Memorandum

Date: May 19, 2021

To: Sean Fischer, Ph.D. Consumer Safety Officer, Division of Food Contact Notification (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2138: polyethylene terephthalate copolyesters (diethylene glycol-isophthalate modified).

Notifier: M&G Polímeros México, S.A. de C.V.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2138, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2138 is for the use of polyethylene terephthalate copolyesters in films and articles for use in contact with aqueous, acidic, low-alcohol, dry, and fatty foods under Conditions of Use A through H, and for use in contact with high-alcohol foods under Conditions of Use E through G.

After this notification becomes effective, copies of this FONSI, an environmental assessment (EA) Revision Sheet, and the notifier's environmental assessment (EA) dated March 11, 2021 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.

Brittany Ott

Attachments:
Finding of No Significant Impact (FONSI);
EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2138, submitted by M&G Polímeros México, S.A. de C.V. for the use of polyethylene terephthalate copolyesters in films and articles for use in contact with aqueous, acidic, low-alcohol, dry, and fatty foods, and for use in contact with high-alcohol foods, except for use in contact with infant formula and human milk, as specified below.

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 11, 2021. 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.

This FCS is intended for use in films and articles for use in contact with aqueous, acidic, low-alcohol (up to 15 percent alcohol), dry, and fatty foods under Conditions of use A through H, and for use in contact with highalcohol foods under Conditions of use E through G. The finished polymer shall contain a total of not more than 10 mole-percent of the diethylene glycol and isophthalate units, with the diethylene glycol content expressed as a mole-percent of the total glycol units and the isophthalate content expressed as a mole-percent of the total isophthalate/terephthalate units. The finished food-contact film or article must meet any applicable specifications and is subject to all applicable conditions of use cited in 21 CFR 177.1630(f), (g), and/or (j). Adjuvant substances permitted for use in polymers complying with 21 CFR 177.1630 may be used in the copolyesters that are the subject of this notification, subject to any applicable limitations. The FCS will not be for use in contact with infant formula and human milk, and as such these uses were not included as part of the intended use of the substance in the FCN.

The subject FCS is intended for use as the base polymer in the fabrication of food-contact articles and will be entirely incorporated into finished food-contact articles. Items manufactured with the FCS are expected to be utilized in patterns corresponding to the population and then disposed of via the disposal patterns described in the U.S. Environmental Protection Agency's (EPA) report, *Advancing Sustainable Materials Management: 2018 Fact Sheet*.[1] Post-consumer disposal of food-contact articles containing the FCS will be by recycling, or to landfills and municipal waste combustors (MWCs) complying with 40 CFR Parts 258 and 60, respectively. Because identical polyester materials are currently recycled and because current plastics manufacturing practices include polymer identification coding, impacts to recycling are not anticipated. EPA's regulations governing landfills at 40 CFR Part 258, preclude leaching into the environment from food-contact articles manufactured with the FCS.

Additionally, as the FCS is a high molecular weight polymer, it does not readily volatize. 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. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

[1] We note that in Nov. 2020 the U.S. EPA issued an update to the Municipal Solid Waste report cited in the EA. Please see the following links:
• https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf
• https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf
We note that this report does not impact the conclusions presented in the EA, so no revision was required. However, the notifier was advised to utilize these reports in their future submissions.

The EA also considered the impact of greenhouse gas (GHG) emissions. Based on estimated market volume information provided in a confidential attachment to the EA, the total annual emissions of the greenhouse gases (GHG) resulting from combustion of items manufactured with the FCS are expected to be below the 25,000 mT GHG reporting threshold described in 40 CFR 98.2.[2]

We do not expect a net increase in the use of energy and resources from the use of the FCS as notified here as this use will be substitutional to the same and similar materials already on the market. Nor do we expect significant environmental impacts, which would necessitate mitigative actions. 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 2138 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 05-19-2021
Brittany Ott, Ph.D.
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 05-19-2021
Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

[2] This statement is supported by data contained in a Confidential Attachment provided by the notifier in conjunction with the EA.

U.S. Food and Drug Administration
Revision Sheet for the March 11, 2021 EA for FCN 2138

May 17, 2021

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of March 11, 2021 for food contact notification (FCN) 2138 concluded that the action will not constitute a significant impact. This revision is issued to make a minor correction 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).

The revision is necessary to include the statement: "The FCS is not for use in contact with infant formula and human milk".

Under Item 4) Description of Proposed Action, the statement, "*the FCS is not for use in contact with infant formula and human milk*" is included in those FCNs to which it applies. In the March 11, 2021 EA, this statement is omitted. However, it is stated elsewhere in the notification, and as such, the review was conducted of the FCS accordingly.

Therefore, Item 4) Description of the Proposed action is revised to contain this statement as follows:

The text …
The clearance established by this Notification would permit the use of the FCS (PET copolymers) in contact with aqueous, acidic, low-alcohol, and fatty foods under Conditions of Use A through H, and high-alcohol foods under Conditions of use E through G.

Is revised to …
The clearance established by this Notification would permit the use of the FCS (PET copolymers) in contact with aqueous, acidic, low-alcohol, and fatty foods under Conditions of Use A through H, and high-alcohol foods under Conditions of use E through G. ***The FCS is not for use in contact with infant formula and human milk, therefore such use is not included in this FCN.***