U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Memorandum

Date: November 25, 2024

From: Leah D. Proffitt, Biologist, Office of Policy and International Engagement, Office of Policy Initiatives and Projects

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2391

Notifier: BASF Corporation

To: Lillian Mawbry, Ph.D., Consumer Safety Officer, Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Chemical Safety, Dietary Supplements & Innovation, Office of Pre-Market Additive Safety

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Attached is the FONSI for FCN 2391 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2391 is for the use of fatty acids, C16-18, [9-(acetyloxy)-3,8,10-triethyl-7,8,10-trimethyl-1,5-dioxa-9-azaspiro[5.5]undec-3-yl]methyl esters (CAS Reg. No. 1422729-07-4) as a rheology modifier in the production of single and repeat use polyolefin polymers complying with 21 CFR 177.1520, 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 September 4, 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.

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Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance (FCS) Notification (FCN) 2391: submitted by BASF Corporation, for the safe use of fatty acids, C16-18, [9-(acetyloxy)-3,8,10-triethyl-7,8,10-trimethyl-1,5-dioxa-9-azaspiro[5.5]undec-3-yl]methyl esters (CAS Reg. No. 1422729-07-4) as a rheology modifier in the production of single and repeat use polyolefin polymers complying with 21 CFR 177.1520, 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 September 4, 2024. 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 will be used at a level not to exceed 0.1 percent by weight of the polyolefin polymers. Food contact articles manufactured with polyolefin polymers modified with the FCS may be used in contact with all types of food under conditions of use A through H as described in Tables 1 and 2, unless restricted by applicable regulations for the polyolefin polymers.

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 Tables and Figures." Discarded items will go to landfills or municipal solid waste (MSW) combustion facilities complying with 40 CFR Parts 258 and 60, respectively. The FCS is expected to compete with, and to some extent replace similar substances already on the market, and items containing the FCS will be disposed similarly to those it replaces. Therefore, there will be no anticipated impact on current or future recycling programs. 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, 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 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 as a rheology modifier in the production of single and repeat use polyolefin polymers complying with 21 CFR 177.1520 will not cause significant adverse impacts on the human environment. Therefore, an EIS will not be prepared.

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