (EG), and 2,2,4,4-tetramethyl-1,3-cyclobutanediol (TMCD) (CAS Reg. No. 185625-67-6) as a component of single and repeat-use 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 FCN becomes effective, copies of this FONSI, EA revision sheet, and the notifier's environmental assessment (EA), dated July 1, 2022, 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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Attachments: FONSI
EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2238, submitted by Eastern Chemical Company for the use of a copolyester made from dimethyl terephthalate (DMT), ethylene glycol (EG), and 2,2,4,4-tetramethyl-1,3-cyclobutanediol (TMCD) (CAS Reg. No. 185625-67-6) as a component of single and repeat-use food-contact articles. The FCS may be used in contact with all food types under Conditions of Use B through H as described in FDA Tables 1 and 2¹, respectively. 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 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 July 1, 2022. 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 intended for use as a basic resin in the fabrication of food-contact articles in single-use applications, such as condiment trays used in fast food restaurants, take-away single-serve yogurt cups and individual butter cups used in restaurants and in repeat-use food contact articles, in contact with all types of food, at temperatures up to 100°C. Finished food-contact articles containing the FCS will be utilized in patterns corresponding to the national 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 (US EPA) Advancing Sustainable Materials Management: Facts and Figures 2018 Fact Sheet². Post-consumer disposal of food-contact articles containing the FCS will be to landfills and municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively. No significant impact on the concentrations of and exposures to any substances in air, water, or soil are anticipated. 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. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

The EA also considered the impact of greenhouse gas (GHG) emissions. Based on information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of food-contact articles manufactured with the FCS in this notification is below 25,000 metric tons CO₂-e, the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, no significant environmental impacts are anticipated.

Food packaging materials containing the FCS are expected to be disposed of according to the same patterns when they are used in place of similar polyester polymers that are already on the market. 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.

¹ <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>, accessed 7/5/22

² https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf
www.fda.gov

As evaluated in the EA, the proposed use of the FCS as described in FCN 2238 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by Antonetta Thompson-
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Thompson-wood -S
Date: 2022.07.06 16:18:34 -04'00' Date: see electronic signature
Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2022.07.06 16:43:05 -04'00' Date: see electronic signature
Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

U.S. Food and Drug Administration Revision Sheet for the FCN 2238 Environmental Assessment (Dated July 1, 2022)

The U.S. Food and Drug Administration (FDA) in its review of the above-described dated Environmental Assessment (EA) concluded that the action will not constitute a significant impact. This revision is issued to document a minor change of an editorial nature, that should be acknowledged, while not making any substantive changes to the EA.

This revision does not impact our Finding of No Significant Impact (FONSI).

These direct edits to the EA are as follows:

1. Page 24, 3 paragraph states:

According to the U.S. Environmental Agency's (US EPA) Advancing Sustainable Materials Management: Facts and Figures 2018, 50.0% of municipal solid waste generally was land disposed, 11.8% was combusted, and 23.6% was recovered for recycling and 8.5% was composted.³

Is revised to state:

According to the U.S. Environmental Agency's (US EPA) Advancing Sustainable Materials Management: Facts and Figures 2018, 50.0% of municipal solid waste generally was land disposed, 11.8% was combusted, and 23.6% was recovered for recycling and 8.5% was composted.⁴ Disposal of the remaining 6.1% of MSW pertains to other pathways for disposal of food wastes and does not relate to articles containing the FCS.

³ https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

⁴ https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf