Memorandum

Date: October 18, 2018

To: Kenneth McAdams, Consumer Safety Officer, Division of Food Contact Notifications, HFS-275
Through: Mariellen Pfeil (Antonetta Thompson-Wood for), Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety (HFS-255)

From: Biologist, Environmental Review Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1903 (poly(glycolic acid-co-isophthalic acid-co-trimethylolpropane))

Notifier: Solvay Specialty Polymers

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1903, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

The Food Contact Substance (FCS) that is the subject of FCN 1903 is poly(glycolic acid-co-isophthalic acid-co-trimethylolpropane). The FCS is intended for use (1) in multilayer structures where the FCS will be separated from food by a layer of polyethylene terephthalate (PET) with a minimum thickness of 60 microns, and (2) at levels of up to 0.5% in blends with PET for direct contact with food. 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.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated August 2, 2018, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment 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.

Sarah C. Winfield

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1903, submitted by Solvay Specialty Polymers for the use of poly(glycolic acid-co-isophthalic acid-co-trimethylolpropane) for use (1) in multilayer structures where the FCS will be separated from food by a layer of polyethylene terephthalate (PET) with a minimum thickness of 60 microns, and (2) at levels of up to 0.5% in blends with PET for direct contact with food. For use in contact with all food types under Conditions of Use C through G, as described in Table 2.[1] 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 August 2, 2018. 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 an additive in food contact articles that contain PET. Once the FCS-containing food contact articles are made, they will be used and then disposed (recycled, landfilled or combusted). We do not expect an impact to recycling, as good manufacturing practices of polymers include proper labeling of end use articles to inform both users and recyclers. The food contact articles made with the FCS that are not recycled will be disposed of in a landfill or combusted. Based on confidential market volume information provided in a confidential attachment to the EA, the FCS will make up a very small portion of the total municipal solid waste (MSW) landfilled and combusted (even when assuming none of the FCS is recycled, which overestimates the amount landfilled and combusted). Because of the Environmental Protection Agency's (EPA's) regulations governing landfills (40 CFR Part 258) and the marginal amount of the FCS that would be landfilled, the FCS is not expected to be introduced to land or water when disposed via landfill. Similarly, when combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60, the regulations governing MSW combustion facilities (based on the composition of the FCS and the marginal amount of FCS compared to all combusted MSW). The EA also considered the impact of greenhouse gas (GHG) emissions in the confidential attachment. The EA confidential attachment estimates the total annual emissions of GHGs, represented as carbon dioxide-equivalents (CO_2-e) in metric tons (mT). The GHG estimate is below 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 MSW combustion facilities. In sum, we do not expect a significant impact to the environment from the use of the FCS as specified in FCN 1903.

As indicated in the EA, we do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to that proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of the materials which the FCS would otherwise replace; such action would have no environmental impact. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts; mitigation measures are not identified.

[1] https://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm, accessed 8/23/18

As evaluated in the EA, the use of the FCS, as described in FCN 1903, as an additive in food contact articles that contain PET, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: Digitally signed 10/18/2018
Sarah C. Winfield
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: Digitally signed 10/18/2018
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