
Memorandum

Date: February 12, 2021

To: Jessica Urbelis, Ph.D., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Notification (FCN) 2115: Ethylene-vinyl acetate-vinyl alcohol (EVOH) copolymers modified with up to 8 mol% 1,2-epoxypropane (CAS Reg. No. 482589-30-0).

Notifier: Kuraray Co., Ltd.

Attached is the FONSI for FCN 2115, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2115 is for the use of the food contact substance (FCS) ethylene-vinyl acetate-vinyl alcohol (EVOH) copolymers modified with up to 8 mol% 1,2-epoxypropane as a component of finished food contact articles. This FCS is intended for use as an internal, non-food-contact layer separated from food by one or more layers having a suitable regulatory status for use in direct contact with food and may be used in both single service and repeated-use food contact articles at levels of up to 25% in blends with EVOH. The finished food-contact articles may be used in contact with infant formula and/or human milk.

After this FCN becomes effective, copies of this FONSI and the notifier's EA, dated November 9, 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.

Mariellen Pfeil

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Notification (FCN) 2115, submitted by Kuraray Co., Ltd., is for the use of the Food Contact Substance (FCS) ethylene-vinyl acetate-vinyl alcohol (EVOH) copolymers modified with up to 8 mol% 1,2-epoxypropane as a component of finished food contact articles. This FCS is intended for use as an internal, non-food-contact layer separated from food by one or more layers having a suitable regulatory status for use in direct contact with food and may be used in both single service and repeated-use food contact articles at levels of up to 25% in blends with EVOH. The finished food-contact articles may be used in contact with infant formula and/or 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 November 9, 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 functions to reduce processing time and to modify the physical properties of finished polyolefin articles. Finished articles include food packaging, repeat-use articles and food service articles (i.e., utensils, cups and plates).

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, EPA 530-F-19-007, "*Advancing Sustainable Materials Management: 2017 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 are not typically recycled, they will not interfere with recycling processes or rates. 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 disposal of the FCS.

Manufacture of the FCS and its use in the production of finished food-contact articles will consume energy and resources in amounts comparable to the manufacture and use of materials already in use. Further, as the use of the FCS is expected to replace, to a certain extent, other substances already in use, no increase in these resources is anticipated.

No significant environmental impacts are expected from use and disposal of the FCS and no extraordinary circumstances relating to the notified FCS and use are identified; 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 for use as an internal non-food-contact layer in food packaging, repeat-use, and food service articles, as described in FCN 2115, will not cause significant adverse impacts on the human environment. Therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 02-12-2021

Mariellen Pfeil

Lead Biologist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration