U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: March 10, 2020

To: Jessica Urbelis, 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: Staff Fellow, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Cellulose acetate (CAS Reg. No. 9004-35-7), and optionally modified with propionate to form cellulose acetate propanoate (CAS Reg. No. 9004-39-1) resulting in up to 49 weight-percent propionate esters.

Notifier: Eastman Chemical Company

Attached is the FONSI for FCN 2043, which is for the use of cellulose acetate, and optionally modified with propionate to form cellulose acetate propanoate as a base resin in the manufacturing of single-use food contact articles, except for use in contact with infant formula and human milk.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated December 13, 2019, 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

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2043, submitted by Eastman Chemical Company for the use of cellulose acetate (CAS Reg. No. 9004-35-7), and optionally modified with propionate to form cellulose acetate propanoate (CAS Reg. No. 9004-39-1) resulting in up to 49 weight-percent propionate esters as a base resin in the manufacturing of single-use food contact articles. The food contact substance (FCS) may be used in food contact articles in contact with fatty foods under COU B through H; in contact with aqueous and acidic foods under COU C through G; and in contact with alcoholic beverages at room temperature or below for up to 2 hours 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 2/28/2020). 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 December 13, 2019. 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 base resin in the manufacturing of single-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. According to 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 materials 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 2043 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 03-10-2020
Denis Wafula, Ph.D.
Staff Fellow, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 03-10-2020
Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration