# Memorandum

**Date:** June 24, 2020

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

**To:** Vivian Gilliam, Consumer Safety Officer, Division of Food Contact Notification (HFS-275)
**Through:** Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

**Subject:** Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2066: Copolymers of terephthalic acid (CAS Reg. No.100-21-0), ethylene glycol (CAS Reg. No. 107-21-1), diethylene glycol (CAS Reg. No. 111-46-6), and 1,4-cyclohexanedimethanol (CAS Reg. No. 105-08-8), optionally branched with trimellitic anhydride (CAS Reg. No. 552-30-7).

**Notifier:** SK Chemicals Co., Ltd.

Attached is the FONSI for FCN 2066, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2066 is for the use of copolymers of terephthalic acid, ethylene glycol, diethylene glycol, and 1,4-cyclohexanedimethanol, optionally branched with trimellitic anhydride as a rigid material used in the manufacture of single- and repeated-use food-contact articles, except for use in contact with infant formula and human milk.

After this FCN becomes effective, copies of this FONSI, an environmental assessment (EA) Revision Sheet, and the notifier's EA, dated May 1, 2020, 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, digitally signed 06-24-2020

Attachment: Finding of No Significant Impact; EA Revision Sheet

# FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2066, submitted SK Chemicals Co., Ltd for the use Copolymers of terephthalic acid (CAS Reg. No.100-21-0), ethylene glycol (CAS Reg. No. 107-21-1), diethylene glycol (CAS Reg. No. 111-46-6), and 1,4-cyclohexanedimethanol (CAS Reg. No. 105-08-8), optionally branched with trimellitic anhydride (CAS Reg. No. 552-30-7). as a rigid material used in the manufacture of single- and repeated-use food-contact articles. The FCS is intended for use in contact with all foods under Conditions of Use C through G as described in Tables 1 and 2 (https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances, accessed 6/16/2020). The FCS is not intended 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 May 1, 2020. 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 rigid material used in the manufacture of single- and repeated-use food-contact articles. Food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of food-contact articles containing the FCS will be to landfills or 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. Per information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), represented as CO2-equivalent (CO2-e) in metric tons (mT), will not exceed the 25,000 mT GHG reporting threshold described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration of the FCS at MWC facilities. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be the continued use of currently approved food-contact substances that the FCS would have replaced. Such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2066 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 06-24-2020
Denis Wafula, 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 06-24-2020
Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
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# U.S. Food and Drug Administration
# Revision Sheet for the May 1, 2020 EA for FCN 2066

June 24, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of May 22, 2020 for food contact notification (FCN) 2066 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 align the intended use of the FCS as stated in the EA with the final regulatory listing:

**Under Item 4. a)** Requested Action, the EA states:
*The FCS is intended for use in contact with aqueous, acidic, low-alcohol (up to 13% by volume alcohol), and fatty foods under Conditions of Use C through G, and in contact with high alcohol foods (up to 50% by volume alcohol) under Conditions of Use E through G.*

To align this statement with the the regulatory listing of the FCN, the statement is revised to state that that:
*The FCS is intended for use in contact with all foods under Conditions of Use C through G.*