FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: December 12, 2019

To: Laura Dye, Ph.D., Division of Food Contact Substances, HFS-275
Through: Sarah C. Winfield, 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 Substance Notification (FCN) 2024 for acetic acid ethenyl ester, polymer with ethene and ethenol (CAS Reg. No. 26221-27-2).

Notifier: Kuraray Co., Ltd., Kuraray America, Inc., Kuraray Europe GmbH, Kuraray Asia Pacific Pte. Ltd.

Attached is the Finding of No Significant Impact (FONSI) for FCN 2024 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2024 is for the use of acetic acid ethenyl ester, polymer with ethene and ethenol as a component in single-use coffee capsules.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated November 25, 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance (FCS) Notification (FCN) 2024: submitted by Kuraray Co., Ltd., Kuraray America, Inc., Kuraray Europe GmbH, Kuraray Asia Pacific Pte. Ltd., for the use of acetic acid ethenyl ester, polymer with ethene and ethenol (CAS Reg. No. 26221-27-2) as a component in single-use coffee capsules. The FCS may be used at levels up to 40% in blends with authorized polymers in single-use coffee capsules that contain ground coffee for storage at room temperature until brewing. During brewing the capsules containing the FCS are exposed to water at a temperature of up to 100°C for up to 2 minutes.

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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA) dated November 25, 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 and is briefly summarized below.

The FCS is intended for use as a component in single-use coffee capsules. 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: Facts and Figures 2015." 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 impact recycling. 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 carbon dioxide-equivalents 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, to a certain extent, other substances 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 currently used.

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 environmental impact.

Consequently, we find that use of the FCS as a component in single-use coffee capsules as described in FCN 2024, will not significantly affect the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 12-12-2019
Leah D. Proffitt
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 12-12-2019
Sarah C. Winfield
Biologist, Environmental Team
Office of Food Additive Safety
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