Memorandum

Date: May 12, 2021

To: Kelly Randolph, D.V.M, M.P.H., Consumer Safety Officer, Division of Food Contact Substances (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 for Food Contact Notification 2136 (Polyethylene terephthalate-azelate copolyester resin [CAS Reg. No. 25609-72-7])

Notifier: DuPont Teijin Films

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2136 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2136 is for the use of Polyethylene terephthalate-azelate copolyester resin in coatings applied to authorized polyethylene terephthalate (PET) polymer films, except for use in contact with infant formula and human milk.

After this FCN becomes effective, copies of this FONSI, the notifier's environmental assessment dated March 5, 2021, and a revision sheet to the EA 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.

Denis Wafula

Attachments:
Finding of No Significant Impact;
EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2136, submitted by DuPont Teijin Films for the use of Polyethylene terephthalate-azelate copolyester resin (CAS Reg. No. 25609-72-7) in coatings applied to authorized polyethylene terephthalate (PET) polymer films, except for use in contact with infant formula and human milk.

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 5, 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 and is briefly summarized below.

Items manufactured with the FCS are expected to be land disposed or combusted proportionately with disposal patterns described in U.S. Environmental Protection Agency's (EPA) report "Advancing Sustainable Materials Management: 2018 Fact Sheet." Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. Since these items will not be recycled, they will not interfere with recycling patterns. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will 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.

Total annual emissions of greenhouse gases (GHG) resulting from disposal of items containing the FCS, are expected to be 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.

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 similar resins already in use. 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 significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

Consequently, we find that use of the FCS in coatings applied to authorized polyethylene terephthalate (PET) polymer films, will not cause significant adverse impacts on the human environment. Therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 05-12-2021
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 05-12-2021
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 March 5, 2021 EA for FCN 2136

May 12, 2021

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of March 5, 2021 for food contact notification (FCN) 2136 concluded that the action will not constitute a significant impact. This revision is issued to make minor corrections that should be acknowledged, while not making any substantive changes to the EA. These revisions do not impact our Finding of No Significant Impact (FONSI).

Under Item 6
To provide an updated explanation to the conclusion reached in the last paragraph of the section (the introduction of the FCS into the environment through landfilling), the last part of the paragraph discussing 40 C.F.R. 258 is modified to read as follows:

EPA regulations require all solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water and to have ground-water monitoring systems (40 C.F.R. Part 258 and Appendix 2). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.